

Original Articles

Developing a Prospective Incident-Reporting System for Clinical Perfusion Practice in the United States

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Abstract: For nearly 20 years, prominent perfusionists have called for a perfusion-centric prospective incident-reporting system to collect near-miss and patient harm incidents that occur during clinical practice in the United States. In this article, we describe the development of a widely available prospective incident-reporting system for use by perfusionists in the United States. The system was developed in three phases: literature review, system incorporation, and submission for listing as a Patient Safety Organization (PSO).

It is anticipated that the knowledge gained from analysis of events contributed to this PSO-protected reporting system will lead to improvements in safety and quality of perfusion services, as well as expanding the understanding of best practices in training, equipment use, system design, and simulation scenarios. **Keywords:** perfusion safety, incident reporting, Patient Safety Organization (PSO), near-miss, accidents, CPB complications. *J Extra Corpor Technol. 2022;54:175–90*

Cardiopulmonary bypass (CPB) and related extracorporeal support procedures have been developed over the past 50 years to allow for the correction of conditions previously deemed inoperable. In the United States, these systems are operated almost exclusively by Certified Clinical Perfusionists (CCPs). Despite advances in techniques and technology, clinical perfusion practice remains a highly complex field and CPB is described as the highest risk procedure hospitals routinely perform (1). The rate of serious adverse events (SAEs) appears higher in perfusion than in related fields such as anesthesia, and some reports have put the occurrence of near-miss events in perfusion as high as 1:138 (2,3).

Outside of the United States, there are multiple perfusion-centric incident-reporting systems in use (4,5). However, the development of a perfusion-centric U.S.-based incident/near-miss reporting system has been elusive. Legal and technical concerns have prevented the use of non-U.S.-based incident-reporting systems by U.S. providers (6). As a result, nearly 20 years have passed since

the first calls for its adoption with no such system in place (6–8). Single center or local systems have been developed and reported previously but widespread use of a prospective incident-reporting system has not been available or used (6,9,10).

The purpose of this article is to describe the process used at Orrum Clinical Analytics (OCA) (Plymouth, MI) to design and build a widely available prospective incident-reporting system for use by perfusionists in the United States.

MATERIALS AND METHODS

Phase One: Literature Review

In support of our goal, a qualitative literature review was undertaken using emergent design. This method is defined as one where “The initial plan for research cannot be tightly prescribed, and some or all phases of the process may change or shift (11).” In general, our literature review had three primary objectives.

1. To identify components of successful incident-reporting systems for perfusion inside and outside of the United States.
2. To identify components of perfusion-centric incident-reporting systems that are noted as desirable but absent from current systems.

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3. To identify general outlines or designs of incident-reporting systems in other healthcare fields that were seen as “minimum standards.”

To capture system components described both inside and outside of peer-reviewed literature, we began our review by conducting parallel google and PubMed searches for the term “perfusion event reporting.” All searches were conducted from February 1, 2020, through October 1, 2020. The complete literature review strategy is outlined in Figure 1. In total, the items included in our review are presented in Table 1.

Following collection, qualitative content analysis of the included literature was undertaken (12). In this analysis, the collection was examined in whole to identify a small number of themes that emerged (11). Each item in the collection was then individually reviewed and coded, and tallies were kept of any content relevant to the literature review objectives (11,12). At the conclusion of this examination, common themes were combined and resulted in a list of eight components that were repeatedly mentioned. Once these components were established, we moved on to phase two, and began system and resource design to incorporate all eight components into a single incident-reporting structure.

Table 1. Number and classification of references included in final literature review collection.

Number of References	Reference Type
8	Perfusion centric, peer-reviewed
4	Perfusion centric, not peer-reviewed
3	Perfusion centric, national report or position statement
1	Non-perfusion centric, peer-reviewed systematic analysis

Phase Two: System and Resource Design and Testing

With the eight desired components identified via literature review, we took each one and designed a system and/or resources to incorporate each component to the greatest extent possible.

Component one: Standardized definitions Standardized definitions of safety or incident events in perfusion have not been formally established. Uncertainty about what to report or how to classify an event once it has been reported has been a noted obstacle to incident reporting in perfusion (6,10). To standardize definitions and encourage capture of “good-catch” and “near-miss” events, the previously published verbiage of a “Non-Routine Event”

