

PERFUSION SAFETY: THE FORGOTTEN PRIORITY

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Declarations: None

This presentation was prepared and written by Gary Grist RN CCP, retired.

How Many Perfusionists Does It Take To Change A Light Bulb (or pump a case)?

- Two: One to perform the task and a second one to cover the first one's ass.
- If you pump by yourself and don't think you need help, **YOU NEED HELP ALL THE MORE!**
- Over confidence is what sank the Titanic, not the iceberg.



A sole pilot can operate a commercial airliner during normal operation. However should an emergency arise, one pilot is needed to fly the airplane while the other trouble shoots the problem. During the course of normal use, a heart lung pump can also be operated by a sole perfusionist. But in an emergency like a failed roller pump, the sole perfusionist cannot hand crank the pump and at the same time fetch and install a replacement without placing the patient at great risk.

Fundamentally the question is; what is perfusion safety? As a profession, perfusion is too overconfident in its ability to deal with out-of-the-ordinary situations? The Titanic carried the number of life boats required by regulations and no more simply because its builders did not envision anyway that the vessel could sink. As a result there were too few life boats available when they were needed.

Objectives

- Decrease adverse events and harmful reactions
- Raise awareness about potential dangers
- Identify specific problems and improve safety procedures
- Promote compliance to safety procedures

The objectives of this presentation can be summarized as an acronym “DRIP”:

1. Decrease adverse events and harmful reactions
2. Raise awareness about potential dangers
3. Identify specific problems and improve safety procedures
4. Promote compliance to safety procedures

**INDEPENDENT RCA OF THE INCIDENT CAUSING THE DEATH OF
A PEDIATRIC CARDIAC SURGERY PATIENT AT UNITED BRISTOL
HEALTH CARE NHS TRUST ON 27 MAY 2005**

Mark Gritten, Independent Chairman, Oct. 2007
<http://www.scps.org.uk/pdfs/GrittenReport.pdf>

- CaCl₂ overdose by the perfusionist.
- Problems of greatest significance:
 1. Lack of regulation of perfusion as a profession: "...little in the way of legislation governing their practice or conduct."
 2. Inconsistently applied perfusion protocols and guidance.
 3. Lack of perfusion checklists and double-checking.
 4. Poor perfusion team communication.
 5. Inadequate risk assessments and performance management by perfusionists.

The Gritten Report was published by the University Hospitals of Bristol National Health Service Foundation Trust on the root cause analysis (RCA) of the death of a 5 month old infant undergoing complex cardiac surgery on May 25, 2005. A police investigation and coroner's inquest found a verdict of 'unlawful killing'. In English law unlawful killing means that the killing was done without lawful excuse and in violation of criminal law including murder, manslaughter and infanticide. The finding of unlawful killing must be beyond reasonable doubt; that is, the evidence must be overwhelmingly obvious that death would result, that no other thing is taken into account. Otherwise a verdict of accidental death or death by misadventure would apply. The death was the result of a calcium overdose by a perfusionist that caused irreversible brain damage and subsequent death the day after surgery. The hospital put safeguards into place immediately to minimize any similar incidents happening again.

The RCA was led by Mark Gritten, a nationally known experienced NHS senior professional who was independent of the hospital. The report concluded that this was a unique but avoidable incident and that the problems of greatest significance were:

1. Lack of regulation of perfusion as a profession: "...little in the way of legislation governing their practice or conduct."
2. Inconsistently applied perfusion protocols and guidance.
3. Lack of perfusion checklists and double-checking.
4. Poor perfusion team communication.
5. Inadequate risk assessments and performance management by perfusionists.

Regulation of Perfusion Services

- "... it would have been prudent to undertake a risk assessment... making it clear that risk existed and was being managed."
- "...the focus of management was not sufficiently risk oriented..."
- "*The national Society of Perfusionists* perhaps carries some responsibility for this incident because it does not appear to have disseminated learning from other perfusion incidents between its members."

The Gritten Report went further by identifying the systems wide failure of perfusionists as a profession in Britain to perform adequate safety precautions:

1. "... it would have been prudent to undertake a risk assessment... making it clear that risk existed and was being managed."
2. "...the focus of management was not sufficiently risk oriented..."
3. "The national society of perfusionists perhaps carries some responsibility for this incident because it does not appear to have disseminated learning from other perfusion incidents between its members."

**Guide to Good Practice in Clinical Perfusion, July 2009
Produced by the Department of Health, NHS, Britain**

- “Clinical perfusion is a complex practice with recognized inherent risks. Local practices, procedures or circumstances which potentially increase these risks need to be identified, assessed and rated with mitigating action identified.”
- “The best way of reducing error rates is to target the underlying system failures and root causes of incidents...”
- There must be a Quality Management Framework and System *which includes...* a Risk Assessment Framework (FMEA)...”

