Örrum
CLINICAL ANALYTICS

The 2024 Annual Report on
Safety in Cardiac Surgery

produced by ORRUM for AmSECT

THE PURPOSE OF THIS REPORT

AmSECT and the Orrum Patient Safety Organization (PSO) are publishing the 2024 Report on Safety in Cardiac Surgery to inform cardiac surgery teams about important safety issues surrounding the provision of care for these patients.

Mitigate 20% of event reports using these three techniques:

N+1 EQUIPMENT LEVELS

THE TOP CLINICAL ACTION TO MITIGATE EVENT REPORTS.

CRITICAL EQUIPMENT FAILURES OFTEN HAPPEN WITH NO BACKUP.

SUGGESTED MORE THAN 15 TIMES IN 24 MONTHS.

HOLISTICALLY TEST GAS SUPPLY

DESCRIBES HOW AND WHY MANY EXISTING GAS SYSTEM TESTS FAIL.

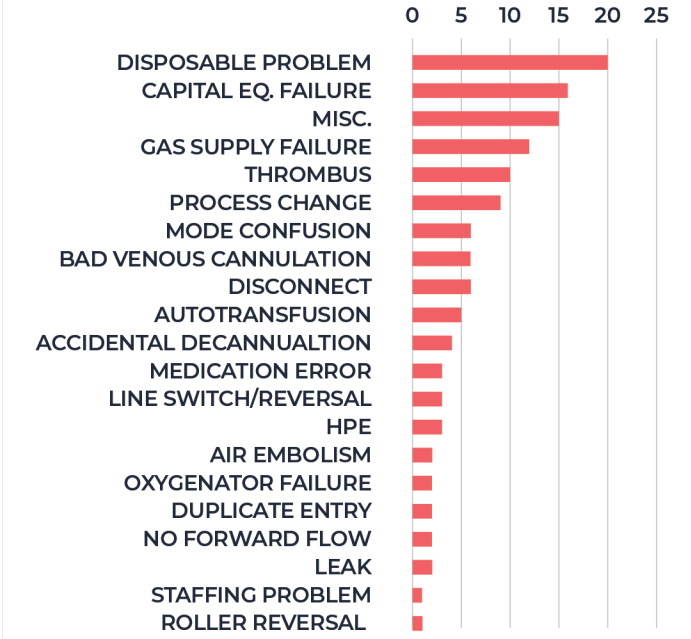
A SIMPLE STEP-BY-STEP PROCESS TO TEST ALL COMPONENTS OF THE GAS SUPPLY SYSTEM.

TEST ALARMS AND INTERVENTIONS

INTERVENTION SYSTEMS CAN TRIGGER INAPPROPRIATELY OR FAIL TO INTERVENE WHEN RELIED UPON.

"GREEN LIGHTS" CAN STILL HIDE MALFUNCTIONS.

REPORT TYPE FREQUENCY



Report your event to add to the learning by using this link

SECTION I

Introduction & Background

Since 2021, the Orrum PSO has been collecting anonymous, confidential reports on near-miss and patient harm events in cardiac surgery. These reports are considered Patient Safety Work Product (PSWP) and are confidential and privileged, protected by the Patient Safety and Quality Improvement Act (PSQIA) of 2006 (1, 2). The Orrum PSO is an officially listed Patient Safety Organization with the U.S. Agency for Healthcare Research and Quality (AHRQ) (3).

Methodology

This year's report will strive to improve upon the 2023 report by including content suggested by the AmSECT Safety Committee, the AmSECT Quality Committee, and the International Consortium for Evidence Based Perfusion (ICEBP). Since inception, the Orrum PSO has received more than 180 reports and used the understandings generated for development of more than 60 novel best practices. In 2024, clinical vignettes have been added to most sections to provide relatability of the content. These vignettes are based on real reports but have been scrubbed of identifying information and have been reviewed by the Orrum PSO Non-Identification Committee to confirm anonymity.

