

The 2026 Annual Report on

**Supply backorders and
product substitutions, risk
factors for adverse events?**

produced by ORRUM for AmSECT

THE PURPOSE OF THIS REPORT

This report focuses on supply backorders and product substitutions, both situations which may lead to practice changes, and create increased risk for adverse events.

BACKGROUND

In 2025, the AmSECT Safety Committee suggested a potential query for the 2026 Orrum PSO Annual Report to AmSECT regarding backorders and device substitutions. Orrum previously undertook a thematic review of event reports and identified “Practice Change” (defined as “Any event which was caused by, suspected to have been caused by, or includes as a salient feature the presence of a new clinical practice, new, different, or substituted disposables or durable hardware, charting systems, EMRs, etc.”) as a recurring theme, which provided a baseline data set for the Safety Committee query.

INTRODUCTION

Being familiar with medical devices and disposables leads to enhanced use and safety. A sudden disruption in the supply of materials can lead to the use of disposables that are either different or unfamiliar, require a new/different protocol, or are simply unknown to the provider (1). That unfamiliarity can lead to a forced change of practice that may be acute, create a delayed provision of care, lead to unintended (mis)use of a disposable, or disposables that are not compatible with the rest of the products used.

Events happening during Cardiopulmonary Bypass (CPB) or ECMO can be especially challenging, given the complexity and rapid sequence of manipulations during procedures, forcing providers to make decisions and find solutions in a timely manner.

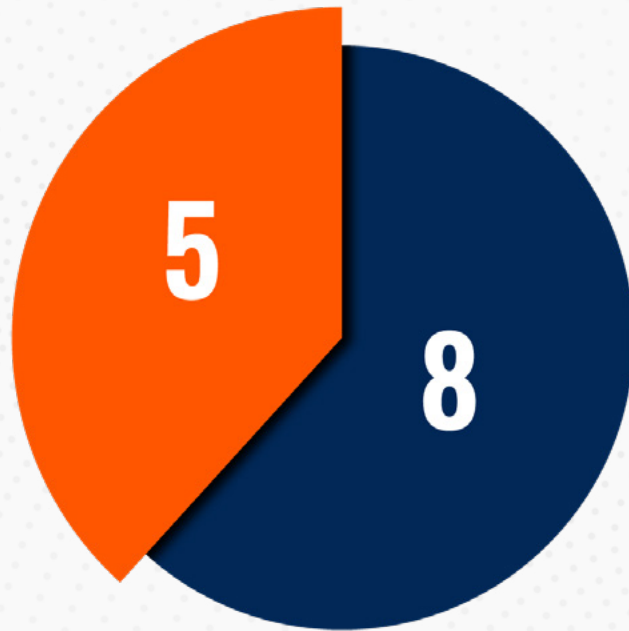
In this year’s report, we reviewed Non-Routine Events (NRE) submitted to the Orrum PSO database, from inception to December 15, 2025. Out of 398 reports submitted during this period, 336 had completed analysis.

We searched all completed NREs, using the “Practice Change” theme. A Boolean search was also conducted on narrative sections of the reports to find additional NREs with the terms, “Backorder”, “Substitution”, “Ordered”, “New Material”, “Practice change”, “Recall”, and “Supply chain.” Initially, 65 reports were identified. Each report was then individually reviewed by two analysts to confirm they met the intent of the Safety Committee query. After this review, 13 reports were used in the final analysis.

DESCRIPTIVE STATISTICS

The 13 reports describe a total of 16 patient incidents.