As a result of this and other lethal perfusion incidents the NHS authored the “Guide to Good Practice in Clinical Perfusion”. The guide comments that:

“Clinical perfusion is a complex practice with recognized inherent risks. Local practices, procedures or circumstances which potentially increase these risks need to be identified, assessed and rated with mitigating action identified.”

“The best way of reducing error rates is to target the underlying system failures and root causes of incidents...”

“There must be a Quality Management Framework and System which includes... a Risk Assessment Framework ...” This is like a Failure Modes Effects Analysis (FMEA) commonly used in the USA.

In addition the Society of Clinical Perfusion Scientists and the College of Clinical Perfusion Scientists of Great Britain and Ireland adopted a new code of practice and revamped their organizations to place the highest priority on perfusion safety. This included a Code of Practice and a special safety committee the purpose of which is to:

1. Advise on matters of patient safety in perfusion practice.
2. Provide expert opinion on safety issues highlighted by SCPS/CCPS members, the medical profession and equipment manufacturers.
3. Liaise with the relevant Department of Health agencies , Medicines and Healthcare products Regulatory Agency (MHRA), National Patient Safety Agency (NPSA) and the medical societies and relevant medical equipment manufacturers, including the British Respiratory Equipment Manufacturers Association (BAREMA), on safety initiatives.
4. Commission seminars and advise on additions to perfusion guidelines on safety related aspects of practice.

AmSECT (USA) vs. Guide to Good Practice in Clinical Perfusion (UK)

- “The mission of AmSECT is to foster improved patient care and safety by providing for the continuing education and professional needs of the extracorporeal circulation technology community.”
- Focus on education and professional needs (CEUs and perfusion meetings).
- “The best way of reducing error rates is to target the underlying system failures and root causes of incidents, rather than focusing solely on the actions of individual members of staff.”
- Focus on systems review and preventing errors (teamwork, human factors, systems design)

AmSECT's promotes patient safety by providing continuing education opportunities for individual perfusionists, primarily in society meeting programs. The Society of Clinical Perfusion Scientists of Great Britain and Ireland through its Guide to Good Practice in Clinical Perfusion promotes patient safety by focusing on systems review and preventing errors, rather than focusing on the education of individuals.

■ AmSECT Standards	■ Guide to Good Practice in Clinical Perfusion
■ 1 Development of Institutionally-based Protocols	■ 1 Quality Management document
■ 2 Qualification, Competency and Support Staff	■ 2 Standard Operating Procedures
■ 3 Perfusion Record	■ 3 <u>Risk assessment</u>
■ 4 Checklist	■ 4 Systematic checking and recording
■ 5 Communication	■ 5 Medicines management: clinical perfusion protocols, <u>patient specific directives (PSDs)</u>
■ 6 Safety Devices	■ 6 <u>Teamwork and human factors training</u>
■ 7 Monitoring	■ 7 <u>Peer review</u>
■ 8 Anticoagulation	
■ 9 Blood Management	
■ 10 Gas Exchange	
■ 11 Blood Flow	
■ 12 Blood Pressure	
■ 13 Quality Improvement	
■ 14 Maintenance	
■ 15 Duty Hours	

In comparing the AmSECT Standards to the British Guide to Good Practice, several differences stand out. The Standards are much more technical and focus on practical application. Whereas the Good Guide focuses much more on risk assessment, patient specific directives, teamwork and peer review; the emphasis being on a culture of safety more so than a culture of technical application. Both are good, but both are incomplete in themselves and would benefit from merging.

**2001 Joint Commission Leadership Standard LD 5.2:
Support of Patient Safety and
Medical/Health Care Error Reduction**

Goal: Reduce sentinel events and significant errors

- Hospitals must prevent adverse events/errors, rather than react to them
- Hospitals must conduct proactive risk assessments
- Sentinel event root cause analysis (RCA) is reactive and will not meet compliance on its own
- Hospitals (perfusionists) must provide a “failure mode analysis” for proactive process review
 - Analysis of a process in active use or a process under revision using an failure mode effects analysis (FMEA) can fulfill the Joint Commission accreditation requirement for proactive risk assessment

Eight years before the incidents in Britain, in 2001 the Joint Commission issued a new “Leadership Standard LD 5.2: Support of Patient Safety and Medical/Health Care Error Reduction” with the goal of reducing sentinel events and significant errors. The Standard requires that hospitals and healthcare workers (including perfusionists):

1. Must prevent adverse events and errors, rather than just react to them.
2. Must conduct proactive risk assessments.
3. Recognize that a sentinel event root cause analysis (RCA) is reactive and will not meet the Standard’s compliance on its own.
- 4 Must provide a “failure mode analysis” for proactive process review.