IMPACT: REPEATING EVENTS

167

NRE REPORTS ANALYZED

64

NOVEL BEST PRACTICES GENERATED

35

NUMBER OF REPEATED SUGGESTIONS

SECTION II

Top Strategies to Improve Safety

In February of 2024, the Orrum PSO undertook a review of all events reported since inception and collected all mitigation strategies suggested. The three most frequently suggested mitigation strategies are reported here. The goal of this approach is to assist clinicians in prioritizing practice changes which will decrease the chances of them having any type of Non-Routine Event (NRE) whether it includes patient harm or not. Any NRE that occurs intraoperatively has been shown to be additive when looking at risk to the patient, such that decreasing the total number of NREs during a procedure should increase the safety of the procedure (4).

Mitigation Strategy 1:
Critical equipment should be kept at an N+1 level, where N is the number of concurrent rooms the facility plans to operate per local policy.

The AmSECT Standards and Guidelines, guideline 15.1, suggest maintaining staffing levels at N+1, where N is the number of concurrent operating rooms (5). While equipment availability is mentioned in AmSECT standard 18.4, "Appropriate backup perfusion supplies and equipment shall be readily available" exact definitions and numeric values are not mentioned, as they are with the N+1 staffing guideline (5). The frequency of reported events where N+1 equipment would partially or wholly mitigate the event indicates this AmSECT standard is either not widely followed or not well understood. In addition, many reports highlight that facilities do not have policies which outline how many cardiac OR rooms can run concurrently, and thus do not have a baseline for the level of equipment needed.

At least 15 NRE reports (9% of all analyzed reports) have generated suggestions to maintain levels of critical equipment at N+1, making this the single most frequently recommended strategy for mitigation. Specific equipment that should be considered under this strategy includes but is not limited to; heater/cooler devices, special cardioplegia devices (i.e. Quest MPS) and special cardioplegia heating/cooling devices, components in the gas supply system (analyzers, vaporizers, etc), and Heart-Lung Machines (HLMs).

CLINICAL VIGNETTE

Pat is a perfusionist at "Hospital Y." Their facility runs one heart room most days, and a few times a month runs two rooms concurrently. They have three heart lung machines and two heater coolers (h/c), one h/c for each room. Their cardioplegia system does not require a h/c.

On Tuesday, Pat is doing a double valve case, has gone on bypass, and the cross clamp has just been placed. The surgeon Pat is working with arrests with a high potassium 4:1 cardioplegia formulation, then switches to continuous cold blood retrograde. Shortly after the initial dose of cardioplegia, Pat's coworker enters the room.

In the next operating room, Pat's coworker, Cody has prepared for the other heart case, a CABx4 with ASD closure. The surgeon has just given heparin and placed the aortic cannula when Cody noted a loud alarm. Cody investigated and saw a large pool of water under the systemic h/c. Biomed is called to the room and finds a large crack has spontaneously formed in the h/c water path. Biomed cannot fix the device immediately, and the leak is sufficient to prevent any use of the heater/cooler.

With Cody's patient heparinized and the aortic cannula placed, the team is left with a difficult decision. They can maintain the patient in a heparinized state for approximately two hours until a heater cooler is available from the other room, or they can remove the aortic cannula, reverse the heparinization, and wait, chest open, for the two hours.

With no good options, the team wonders why they have no redundancy for this scenario.

Mitigation Strategy 2:
Use the following six-step process to test gas supply to any extracorporeal circuit.

Gas supply failures are a frequently reported event type, with at least 14 gas supply failures having been reported. In addition to gas supply failures, other error types, (such as an accidental reversal of in/out blood flow on an oxygenator, or accidental connection of a gas supply to the gas exhaust of an oxygenator), can lead to a false suspicion of a gas supply failure, which would need to be ruled out. To rule out gas supply failures, and make diagnosis of problems with gas exchange easier, perfusionists should consider use of the following six step process for checking the gas supply as part of the pre-CPB or pre-ECLS checklist:

1. A passive gas flow meter should be permanently placed in-line in the gas supply line just prior to the oxygenator (the last thing before the gas filter, after any oxygen analyzer and/or vaporizer) in the field of view of the perfusionist/specialist (6).
2. During recirculation of the prime, the gas supply should be turned on to a moderate rate, 4-6 LPM in adult circuits, enough to visualize the set rate on the blender and the measured gas flow rates on the passive meter.
3. The vaporizer should be turned on to a level that will be used during the case (typically a MAC of one to two).
4. The perfusionist/ECLS specialist should visualize the passive flow meter and visually confirm the "reading" on the passive meter closely approximates the setting on the blender.
5. The perfusionist should visually confirm the gas supply line is connected to the "gas in" port of the oxygenator.
6. If the two readings closely approximate, the vaporizer and blender can be turned off until extracorporeal circulation is established.

Additional testing may help to confirm gas supply, depending on equipment use and availability. A "blood gas" of the prime (or continuous CO2 and O2 readings if using a Terumo CDI or Quantum Ventilation Module) can be taken before and after steps one through five to confirm a rise in pO2 and a drop in pCO2 in the prime. Use of the Nomoline sampler on the Quantum Ventilation Module, or a Draeger Vamos anesthetic gas monitor, can confirm a competent gas supply by confirming adequate anesthetic gas is reaching the oxygenator. Consider these tests as adjuncts to the six-step process.

NOTE - Occlusion of the gas supply line/system is not recommended as it has been indicated in dislodging FdO2 sensors/oxygen sensors and damaging vaporizer gaskets.

Using this technique would have mitigated at least 14 reported events (8% of all analyzed reports), including multiple failures to oxygenate discovered during CPB, leaks in vaporizers, improperly mounted vaporizers, leaking and missing oxygen analyzers, and improperly connected gas supply systems.

CLINICAL VIGNETTE

Cody is the perfusionist for a first start CAB/AVR procedure with "Surgeon A." Cody's facility uses a robust checklist to confirm their gas supply is working, including checking the flow meter and gas blender function, tracing the gas line from the blender to the oxygenator, and connecting an anesthetic gas scavenging line with appropriate venting, to the gas exhaust.

Cody goes on bypass with this skilled and quick surgeon. Venous return, flows, line pressure, and color change are acceptable, and the cross clamp is quickly placed. After the initial dose of cardioplegia arrests the heart, Cody notes that, while there is still Arterial/Venous color change, it is not as robust as a few moments ago. As the cardioplegia is completed, Cody notes a dropping SvO2, pO2, SaO2, and rising CO2, along with an even darker arterial line. Extensive troubleshooting eventually leads Cody to increase the sweep to 8 LPM, at which time a sound is heard near the vaporizer. The vaporizer is turned to the "zero" setting and immediately the color and blood gas readings begin to normalize, reaching expected levels in less than a minute. Anesthesia notes that while the NIRS readings dropped during this period, they did not go below the recommended threshold.

The patient is switched to I.V. anesthetic and the case is completed without further incident. The patient suffers no known effects from the event. The vaporizer is inspected by a qualified technician and is found to have a gasket that failed inside the vaporizing chamber, leading to a gas "steal" that was a high proportion of total gas flow, especially at low sweep settings, but which would not have been evident if the gas supply was not routed through the vaporizing chamber.

Mitigation Strategy 3:
Test alarm function during the Pre-CPB or Pre-ECLS checklist.

As outlined in the 2023 Report to AmSECT, confusion arising from the mode(s) and alarms used during CPB/ECLS has been linked to a large number of reports. The number and combination of alarm settings and automated interventions has increased exponentially in recent years due to new technologies.

To reduce the risk of mode and alarm confusion, each alarm system should be tested as part of the pre-CPB checklist. This test should simulate the alarm condition and then resolving it. During the test, each alarm system should be checked for function (alarm triggers when alarm condition is simulated), audible alert is loud enough to be heard, and linked intervention functions as expected (automated arterial clamp, servoregulation of correct pump, etc).

The systems tested via this method should include but are not limited to; low level alarm(s), bubble detector(s), pressure alarm(s), and any alarm that can be linked to interventions interrupting flow of either the systemic or cardioplegia pump(s).

