Örrum
CLINICAL ANALYTICS

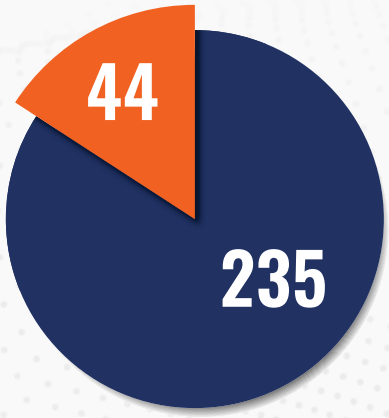
The 2025 Annual Report on

Safety in Cardiac Surgery

produced by ORRUM for AmSECT

THE PURPOSE OF THIS REPORT

The 2025 Orrum PSO Annual Report to AmSECT: Detecting equipment failures and minimizing patient harm.



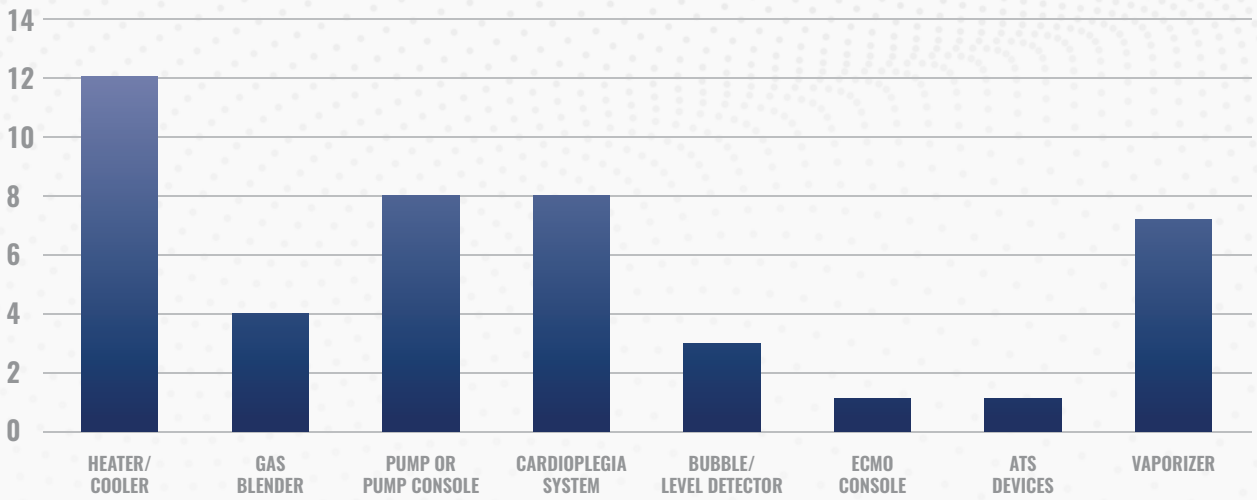
This report focuses on equipment failures and opportunities for clinicians to decrease risk by mitigating the impact of such failures. For this report, we reviewed Non-Routine Events submitted to the Orrum PSO from May 1, 2021, through November 19, 2024. Out of 288 reports submitted during this period, 279 had completed analysis by November 19, 2024. Of these analyzed reports, 44 involved capital equipment failures (1), representing approximately 15% of all reports.

% OF REPORTS THAT INVOLVE CAPITAL EQUIPMENT FAILURE

Involved Capital Equipment Failure

Completed Analysis – No Failure

When evaluating the reports, eight different categories of equipment were identified. In the chart below, the prevalence of each equipment type is listed.