The analysis of a process in active use or a process under revision using an FMEA can fulfill the Joint Commission accreditation requirement for proactive risk assessment.

Perfusion Safety

- The avoidance of unnecessary incidents that result in adverse patient outcomes
 - Malfunctioning/defective equipment and supplies
 - Communication failure between healthcare professionals
 - Human error or incorrect execution of procedures
 - Failure to anticipate adverse events

So what is Perfusion Safety? A good definition is the avoidance of unnecessary incidents that result in adverse patient outcomes. These incidents can be categorized into four major groups:

1. Malfunctioning or defective equipment and supplies
2. Communication failure between healthcare professionals
3. Human error or incorrect execution of procedures
4. Failure to anticipate adverse events

Items 2-4 would seem to be directly related to human error of some sort. Malfunctioning or defective equipment and supplies would seem to be independent of human deviation from intention, expectation or desirability. However many mechanical or material failures can be detected before devices are put to clinical use. Such an oversight would certainly be attributable to human error.

Seven Steps to Perfusion Safety

1. Policies, Processes and Procedures: authorization and instructions for a specific task in the safest, most effective manner
2. Safety devices: hardware to prevent injury or accidents
3. Checklists: ensure consistency, completeness and compensate for limits of memory and attention
4. Documented Competency: used to ensure that personnel are fulfilling their duties as required by the appropriate authority.
5. Trouble shooting: problem solving for failures as they occur
6. Root Cause Analysis (RCA): a structured method used to analyze serious adverse events after they occur. It retroactively identifies the cause of a serious failure and proposes actions and conditions that could have prevented the failure (Gritten Report).
7. Failure Mode Effects Analysis (FMEA): a method for identifying potential design and process failures before they occur, with the intent to eliminate them or minimize the risk associated with them. It proactively examines how a system can fail before the failure occurs.

There are at least seven steps to perfusion safety:

1. Policies, processes and procedures provide authorization and specific instructions to perform specific tasks in the safest, most effective manner.
2. Safety devices include hardware that can prevent injury or accidents.
3. Checklists ensure consistency and completeness of a task and compensate for limits of memory and attention.
4. Documented competency is used to ensure that personnel are fulfilling their duties properly as required by the appropriate authority.
5. Trouble shooting is problem solving for failures as they occur.
6. Root cause analysis (RCA) identifies the cause of a serious failure and proposes actions and conditions that could have prevented the failure. The Gritten Report is an RCA.
7. Failure mode effects analysis (FMEA) examines how a system can fail before the failure occurs.

Policy Definition

- A policy is a documented general principle that guides (directs) present and future decisions.
- Example: “Perfusion License Policy: all perfusionists will be licensed or have a provisional license at the time of employment.”

A policy is a documented general principle that guides (directs) present and future decisions. For example a “Perfusion License Policy” can state that all perfusionists in a hospital, organization or state will be licensed or have a provisional license at the time of employment.

Process Definition

- A **process** is a set of related tasks, activities or procedures that accomplish a work goal, i.e., that transforms input into output products and services.
- Example: CPB Process; contains the itemization of the many procedures used in the operation of the open heart pump, i.e., priming, DHCA, cardioplegia, ultrafiltration, sweep gas control, etc.

A process is a set of related tasks, activities or procedures that accomplish a work goal, i.e., that transforms input into output products and services. For example the cardiopulmonary bypass (CPB) process contains many procedures used in the operation of the open heart pump, i.e., pump priming, deep hypothermic circulatory arrest, cardioplegia administration, ultrafiltration, sweep gas control, etc.

Procedure Definition

- A procedure is a set of tasks usually performed by one person according to instructions.
- Example: Priming the CPB pump.

A procedure is a task usually performed by one person according to instructions. Priming the CPB pump is one example.

Safety Devices and Checklists

- Common safety devices are hand cranks, arterial line filters, blood line pressure pump shut off, gas line filters, flash lights extra tubing clamps, independent flow meters, air bubble and level detectors, etc.
- Checklists ensure that the pump and all its ancillary equipment is available and operating properly and that the equipment and personnel are prepared.

Common safety devices are hand cranks, arterial line filters, blood line pressure pump shut off, gas line filters, flash lights extra tubing clamps, independent flow meters, air bubble and level detectors, etc.

A checklist ensures that the pump and all its ancillary equipment is available and operating properly and that the equipment and personnel are prepared for clinical use.

Competency is a record of personnel training and/or performance of a process or procedure.

- Example: CPB orientation competency. When a trainee performs a procedure correctly, competency is documented. When competency of all of the procedures needed to operate the open heart pump are documented, the trainee becomes competent in the CPB process.
- Example: Case review. When a qualified perfusionist reviews the clinical performance of another and documents his/her actions based on specific criteria. The results are compiled and maintained annually.