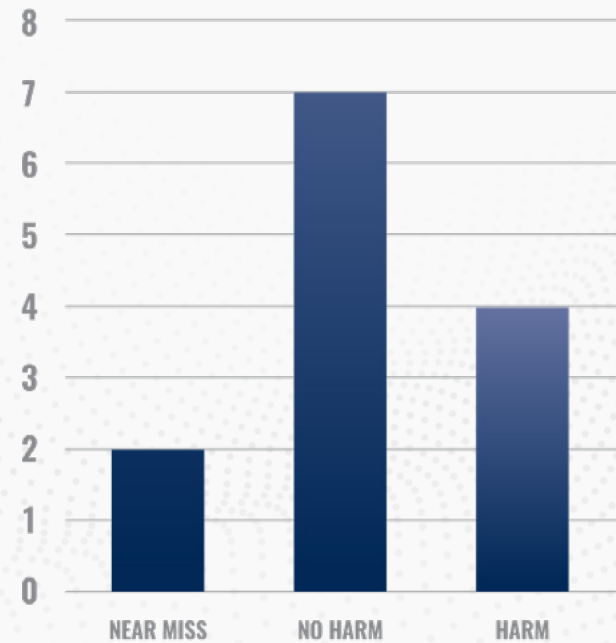
PERCENT RELATED TO SUPPLY BACKORDERS



■ Related to Supply Backorders ■ Not Related

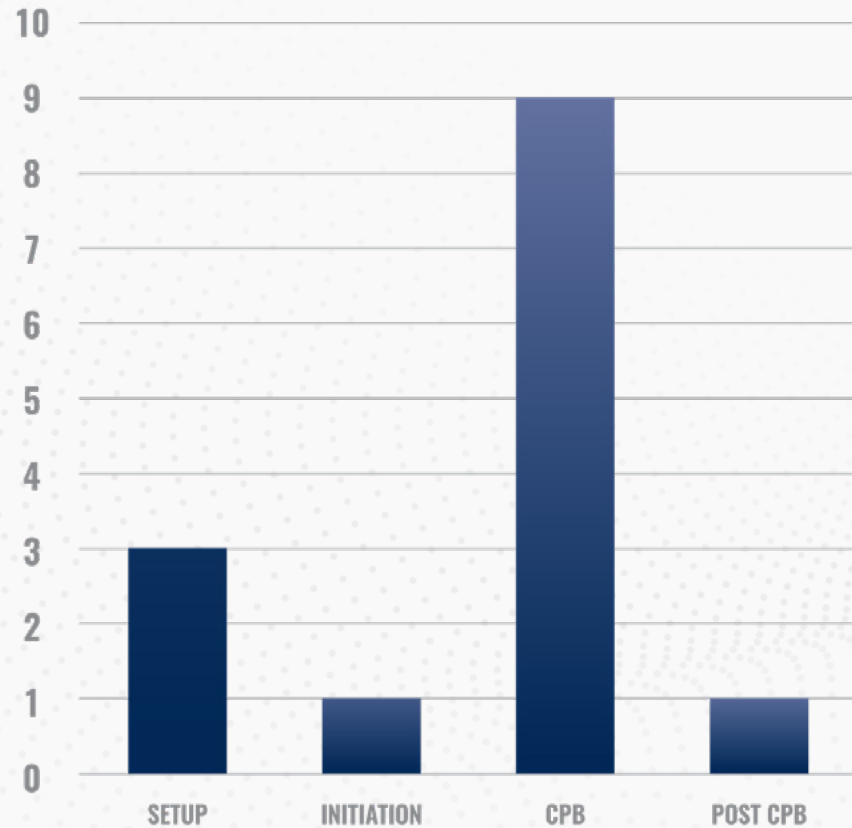
Of those 13 reports, 8 were directly related to a supply backorder of disposables, forcing the healthcare provider to use a different product, sometimes for the first time.

EVENT CATEGORIES



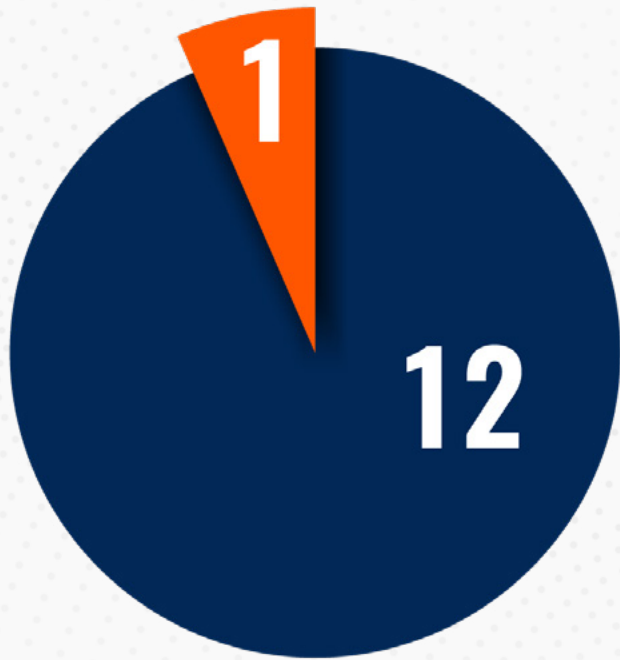
Of the 13 reports, 2 were deemed Good Catch/ Near Miss, 7 were Good Catch/No Harm, and 4 were deemed Harmful.