Using this technique would have mitigated at least 10 reported events (6% of all analyzed events), including unplanned interruptions of flow during CPB, air entry into circuit, failure of alarms to trigger, and inability to diagnose patient condition due to mistaken alarm settings.

CLINICAL VIGNETTE

Riley is a perfusionist at pediatric cardiac surgery facility "Z." The team uses a 5-position roller pump, but the main (arterial) pump has been having problems with occlusion, so it was pulled by the facility biomed and serviced. Yesterday afternoon, after cases were done, biomed returned the roller pump to the Heart Lung Machine.

Riley came in early and prepared for a relatively straightforward case on an adult congenital patient. Riley's team uses a checklist that includes checking that safety devices are "operational, audible, and engaged (7)." Riley confirms that the level sensor is turned on and that the volume is turned up to 20%, which Riley knows from past experience will be audible in the room.

The case proceeds uneventfully, and the venous cannula is removed. Riley is giving volume and almost at the low-level sensor. The patient's saturations begin to drop, and Riley turns to receive a sample from anesthesia to run a Point of Care test. The jacket Riley is wearing catches on the knob of the arterial pump head, turning the flow up significantly.

The low-level alarm produces an audible alarm but does not stop the roller pump and the line, including the oxygenator, quickly fills with air before Riley can stop the pump. At this time, the surgeon announces they will need to urgently return to CPB, but Riley informs the surgeon they will need to de-air the system first, which produces an extended delay in returning to CPB, which the surgeon believes impacts the patient outcome.

A post-case debrief and assistance from another perfusionist helps to identify that the roller pump returned to the HLM by biomed was not properly connected to the low level alarm intervention, creating a situation where the display indicated the low level alarm was functional, but not linking the servoregulation to the correct roller pump. The practice of the perfusion team has been to turn the alarm on, look for the indicator light to confirm no alarm situation is present, and then check the audible volume, which did not catch the improper intervention linkage. Riley notes in the debrief that even a half second further delay in turning off the roller pump would have resulted in catastrophic consequences for the patient.

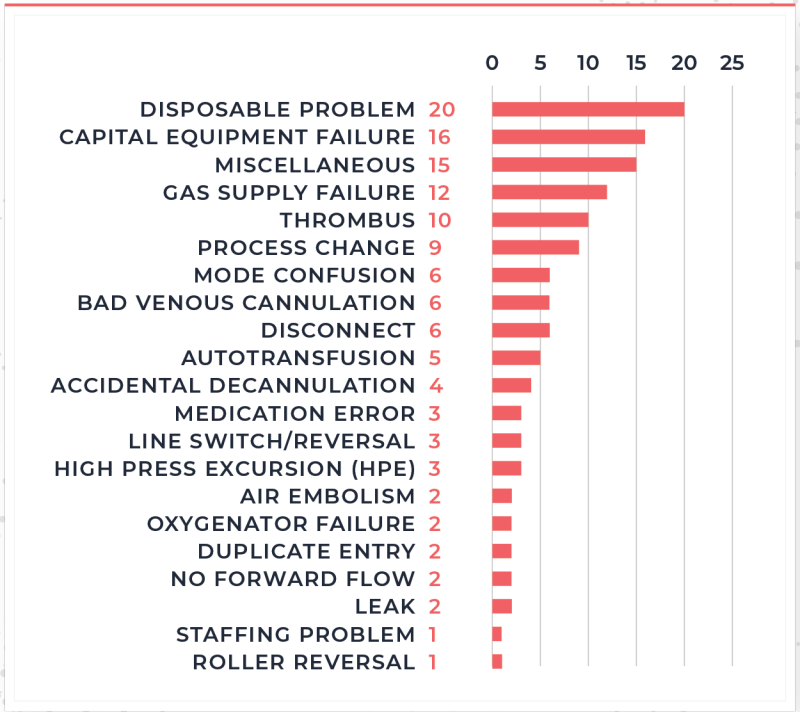
SECTION III

Report Types

Based on recommendations from the AmSECT Quality committee, an ad-hoc categorization of report types was undertaken to help understand what other safety concerns are present. This process is part of a larger emerging collaborative in which The Society of Clinical Perfusion Scientists (SCPS) of Great Britain and Ireland, and the Perfusion Improvement Reporting System II (PIRS-II) of the Australian and New Zealand College of Perfusionists, have been invited to help develop a common taxonomy for report types.