Competency is a record of personnel training and/or performance for a process or procedure. For example a cardiopulmonary bypass (CPB) pump orientation competency. When a trainee performs a procedure correctly, competency is documented. When competency of all of the procedures needed to operate the open heart pump are documented, the trainee becomes competent in the CPB process. Or a qualified perfusionist reviews the clinical performance of another based on specific criteria. At the Children's Mercy Hospital in Kansas City, Missouri 6 case reviews per perfusionist are performed every year. The results and accompanying comments are compiled annually and maintained.

Children's Mercy Hospital Perfusion Department Cardiopulmonary Bypass Case Management Review <small>(Perfusion Practice Competency Validation Tool by Date Given 03/05/09 Chief Perfusionist 2/22/09)</small>				Date	Positive Comments	Negative Comments
Dates: 9/27/13, 5/3/13, 5/2/13, 5/1/13, 4/30/13, 4/10/13, 1/14/13, 6/18/12, 4/19/12, 4/6/12, 7/19/11, 6/21/11, 3/24/11, 3/10/11, 1/27/11, 7/29/10, 7/28/10, 6/23/10, 5/10/10, 10/8/08, 9/9/08, 8/1/08, 6/2/08, 3/31/08, 3/25/08, 3/3/08		Age: Neonate [] Infant [] Peds [] Adult []		9/27/13	Circuit set-up by (another perfusionist). Good job.	No comments.
Perfusionist: Fenton, Jason Surgeon: LOGA, OBJA, GAKI, PAPE		Reviewer: Perfusion staff Dx/Procedure: CPB		5/3/13	Nice case.	No comments.
Review or comment on each item as appropriate. Utilize positive comments as well as constructive criticism to describe the perfusionist's performance. Overall goal of this review is to improve the performance of all perfusionists by minimizing ineffective technique and reinforcing effective technique through observation and communication. "Needs improve" always requires a comment. SCORE > 100%		Well done Needs improve Not appl		5/2/13	Flaw job! I learned that Jason will sometimes utilize the anesthesia EtCO2 value to adjust sweep when they are ventilating...ingenious!	No comments.
1. Utilizes appropriate circuit for procedure as it relates to preoperative assessment, perfusion department guidelines & age specific criteria. Comments:		100%		5/1/13	If takes his vacuum off before coming off CPB. I like that. Keeps level and bubble on when coming off pump. Great work. Excellent perfusionist!	No comments.
2. Able to set up circuit safely and aseptically within 30 minutes. Comments:		26		4/30/13	Very detailed. Excellent job. Great communication and well done bypass case.	No comments.
3. Confirms blood product availability and uses proper procedure for the administration of blood products. Comments:		25		4/10/13	Jason does a fantastic job communicating with the surgeon and was very accommodating on his 1st case (with the new surgeon).	No comments.
4. Is fully prepared to commence bypass as per checklist prior to aortic purse strings or as situation dictates. Comments:		26		1/14/13	Excellent case. I give cardioplegia same as you do. I learned from you.	No comments.
5. Initiates & terminates bypass in a mechanically & physiologically smooth & safe manner. Comments:		25		6/18/12	No comments.	No comments.
6. Maintains acceptable patient parameters as per perfusion department guidelines. Comments:		25		4/19/12	No comments.	No comments.
7. Effectively communicates with open-heart team and responds to "action" orders by verbal repetition. Comments:		26		4/6/12	Went on and off CPB four times. Managed hemodynamics, physiology, and admin blood very similar to me.	No comments.
8. Utilizes safety devices and universal precautions. Comments:		26		7/19/11	Pumps pretty similar.	No comments.
9. Able to recognize & resolve variances & abnormal situations. Comments:		26		6/21/11	Flow 1500 - went on clear & no blood given. A awesome job on blood management.	No comments.
10. Performs ancillary procedures such as temp control, cardioplegia, ultrafiltration, & MUF safely and effectively. Comments:		26		3/24/11	No blood today! Hct = 32%. Anesthesia took 600cc autologous G. Always calculates post-dilutional hcts with adults and autologous blood collection.	Gives mannitol prior to X-clamp removal. However, did give Ca before clamp removal.
11. Exercises due diligence during entire procedure. Comments:		26		3/10/11	Clear prime - good management with blood hemococoncentration.	No comments.
				1/27/11	Flow was 1600. I might have considered a 2100. FX worked great at flows 2L/min. Blood primed due to low hct based on post-dilutional calc. Even with a student Jason does an excellent job! Calm, cool and collected.	No comments.
				7/29/10	Good job - nice case. Left-hand emptied heart "ever" - You rock!	No comments.
				7/28/10	Thought of clear prime - ruled out due to other co-morbidities - good thought. Great job!	No comments.
				6/23/10	Completely prepared - all appropriate equipment available for ride. Great case.	No comments.
				5/10/10	Jason had good grasp of how cannulation would take place with this pt having Fontan circulation.	No comments.