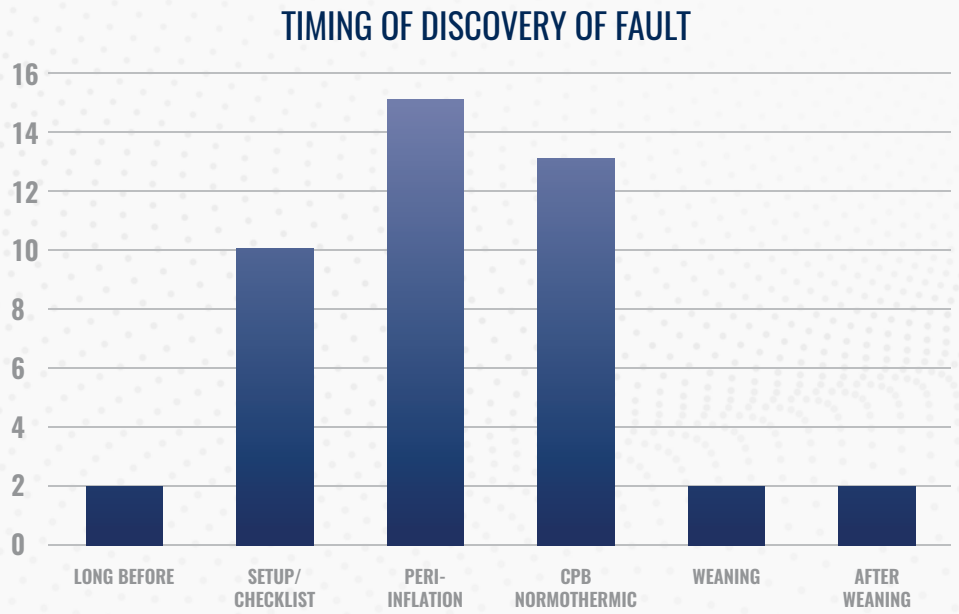


TYPE OF EQUIPMENT INVOLVED IN REPORT

EVENT DETECTION

The prevalence of event detection during each phase of the procedure was reviewed. The timing of event detection is crucial in mitigating the impact of equipment failures on the patient. The Orrum PSO reporting system allows the clinician to self-report the detection of the event in one of six phases of the procedure. The prevalence of detection during each phase is shown in the graph below.

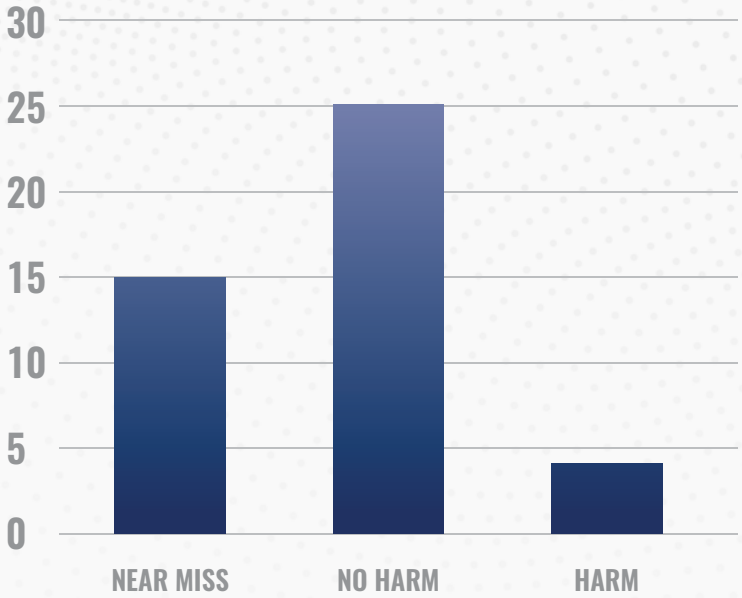
A concerning trend was observed whereby only 25% of defects were detected early in the procedure (before the patient entered the room or during the pre-bypass checklist), with the remaining majority detected as bypass was initiated or during middle portion of the bypass run. A relatively small number of defects were not found until the patient was being weaned from bypass or after the patient was off bypass.



This distribution of detection times highlights a significant opportunity for improvement in early identification of equipment issues. The high proportion of mid-procedure detections suggests that current pre-operative checks may not be sufficient or that some defects only become apparent under operational conditions.