TIMING OF EVENT DETECTION

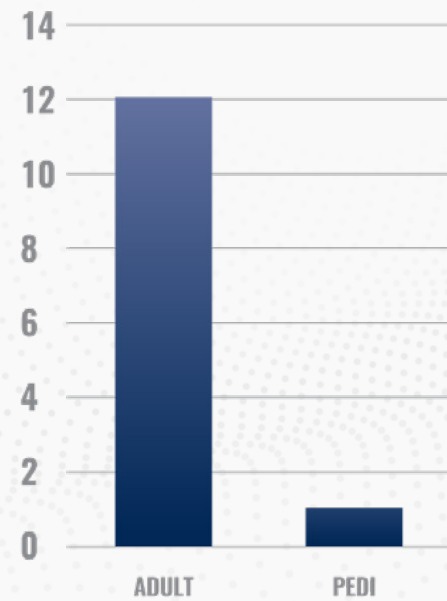


With regards to the timing, three happened/were discovered during set-up or priming, one at initiation of (CPB), nine during CPB, and one happened post-bypass.

PROCEDURE ACUITY



PATIENT POPULATION



In all but one case, the acuity of the procedure was elective. In all but one case, the patients involved were adults.

CLINICAL VIGNETTES/CASE REPORTS

The following clinical vignettes are based closely on real-world events but have been anonymized to prevent identification. All vignettes have been reviewed by the Orrum Non-identification committee.

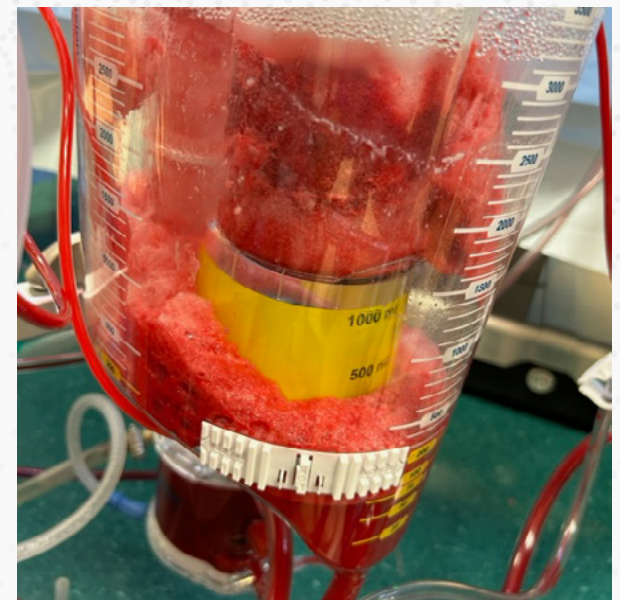
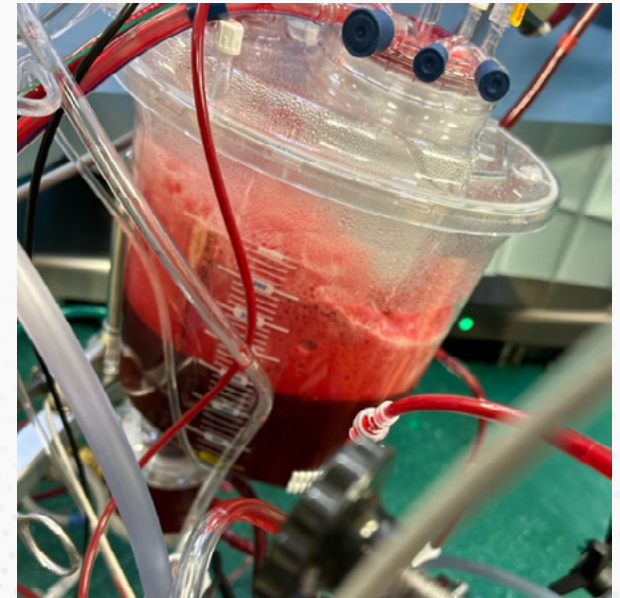
CASE #1: FOAM BUILDUP IN THE VENOUS RESERVOIR USING NEW DISPOSABLES

A facility recently began using a new tubing pack, with oxygenator, as the previous supply was unavailable due to manufacturer backorder.

During a minimally invasive procedure, the perfusionist initiated CPB using VAVD set at less than -40mmHg. The clinical group chose a specific configuration for return of sucker/vent lines and the return of blood coming from the hemoconcentrator. The specific line placements were not contraindicated but had previously been reported to cause foam development under specific conditions (using VAVD on minimally invasive procedures).