This is a case review summary that records the performance of a single perfusionist by several other perfusionists over a six year period. Each category of performance is rated as "Well Done", "Needs Improvement" or "Not Applicable" in a specific review. Positive and negative comments are also recorded. In this way the ongoing competency of a perfusionist can be documented by other perfusionists over a period of time.

Trouble Shooting/RCA vs FMEA

- Trouble shooting deals with an unanticipated failure while it is occurring
 - Identify the failure
 - Devise a plan to solve the failure
 - Implement the plan
 - Assess results
- A RCA examines why a system failed, after the failure occurs
 - Choose investigators
 - Get the facts
 - Identify the hazards
 - Identify why controls failed
 - Plan for future events
 - Inform all players
 - Follow-up

The FMEA examines how a system can fail before the failure occurs and assesses the risks

Trouble shooting deals with an unanticipated failure while it is occurring by:

1. Identifying the failure
2. Devising a plan to solve the failure
3. Implementing a plan to mitigate the failure
4. Assessing the results of the plan

An RCA examines why a system failed after the failure occurs by:

1. Choosing qualified investigators
2. Gathering the facts
3. Identifying the hazards
4. Identifying why the controls failed
5. Making plans to prevent future events
6. Informing all interested players
7. Performing follow-up investigations to ensure compliance

The FMEA examines how a system can fail before the failure occurs.

FMEA Practical Benefits

- Self-assessment exercise that reveals just how well prepared a CPB program is for an emergency
- Provides documentation of rare incidents dealt with in the past so that perfusionists and their patients can benefit if a future incident occurs
- Provides exemplary documentation for self-assessment, risk assessment and evaluation by hospital risk managers & outside assessors
 - Joint Commission
 - Centers for Medicare and Medicaid Services
 - Patient Safety Organizations
 - Liability and healthcare insurance carriers

The practical benefits of a perfusion FMEA include:

1. A self-assessment exercise that reveals just how well prepared a CPB program is for an emergency.
2. Providing documentation of rare incidents dealt with in the past so that perfusionists and their patients can benefit if a similar incident occurs in the future. This is a tool for institutional memory allowing newer perfusionists to benefit from the experience of older perfusionists.
3. Providing exemplary documentation for self-assessment and evaluation by hospital risk managers & outside assessors such as:
 - a. Joint Commission
 - b. Centers for Medicare and Medicaid Services
 - c. Patient Safety Organizations
 - d. Liability and healthcare insurance carriers

FMEA Description

The FMEA identifies potential problems in a design or process:

1. Itemizes the conceivable failures such as:
 - a. personnel issues / operator error / treatment error
 - b. disposable component failure
 - c. equipment failure
2. Describes the consequences of a failure.
3. Describes the specific configuration or action causing the failure.
4. Lists specific actions that can prevent or mitigate the failure.
5. Ranks the risk of each failure; how dangerous is the failure?

The FMEA identifies potential problems in a design or process by:

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3. Describing the specific configuration or action causing the failure.
4. Listing specific actions that can prevent or mitigate the failure.
5. Ranking the risk of each failure; how dangerous is the failure?

FMEA Template: Five Column Headings

- Column I. Failure Mode
- Column II. Potential Effects of Failure
- Column III. Potential Cause of Failure
- Column IV. Intervention
- Column V. Risk Priority Number

The FMEA template organizes each item into a column with the following headings:

Column I. Failure Mode
Column II. Potential Effects of Failure
Column III. Potential Cause of Failure
Column IV. Intervention
Column V. Risk Priority Number

Column I. Failure Mode

- Two failures will be examined; one more dangerous than the other:
 - Failure example: open purge line at weaning
 - Failure example: roller pump failure to turn

Two failures will be examined; one more dangerous than the other:

1. Failure example: purge line left open at weaning
2. Failure example: roller pump failure to turn

Column II. Potential Effects of Failure

- Possible consequences of the failure
 - Failure example: open purge line at weaning
 - Bleed back to cardiotomy reservoir
 - Hypotension after CPB
 - Failure example: roller pump failure to turn
 - Hypotension during CPB
 - Loss of perfusion
 - Death

Possible consequences of each failure example:

1. Failure example: purge line left open at weaning
 - a. Bleed back to cardiotomy reservoir
 - b. Hypotension after CPB
2. Failure example: roller pump failure to turn
 - a. Hypotension during CPB
 - b. Loss of perfusion
 - c. Death

Column III. Potential Cause of Failure

- The specific action that can result in the failure
 - Failure example: open purge line at weaning
 - Perfusionist lack of attention
 - Failure example: roller pump failure to turn
 - Loss of power
 - Failure to maintain pump
 - Unknown cause