These categories focus on a single descriptive cause of the event, similar to descriptions used by the SCPS and PIRS-II websites (8, 9) but do not connect strategies for mitigation to the reports. This project captured information from the first 138 reports and lists the top 20 report categories.

REPORTS BY CATEGORY



SECTION IV

Conclusion

Based on the frequency of reports, using the three mitigation strategies listed in section two may prevent, or allow earlier identification of, NREs at a rate of about 39/167 or roughly 23%. With the exception of N+1 equipment levels, these suggestions are low/no cost and can easily be incorporated by any clinician.

Nearly all actionable information generated for this report came from anonymous events submitted by cardiac surgery Providers across the country. Reporting of such events, with permission for anonymized follow up, functions to create a powerful database of knowledge which can identify risks, determine causes, and inform actions aimed at mitigation.

AmSECT and the Orrum PSO encourage Providers to submit Non-Routine Event reports (NRE) here:

www.PerfusionSafety.org

REFERENCES

1. Agency for Healthcare Research and Quality. Patient Safety Organization (PSO) program. No date. Available at https://pso.ahrq.gov/. Accessed on March 6, 2024.
2. Office of Civil Rights. Patient safety and quality improvement act of 2005 statute and rule. 2017;June. Available at https://www.hhs.gov/hipaa/for-professionals/patient-safety/statute-and-rule/index.html. Accessed on March 6, 2024.
3. Agency for Healthcare Research and Quality. The Orrum PSO. April 1, 2021. Available at https://pso.ahrq.gov/pso/orrum-pso. Accessed on March 6, 2024.
4. de Leval MR, Carthey J, Wright DJ, Farewell VT, Reason JT. Human factors and cardiac surgery: A multicenter study. J Thorac Cardiovasc Surg. 2000;119(4):661-672.
5. American Society of ExtraCorporeal Technology. AmSECT Standards and Guidelines for Perfusion Practice. 2023. Available at https://www.amsect.org/Portals/0/AmSECT_Perfusion_S%26G_2023%20Ratified%20021023_Digital%20edition.pdf. Accessed March 8, 2024.
6. Dwyer. Series VF Visi-Float Acrylic Flowmeter. No date. Available at https://dwyer-inst.com/en/products/flow/flowmeters/variable-area/series-vf-visi-floatr-acrylic-flowmeter.html, Accessed March 11, 2024.
7. American Society of ExtraCorporeal Technology. AmSECT Standards and Guidelines for Pediatric and Congenital Perfusion Practice. 2019. Available at https://www.amsect.org/Portals/0/AmSECT%20Documents/Pediatric%20and%20Congenital%20Standards%20and%20Guidelines%20Final%20May%202019%20(1).pdf. Accessed March 11, 2024.
8. Australian and New Zealand College of Perfusionists. PIRS – 2 Reports. No date. Available at https://anzcp.org/pirs-ii/pirs-ii-reports/. Accessed March 11, 2024.
9. Society of Clinical Perfusion Scientists of Great Britain and Ireland. Safety Archive: Perfusion Reports. No date. Available at https://www.scps.org.uk/safety/safety-archive. Accessed March 11, 2024.

Strategies for mitigation suggested by the Orrum PSO are based upon clinical experience and our team's opinions specific to general care and/or individual events at the time that the recommendations are issued. These recommendations are believed to be in line with standards of care but will often promote specific techniques or increased diligence based on knowledge of the nature and frequency of events reported. Your organization should consult with internal experts when considering the Orrum PSO suggestions for mitigation. Orrum PSO analysts are available to members at no cost to review individual reports or application of specific mitigation suggestions.