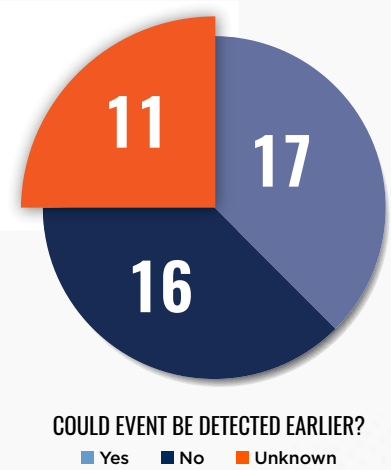
IMPACT ON PATIENTS

The impact on patients, as defined by the World Health Organization (2), closely mirrored the proportion seen in the timing of detection, with 34% found before reaching the patient (near miss), 57% found after reaching the patient but not resulting in harm (no harm), and 9% being found after reaching the patient and causing harm (harm).



IS EARLIER DETECTION POSSIBLE?

To understand why many defects are not found until later phases of care, each event in the series was reviewed to determine if different clinical techniques could have allowed earlier detection. In only 36% of the cases, the defect was detected as early as was reasonably possible. In 17 reports, approximately 39%, the defect could have been detected earlier using different clinical techniques. 25% of the reports lacked sufficient clarity in descriptions of equipment setup, testing, and checklist utilization to determine if earlier detection was possible. This group included mostly anonymous reports without follow-up contact information.



CONCLUSION:

A significant portion (15%) of reported events are related to equipment failures. These failures involve a wide collection of different equipment types and are often not discovered until the initiation of cardiopulmonary bypass. Case by case review indicates a significant number of these events could be detected much earlier, which would likely lessen patient impact.

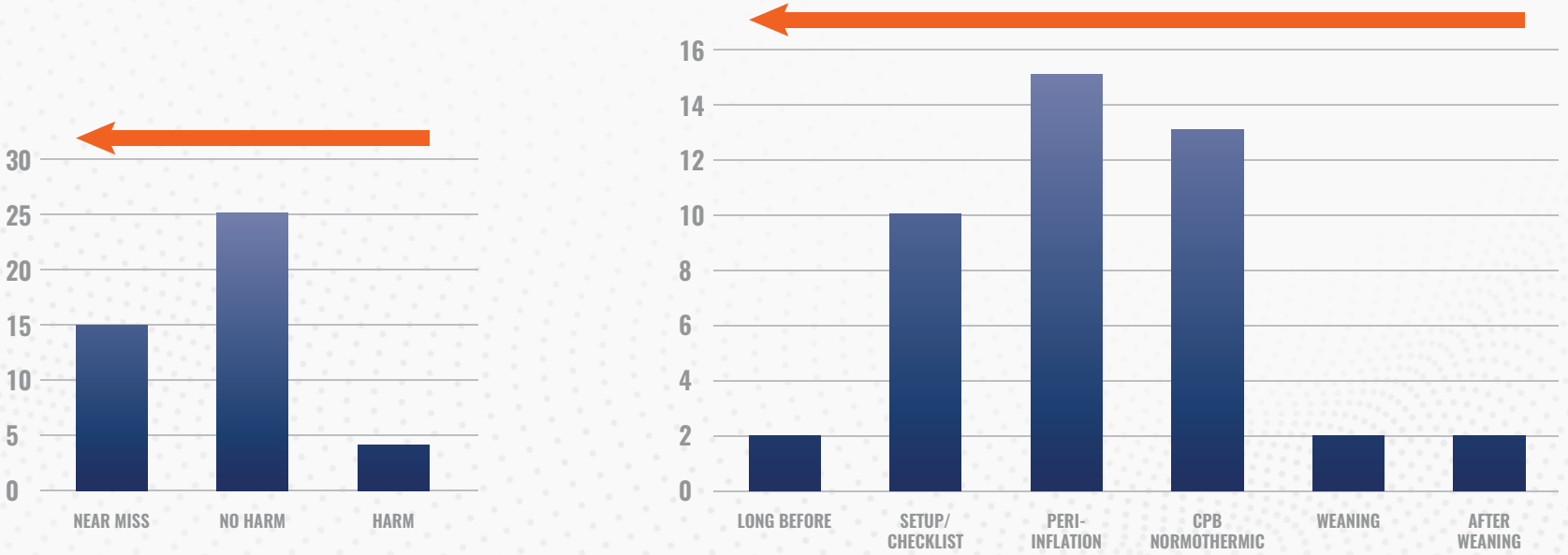
DISCUSSION:

Thematically, the data may represent reports that fall into three general categories, with likely overlap between each.