The specific action that can result in the failure

1. Failure example: purge line left open at weaning
 - a. Perfusionist lack of attention
2. Failure example: roller pump failure to turn
 - a. Loss of power
 - b. Failure to maintain pump
 - c. Unknown cause

Column IV. Intervention

- Lists specific actions to prevent each failure
- May be several actions needed to prevent occurrence of a failure
- The most important interventions are often preemptive
 - Failure example: open purge line at weaning
 - Wean from CPB checklist: close purge line (pre-emptive)
 - Clamp arterial line distal to the purge line
 - Failure example: roller pump failure to turn
 - Perform recommended routine maintenance (pre-emptive)
 - Purchase back-up pump (pre-emptive)
 - Have secondary personnel available to help crank and change the pump (pre-emptive)
 - Hand crank pump
 - Change pump
- With some failure modes preemptive interventions are not possible
 - Failure example: intra-operative aortic cannula dislodgement
 - Failure example: intra-operative oxygenator failure

The fourth column lists specific actions to prevent each failure. There may be several actions needed to prevent the occurrence of a failure. The most important interventions are often preemptive.

In the first failure example, the open purge line at weaning can be prevented by using a weaning checklist that itemizes the closing of the purge line before weaning off or clamping the arterial line distal to the purge line immediately after weaning off. This would be an example of pre-emptive management.

In the second example, the roller pump failure to turn can be prevented by performing the recommended routine maintenance, purchasing a back-up pump, having secondary personnel available to help crank and change the pump if needed. These are all pre-emptive management actions. If the pump should fail then hand cranking and quickly incorporating a backup pump would be management actions that the pre-emptive actions prepared for.

With some failure modes preemptive interventions are not possible. For example, intra-operative aortic cannula dislodgement or intra-operative oxygenator failure.

Column V. Risk Priority Number (RPN) Sub Columns

- Sub-column A. Severity Rating Scale: how harmful the failure can be
 - 1. Slightly harmful (open purge line)
 - 2. Low level harm
 - 3. Moderately harmful (roller pump failure)
 - 4. Seriously harmful
 - 5. Critically harmful
- Sub-column B. Occurrence Rating Scale: how frequently the failure occurs
 - 1. Rarely occurs (roller pump failure)
 - 2. Infrequently occurs (open purge line)
 - 3. Moderate occurrence
 - 4. Frequently occurs
 - 5. Commonly occurs
- Sub-column C. Detection rating Scale: how easily the potential failure can be detected before it occurs
 - 1. Very easily detected (open purge line)
 - 2. Easily detected
 - 3. Moderately easy to detect
 - 4. Difficult to detect
 - 5. No means of detection (roller pump failure)
- Sub-column D. Patient Frequency Rating Scale: how often the failure occurs in the total patient population
 - 1. Few patients are at risk
 - 2. A significant number of patients are at risk
 - 3. All patients are at risk (roller pump failure), (open purge line)
- Sub-column E. Calculated RPN: $A*B*C*D = E$
 - Roller pump failure: $45/375$
 - Open purge line: $6/375$

The fifth column lists four sub columns that categorizes and ranks the risk of each failure and a fifth sub column that summarizes the risk by multiplying all the rankings. The rankings are purely subjective and based upon the consensus of the attending experts.

A. The Severity rating scale ranks how harmful the failure can be from slightly harmful to critical. The risks of leaving the purge line open after CPB would be much less than having the arterial pump fail.

B. The Occurrence rating scale ranks how frequently the failure can be expected to occur.

C. The Detection rating scale ranks how easily the failure can be detected before it occurs.

D. The Patient Frequency rating scale ranks how often the failure occurs in the patient population. Certain failures could occur in all patients. But unique variations in anatomy or physiology could endanger only a small group of patients. For example patients with congenital heart lesions may be at risk from under perfusion due to collateral vessel blood run off during CPB while patients with acquired heart disease would not usually be at risk from collateral circulation.

E. Summarizing the risk simply multiplies the four rankings; $A*B*C*D = E$. The maximum risk would be $5*5*5*3 = 375$.

The risk for the open purge line example would be $1*2*1*3 = 6$. Six divided by 375 ($6/375*100$) would be 1.6%; meaning that the failure has the potential to harm the patient in 1.6% of the cases.

Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected. The purpose of the FMEA is to describe the actions needed to eliminate or reduce failures, starting with the highest-priority ones. The risk for this roller pump failure example would be $3*1*5*3 = 45$. Forty-five divided by 375 ($45/375*100$) would be 12%; meaning that the failure has the potential to harm a patient in 12% of the cases, provided that a back-up pump and personnel were readily available. If no back up unit was available and there was no help readily available to help change the pump the risk would be $5*2*5*3 = 150$. One hundred and fifty divided by 375 ($150/375*100$) equals 40%; meaning that the failure has the potential to harm the patient in 40% of the cases. A RPN of 150 would prioritize this risk and indicate that steps needed to be taken (buy a backup pump and have additional trained personnel readily available) to reduce the risk to the 12% level.