Twenty minutes into the procedure, the perfusionist noted acute foam building in the venous reservoir. The buildup continued and hemoconcentration was stopped to preserve reservoir volume level, which also halted foam buildup.

After a PSO protected interview with the provider, it appears that the foam buildup was due to the same root cause as the previous report (specific use case, not product defect). A mitigation strategy had been developed, but the acute change in supplies left the clinicians unprepared to deploy a mitigation technique for a product they had previously never used. As a result, this case was coded as a Practice Change themed report.



CASE #2: GROSS AIR ENTRAINMENT IN CARDIOPLEGIA SYSTEM

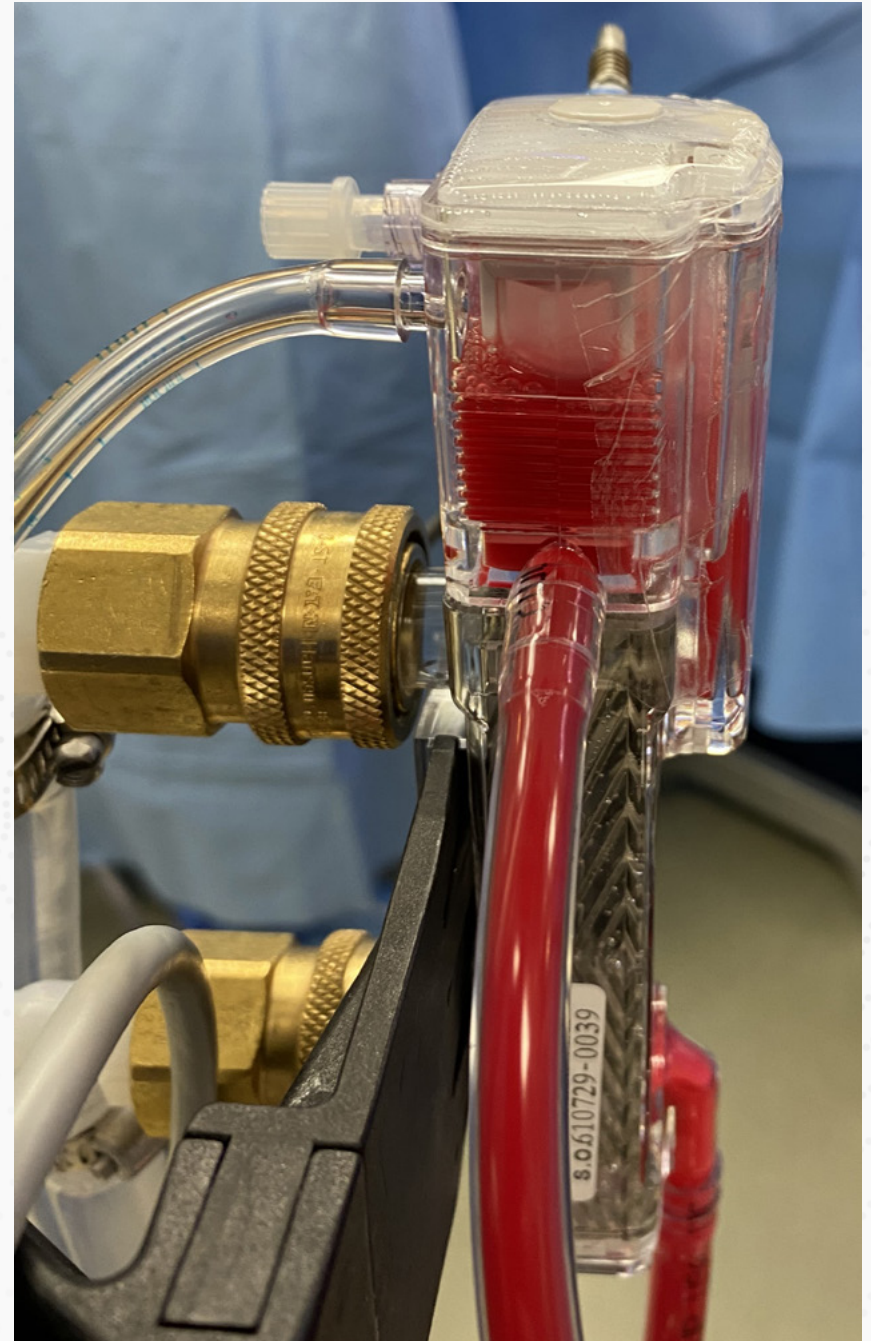
A facility transitioned to a new tubing pack due to supply chain disruptions. The new pack included a redesigned cardioplegia delivery configuration and a new disposable device containing a hydrophobic filter.

