This presentation was prepared and written by Gary Grist RN CCP, retired.
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.
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
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.
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.”
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 (FMEA)…”

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’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.
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.

<table>
<thead>
<tr>
<th>AmSECT Standards</th>
<th>Guide to Good Practice in Clinical Perfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Development of Institutionally-based Protocols</td>
<td>1 Quality Management document</td>
</tr>
<tr>
<td>2 Qualification, Competency and Support Staff</td>
<td>2 Standard Operating Procedures</td>
</tr>
<tr>
<td>3 Perfusion Record</td>
<td>3 Risk assessment</td>
</tr>
<tr>
<td>4 Checklist</td>
<td>4 Systematic checking and recording</td>
</tr>
<tr>
<td>5 Communication</td>
<td>5 Medicines management; clinical perfusion protocols, patient specific directives (PSDs)</td>
</tr>
<tr>
<td>6 Safety Devices</td>
<td>6 Teamwork and human factors training</td>
</tr>
<tr>
<td>7 Monitoring</td>
<td>7 Peer review</td>
</tr>
<tr>
<td>8 Anticoagulation</td>
<td></td>
</tr>
<tr>
<td>9 Blood Management</td>
<td></td>
</tr>
<tr>
<td>10 Gas Exchange</td>
<td></td>
</tr>
<tr>
<td>11 Blood Flow</td>
<td></td>
</tr>
<tr>
<td>12 Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>13 Quality Improvement</td>
<td></td>
</tr>
<tr>
<td>14 Maintenance</td>
<td></td>
</tr>
<tr>
<td>15 Duty Hours</td>
<td></td>
</tr>
</tbody>
</table>
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.
There are at least 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.
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 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 procedure is a task usually performed by one person according to instructions. Priming the CPB pump is one example.
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 complied 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 complied annually and maintained.
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 deals with an unanticipated failure while it is occurring by:
1. Identifying the failure
2. Devising a plan to solve the failure
3. Implementing the plan
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 and assesses the risks.
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
The FMEA identifies potential problems in a design or process by:

1. Itemizing the conceivable failures such as:
   a. personnel issues / operator error / treatment error
   b. disposable component failure
   c. equipment failure
2. Describing the consequences of a failure.
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?
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
Two failures will be examined; one more dangerous than the other:
1. Failure example: open purge line 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
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
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.
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; \( A \times B \times C \times D = E \). The maximum risk would be \( 5 \times 5 \times 5 \times 3 = 375 \).

The risk for the open purge line example would be \( 1 \times 2 \times 1 \times 3 = 6 \). Six divided by 375 (\( 6/375 \times 100 \)) 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 would be \( 3 \times 1 \times 5 \times 3 = 45 \). Forty-five divided by 375 (\( 45/375 \times 100 \)) 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 \( 5 \times 2 \times 5 \times 3 = 150 \). One hundred and fifty divided by 375 (\( 150/375 \times 100 \)) 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.
This represents a perfusion FMEA template. Modifications from the generic FMEA form include Preemptive management and Management interventions and Patient Frequency rating.

<table>
<thead>
<tr>
<th>I. Failure Mode</th>
<th>II. Potential Effects of Failure</th>
<th>III. Potential Cause of Failure</th>
<th>IV. Management/Intervention</th>
<th>V. RPN</th>
</tr>
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<tbody>
<tr>
<td>A1. FAILURE: Roller pump failure to turn.</td>
<td><strong>EFFECT:</strong> 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. Hypocapnia 5. Hypopaxia 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.</td>
<td><strong>CAUSE:</strong> 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.</td>
<td><strong>PRE-EMPTIVE MANAGEMENT:</strong> 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. <strong>MANAGEMENT:</strong> 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.</td>
<td><strong>R. Severity</strong></td>
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The FMEA can also be used to rank reductions (or increases) in risk. The average overall risk for 2012 was \( (37.4/375) \times 100 = 9.97\% \). For 2013 the overall average risk was \( (36.8/375) \times 100 = 9.81\% \); 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 24.) 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.
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.
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 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 one that did not have escape hatches? Would you board a plane 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!)

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.
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