- **Theme 1:** Gold standard: Reports where the event was detected prior to the procedure or during the pre-CPB checklist, were categorized as “near miss,” and where analysis found no clinical technique could have led to earlier detection.
- **Theme 2:** Opportunity for Improvement: Reports where the event was detected at the initiation of CPB or after, were categorized as “no harm,” and where analysis found earlier detection was possible.
- **Theme 3:** Great Unknown: Reports where event was detected after the initiation of CPB or later, were categorized as “no harm” or “harm,” and where insufficient detail prevented understanding if earlier detection was possible, but where description of the failure allowed the possibility of earlier detection.

INDICATIONS FOR CLINICAL PRACTICE:

The prevalence of equipment failures highlights the need for enhanced vigilance and improved protocols in assembly and testing of surgical equipment to ensure patient safety. The data surrounding detection timing suggests that it is possible to "Shift the curve to the left." In this case, it may be possible to shift the curve for both event discovery and patient impact to the left, resulting in earlier detection and less patient harm.



Two specific examples for "shifting the curve" include the 2023 Report to AmSECT (3), which outlines techniques for testing Heart Lung Machine (HLM) alarm systems to detect failures, which were three of the events reported here. Additionally, the 2024 Report to AmSECT (4) outlines specific techniques for testing the HLM gas supply system for failure points, which were 11 of the events reported.

The large number of reports which include Heater/Cooler failures (12 reports) suggest an opportunity to use improved clinical techniques to make further significant advances in the timing of event detection. Load or "stress" testing of Heater/Coolers was suggested by Gary Grist in the AmSECT FMEA archive and provides a good starting point for development of a more holistic approach which may significantly improve the timing of detection for these types of events (5).

With over 300 Non-Routine Event reports received, the Orrum PSO has generated more than 70 novel recommendations for clinical practice, many of which directly address the need to shift the detection and impact curve identified here. The continuous development and refinement of potential mitigation strategies demonstrates the Orrum PSO's ongoing commitment to improvement in patient safety.

OUR SAFETY IMPACT

317
NRE REPORTS ANALYZED

180
PARTICIPATING FACILITIES

>70
NOVEL BEST PRACTICES GENERATED

400
PSO PROTECTED SIMULATION TRAININGS

REFERENCES & DEFINITIONS:

1. Capital Equipment = Defined as any piece of equipment not discarded at the end of a case, including pumps, cell salvage devices, and gas blenders, but excluding tubing, oxygenators, or reservoirs.
2. World Health Organization. Conceptual Framework for the International Classification for Patient Safety. 2009. Available at https://iris.who.int/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf. Accessed on 2/4/25.
3. Orrum Patient Safety Organization (PSO). The 2023 Annual Report on Safety in Cardiac Surgery. 2023. Available at https://amsect.org/policy-practice/orrum. Accessed on 2/4/25.
4. Orrum Patient Safety Organization (PSO). The 2024 Annual Report on Safety in Cardiac Surgery. 2024. Available at https://amsect.org/policy-practice/perfusion-safety. Accessed on 2/4/25.
5. Grist, G. Cardiopulmonary Bypass (CPB) Safety Program and Failure Mode Effect Analysis (FMEA): Open circuit, roller and centrifugal pump. Rev. 8/1/16. Available at https://amsect.org/Portals/0/AmSECT%20Documents/FMEA%20Archives/CPB%20FMEA%208%201%2016%20revision.doc. Accessed on 2/4/25.

Suggestions from 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 Orrum PSO suggestions. Orrum PSO analysts are available to members at no cost to review individual reports or application of specific suggestions.