I. Failure Mode	II. Potential Effects of Failure	III. Potential Cause of Failure	IV. Management/Intervention	V. RPN				
				A. Harmfulness	B. Occurrence	C. Detectability	D. Frequency	E. Risk Priority
A1. FAILURE: Roller pump failure to turn.	EFFECT: Failure to initiate CPB or unintentional termination of CPB if arterial roller pump fails. 1. No blood being delivered to patient 2. Hypotension 3. Acidosis 4. Hypercapnea 5. Hypoxia 6. Need to hand crank pump 7. Organ failure 8. Death Failure to initiate cardioplegia, ultrafiltration, ventricular venting or field suckers if secondary pumps fail.	CAUSE: Internal mechanical or electrical malfunction 1. Power cable loose, disconnected or power supply failure 2. Internal overload tripped due to over occlusion 3. Pump motor, drive belt, main bearing or speed control failure.	PRE-EMPTIVE MANAGEMENT: 1. All pumps instrument stacks have an uninterruptable DC battery power source should the AC power source fail. 2. Confirm by checklist secure placement of wall plug and proper operation of individual components during set-up and prime. 3. Etc. MANAGEMENT: 1. Power loss can be to the entire heart-lung unit or be localized to individual components of the heart-lung unit. 2. Check for displacement of electrical plug from wall power or at main connection to pump if entire instrument stack becomes powerless. 3. Etc.	3	1	5	3	45

This represents a perfusion FMEA template. Modifications from the generic FMEA form include Preemptive management and Management interventions and Patient Frequency rating.

Tracking Annual Risk Reduction

Risk Reduction	V. RPN				
	A. Harmfulness	B. Occurrence	C. Detectability	D. Frequency	E. Risk Priority
AVG RPN:2012 2012 RISK: $40.1/375 * 100 = 10.69\%$	3.4	1.9	2.3	2.7	40.1
AVG RPN:2013 2013 RISK: $36.7/375 * 100 = 9.78\%$	3.4	1.8	2.4	2.5	36.7

Absolute Risk Reduction; $10.69\% - 9.78\% = 0.91\%$

Relative Risk Reduction: $0.91\% / 10.69\% = 8.51\%$

The FMEA can also be used to rank reductions (or increases) in risk. The average overall risk for 2012 was $(37.4/375)*100 = 9.97\%$. For 2013 the overall average risk was $(36.8/375)*100 = 9.81\%$; an average overall risk reduction of 1.6%. This was the result of a reduction in Occurrence risk (from 1.9 to 1.8) and a reduction in Frequency risk (from 2.7 to 2.5). These were probably the result of new safety devices or new safety procedures. There was an increase in the Detectability risk (from 2.3 to 2.4) which could have been the result of new personnel or the addition of high risk procedures not previously used.

Calculations of this type can confirm to both inside and outside safety assessors that perfusionists are improving the safety of CPB from year to year.

Example of Risk Reduction

I. Failure Mode	II. Potential Effects of Failure	III. Potential Cause of Failure	IV. Management/Intervention	V. RPN				
				A. Harmfulness	B. Occurrence	C. Detectability	D. Frequency	E. Risk Priority
A2. FAILURE: Mismatch of roller pump read out and actual blood flow delivered <u>without</u> an independent Doppler flow meter.	EFFECT: If arterial pump is affected, there will be inadequate blood supply to the patient causing 1. Hypotension 2. Etc.	CAUSE: 1. Roller-head occlusion not properly adjusted. 2. Pump read out not set to proper tubing size	PRE-EMPTIVE MANAGEMENT: 1. Confirm with checklist the proper tubing size calibration on the pump readout. 2. Etc. MANAGEMENT: 1. Etc.	3	1	3	3	27
A2. FAILURE: Mismatch of roller pump read out and actual blood flow delivered <u>with</u> and independent Doppler flow meter.	EFFECT: If arterial pump is affected, there will be inadequate blood supply to the patient causing 1. Hypotension 2. Etc.	CAUSE: 1. Roller-head occlusion not properly adjusted. 2. Pump read out not set to proper tubing size.	PRE-EMPTIVE MANAGEMENT: 1. The blood flow of the arterial pump is continuously measured using a separate and independently operated Doppler flow meter used to assure adequate flow if occlusion is too loose. 2. Etc. MANAGEMENT: 1. Etc.	3	1	1	3	9

As an example of reducing risk, a program incorporates Transonic Doppler flow meters for independent confirmation of blood flow separate from the pump flowmeter. This reduced the RPN from 27 to 9 based on expert consensus because it eliminated any risk of under occlusion or readout error on a roller pump. It would also quantify blood flow should hand cranking be necessary for either a roller or centrifugal pump.