Under the previous setup, the aortic root vent design isolated the cardioplegia system when venting, preventing communication between the aortic root vent and the cardioplegia delivery line. The prior cardioplegia delivery device did not contain a hydrophobic filter.

During an early case using the new system, full dose cardioplegia was administered with appropriate arrest achieved. Later in the case, significant air was observed within the bubble trap of the cardioplegia heat exchanger. No air was visualized in the patient delivery line, and no adverse patient effects occurred.

Investigation determined that assembly of the new configuration inadvertently created a continuous fluid pathway between the aortic root vent and the cardioplegia delivery line. This exposed the hydrophobic filter in the new delivery device to sustained negative pressure during venting. As no air was present proximal or distal to the cardioplegia device, it is believed that this negative pressure allowed retrograde air entrainment across the hydrophobic filter membrane, resulting in gross air accumulation within the heat exchanger.

Because both the altered vent configuration and the introduction of the hydrophobic filter were directly related to the tubing pack substitution, this event was categorized as a Practice Change themed report.



CASE #3: ARTERIAL / VENOUS LINE REVERSAL

During an emergency procedure on a redo chest, the surgical team was forced to utilize femoral arterial and venous cannulation. The venous cannula was new to the facility and included a $\frac{3}{8} \times \frac{1}{2}$ " tubing hank for adapting to a standard $\frac{1}{2}$ " venous line. While attempting to urgently place the patient on CPB, the tubing hank, which is not tethered or connected to the cannula, was accidentally connected to the arterial cannula after it was placed. This led to inadvertent reversal of the arterial and venous lines.

Upon initiation of CPB, difficulty with drainage and low MAPs were masked by the patient's condition (in extremis). Moments later the switch was identified visually by slight differences in the cannula appearance at the distal connector.

Because the line reversal was in part due to the new venous cannula (the previous model did not have a $\frac{3}{8} \times \frac{1}{2}$ " hank), and the surgical team was unfamiliar with the risk of switch, this case was coded as a Practice Change themed report.

CONCLUSIONS:

Disruptions in the supply chain may lead to the use of materials that are not standard to the provider, who often has little notice to familiarize themselves with new products. This can generate non-routine events that subject patients to a heightened risk of harm or potential lifechanging complications. These complications can lead to frustration, demotivation, a sense of incompetence, and insecurity for the provider. When the cause is due to an overwhelming number of patients, such as during the latest COVID-19 pandemic, the effects can be compounded (2).

It should also be noted that although this sample size is extremely small, the proportion of events in this collection which were categorized as resulting in patient harm was exceptionally high when compared to all known safety reporting systems in health care (3).

Prevention of adverse events due to supply backorders can be done on two levels: avoiding or anticipating the disruption/shortage and, when change is inevitable, preparation.

Suggestions for avoiding supply chain disruptions (adapted from ref (4)):

1. Identify and purchase key supplies (those w/o substitutions) from more than one supplier.
2. Substituted medications or supplies should ideally be similar to those already used by providers.
3. Inventories should be tracked electronically to monitor supply levels.

4. Consider higher inventories of supplies known or projected to be in short supply (for example the latest recall of aortic root needles (5)).
5. Institute alternate use protocols when a (potential) shortage is identified.
6. Support government and non-governmental organizations in efforts to address supply chain vulnerability (such as ELSO Supplies Exchange Platform for ECMO Equipment Sharing (6)).

Suggestions for preparing practice change:

1. Be aware of the alternatives on the market.
2. Familiarize yourself with the new product. PSOs can assist with this process.
3. Read new product IFUs.
4. Make sure the product can be integrated into the existing practice (flow limitations, connections, etc.)
5. Prepare any necessary protocols for the new product.
6. Ask colleagues to share experience on the use of a new product. PSOs can provide/facilitate this information.
7. Request information from the manufacturer on the correct use and pitfalls. PSOs can assist with identification of pitfalls.
8. Be aware of upcoming potential shortages (4).

Further suggestions to mitigate product supply disruptions, can be found in the National Academies of Sciences, Engineering, and Medicine Consensus Report that suggests a framework based on Awareness, Mitigation, Preparedness and Response (1).

We hope that the collection of events caused by supply chain disruption, and the reporting of their analysis, can make the provider aware of the dangers and possible consequences, not only for the patient, but also for the providers themselves.

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