REPORT APPENDIX

- 64 Report describes a pump failure during initiation of CPB, leading to an inability to achieve flow.
- 69 Report describes failure of a centrifugal pump controller unit just prior to initiation of CPB.
- 71 Report describes power loss to a centrifugal pump controller unit during CPB.
- 79 Report describes a low level sensor which failed to alarm or intervene during CPB depsite a low level in the reservoir.
- 88 Report describes a vaporizer failure which resulted in failure to oxygenate during the initiation of CPB.
- 94 Report describes a bubble detector which alerted with a false positive just prior to CPB.
- 95 Report describes a centrifugal pump head which was discovered to be irreversibly locked into the centrifugal motor after the completion of CPB.
- 103 Report describes a bubble detector which alarmed false positives multiple times during setup and testing for a CPB procedure.
- 110 Report describes failure of a heater/cooler, with no backup available, as the surgeon was cannulating.
- 111 Report describes a cell salvage device which spontaneously stopped working (centrifuge) in the middle of a procedure.
- 119 Report describes the discovery of a malfuntioning heater/cooler during the setup and checklist phase of a procedure.
- 126 Report describes an electrical short of a heater/cooler with no back up on site, discovered as the patient entered the OR for surgery.
- 133 Report describes a heater/cooler that was rendered unusable during the setup and checklist phase of a procedure when a plastic connector broke off inside the hanson fitting.
- 135 Report describes a patient whose temperatures could not be maintained at the desired set point during CPB due to complications with heater/cooler water lines.
- 137 Report describes the failure of a mast mounted roller pump controller as the patient was entering the OR for surgery.
- 140 Report describes a cardioplegia delivery system which could not achieve desired temperatures during cardioplegia delivery and later gave multiple alarms and was powered down due to suspicion of heating element malfunction.
- 146 Report describes a malfunctioning vaporizer discovered shortly after initating CPB.
- 154 Report describes failure of an electric gas blender that occurred during cannulation.
- 181 Report describes a malfunctioning vaporizer discovered during the initiation of CPB.
- 189 Report describes failure of a cardioplegia delviery system discovered just after the initiation of CPB.
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- 191 Report describes failure of a cardioplegia delivery system discovered just after the initiation of CPB.
- 205 Report describes a partial gas supply failure discovered after the placement of the aortic cross clamp, caused by a defective vaporizer.
- 215 Report describes a faulty cardioplegia delivery device discovered during setup and testing for a CPB procedure.
- 229 Report describes a faulty heater/cooler that was discovered during routine cleaning.
- 235 Report describes a suspected heater/cooler failure that was discovered during setup and testing for a CPB procedure.
- 246 Report describes an ECMO console which had a catastrophic failure while in use on a stable ECMO patient.
- 251 Report describes a suspected heater/cooler failure that occurred during a Deep Hypothermic Circulatory Arrest case.
- 263 Report describes a damaged gas blender that was discovered during CPB as a result of hypercapnia on CPB.
- 272 Report describes a heater/cooler which failed during the CPB rewarming period with no functioning backup in the facility.
- 284 Report describes the failure of a mast mounted roller pump controller while a patient was on CPB with cross clamp in place.
- 288 Report describes a faulty vaporizer discovered during the initiation of CPB.
- 292 Report describes a faulty vaporizer discovered during the initation of CPB.
- 297 Report describes a faulty heater/cooler discovered during the setup and testing period for a CPB procedure.
- 299 Report describes the catastrophic failure of a centrifugal pump controller module in the period just after weaning from CPB.
- 303 Report describes a complicated course which may include malfunction of the centrifugal pump or pump controller in the period just after the initiation of CPB.
- 313 Report describes the failure of a cardioplegia delivery device midway through a CPB procedure.
- 314 Report describes the failure of a cardioplegia delivery devcie midway through a CPB procedure.
- 326 Report describes the failure of a cardioplegia delviery device after the initation of CPB but prior to cross clamp placement.
- 331 Report describes a faulty vaporizer that was discovered during the initiation of CPB.
- 335 Report describes the failure of a heater/cooler that was discovered while the surgeon was taking down the mammary for a CABG procedure.
- 348 Report describes a defective heater cooler discovered during the rewarming phase of a CPB procedure.
- 349 Report describes a defective gas blender that was discovered during setup and testing for an off-pump procedure.
- 353 Report describes a defective gas blender that was discovered during setup and testing for a CPB procedure.