Things That Can Reduce Risk

- Use of an independent Doppler blood flow meter to confirm adequate blood flow
- Standby O2 E-tank always available in the room
- Standby centrifugal pump in the room to replace arterial pump if only one perfusionist
- Pronto line, spare oxygenator, tube cutting supplies and pump mounted holder in the room to change an oxygenator if only one perfusionist
- Replacement connectors/tubing and cutting supplies
- Flashlight
- Other backup equipment readily available if you currently don't have it (backup heater/cooler, backup ACT equipment, backup personnel)
- All these things and more make the system safer and reduce the RPN.

Safety equipment such as level detectors, arterial line bubble detectors, pressure shut-off control and temperature alarms are used by most perfusionists to make CPB safer. However many programs do not incorporate other safety practices. For example many programs do not use an independent Doppler blood flow meter. Not all have a standby O2 E-tank always available in the room or a standby stand alone centrifugal pump in the room to replace the arterial pump (roller or centrifugal), particularly if only one perfusionist is doing the case to trouble shoot. Most circuits do not incorporate a PRONTO line (Parallel Replacement of the Oxygenator that is Not Transferring Oxygen). There may be no spare oxygenator, tube cutting supplies and pump mounted holder in the room to change an oxygenator. Replacement connectors, tubing and cutting supplies are frequently not at hand. A good flashlight on the pump is essential. Other backup equipment (backup heater/cooler, backup ACT equipment, etc.) and personnel need to be readily available All these things and more make the system safer and reduce the RPN.

Perfusion Safety is a Measureable Variable

- The risk of an airliner crashing is one in eight million. But would you ride on one that did not have escape hatches? Would you ride on one that had no co-pilot?
- Would you work in your hospital there if there were no fire extinguishers because the hospital was trying to save money?
 - 6,240 healthcare structure fires annually w/ 171 injuries & 6 deaths
 - 600 surgical fires annually w/ 2 deaths and 25 injuries
- Would you want to be a patient on a heart/lung machine if there were no backup oxygen source, backup oxygenator or backup pump readily available?
 - Pump related incidents = 0.5% - 0.8%
 - Pump related serious/permanent injuries = 0.01% - 0.05%
 - Pump related deaths = 0.021% - 0.025%
- Risk of dying from a CPB incident is 2600 times greater than dying in a plane crash (= 2 airliners crashing every day!)

Perfusion safety is a measurable variable. In the FMEA discussed in this presentation, the risk of a failure occurring (either minor or major) is roughly one in every ten cases.

The risk of an airliner crashing is only one in eight million. But would you ride on an airliner that did not have escape hatches? Would you board a plane that had no co-pilot? The risk that the hospital where you work will burn down is also very remote. But would you work there if there were no fire extinguishers because the hospital was trying to save money? Or would you work there if there were no firemen within a reasonable distance to respond to an emergency? But there are escape hatches, co-pilots, fire extinguishers and firemen. All these things are mandated by governmental authority.

But there is no governmental mandate for perfusion safety. Nor should we wait for one as a profession. Would you want to be a patient on a heart/lung machine if there were no backup oxygen source, no backup oxygenator or no backup pump readily available? Or would you undergo heart surgery on cardiopulmonary bypass knowing that if the perfusionist got into trouble there was no other trained individual to help him? The choice is ours as individual perfusionists and as a profession.

If you don't have adequate help or safety equipment, what should you do?

- Show this FMEA to your hospital or proprietary risk manager.
- Point out all the things that can go wrong during CPB that are beyond your control and all the disastrous results that can occur.
- Get the risk manager to support your petition for help and additional equipment and personnel from the hospital or your proprietary business managers.
- Saving money on employee and equipment costs is no excuse should an unexpected accident occur.

What should be done if your perfusion program or parts of your program are unsafe based on your self evaluation. First show the FMEA to your hospital or proprietary risk manager. Point out all the things that can go wrong during CPB that are beyond your control and all the disastrous results that can occur. Get the risk manager to support your petition for help and additional equipment and personnel from the hospital or your proprietary business managers. Saving money on employee and equipment costs is no excuse should an unexpected accident occur.

GETTING STARTED

- Wehrli-Veit M, Riley JB, Austin JW. A failure mode effect analysis on extracorporeal circuits for cardiopulmonary bypass. J Extra Corpor Technol. 2004 Dec;36(4):351-7.
- Grist G. Emergency Preparedness: The Need for a Cardiopulmonary Bypass Failure Mode Effects Analysis. AmSECT Today, Mar/Apr 2012, pg 4 & 5.