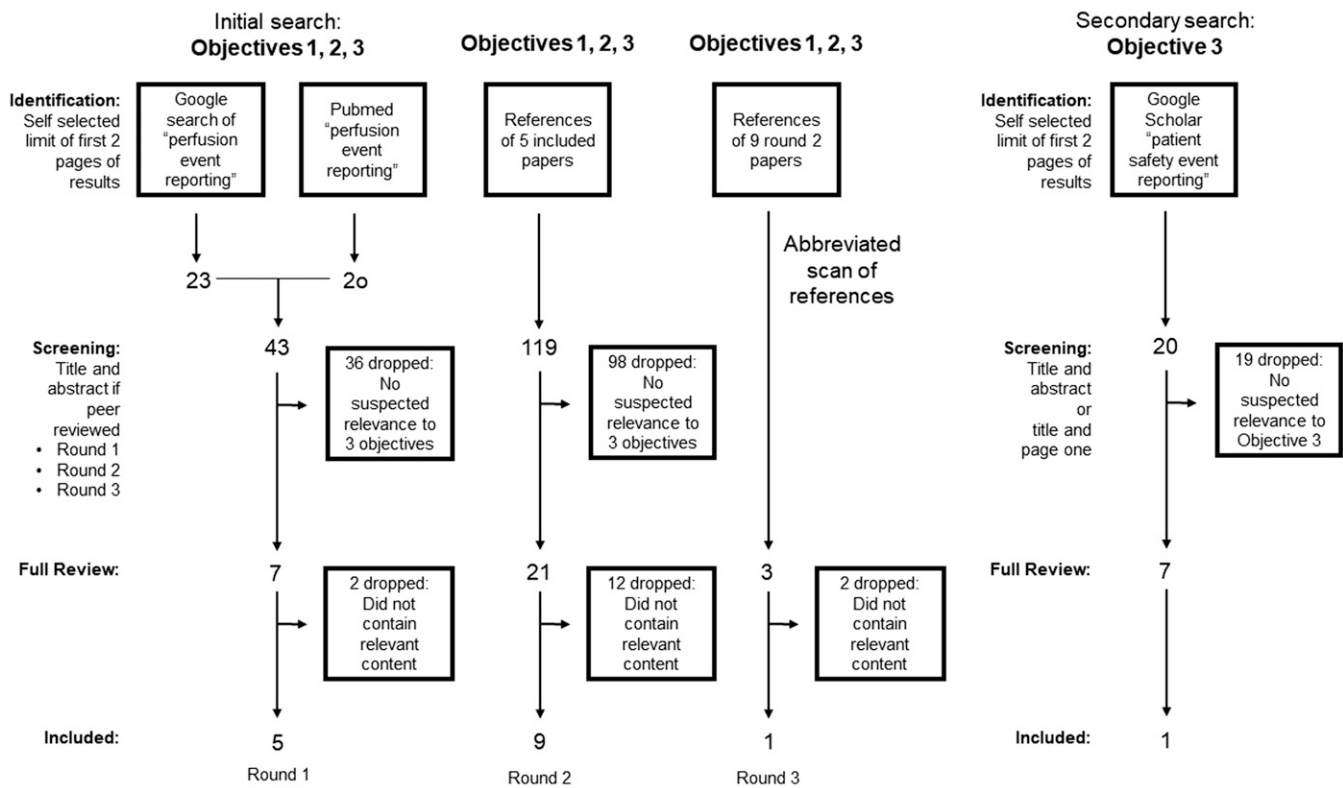


Figure 1. Literature review strategy.

(NRE) was adopted (10). To make this perfusion-centric verbiage standardized, we integrated it with suggestions on defect reporting from the Agency for Healthcare Research and Quality (AHRQ), thus an NRE was defined as any “Event...you would not want to have happen again” (13). Thus, any NRE can be reported to the system. This allows clinicians wide leeway in reporting.

The reporting form, (Appendix A), was modeled after the ANZCP (Australian and New Zealand College of Perfusionists) PIRS-II (Perfusion Improvement Reporting System – II) and SCPS/CCPS (The Society of Clinical Perfusion Scientists/College of Clinical Perfusion Scientists) Safety Committee reporting forms (14,15) for standardization, satisfaction of World Health Organization (WHO) criteria, and in hopes of enabling international participation (16). Additional fields and definitions were added to address shortcomings in previous reporting models (6,10).

Component two: Reporting that is customizable, prospective, anonymous, online, secure, and encrypted. Multiple sophisticated patient safety reporting systems are commercially available today (17–19). These systems possess many features, of which, the desired ones can be organized into three broad categories.

1. Secure and encrypted online reporting. Secure, encrypted transmission, and data storage from across the country (20).
2. The ability to develop and customize workflow for report analysis (6,8,10,20–22).
3. The ability to submit anonymous reports and still receive feedback (6,8,10,23).

Origami Risk (Chicago, IL) was selected as our vendor of choice based on their ability to meet these requirements. Origami Risk is a web-based reporting system that permits submission from anywhere in the world. Anonymous submissions have been shown to significantly increase event reports in other healthcare fields (24). Security is maintained through Origami using encryption and password access. The reporter has discretion regarding the extent of contact information they may wish to provide (Appendix A, question seven). Analysts obtaining the information are trained on the confidential and privileged nature of NRE reports and are required to sign a confidentiality agreement.

Component three: Capture “good-catch” and “near-miss” events. Previously published reports have highlighted the increased knowledge and power from capture of near-miss events (6,8,10,22,25–28). To maximize the reporting of these events to the system, a three-part approach was developed.

First, standardized definitions were adopted that were broad and intended to follow published definitions, which include “good-catch” and “near-miss” events (6). Second, the reporting form had defined data entry points to allow for capture of what was included as part of a good catch or near-miss event (21,26,29). Finally, the reporting form avoided requiring the reporter to categorize the event, as this has been suggested to create an obstacle for clinicians who are unsure about patient outcome or other definitions required to categorize the event (i.e., Was the event a good catch or not?) (6).

Component four: Narrative event entry with automated validation techniques. In following established practices for similar reporting systems, most data elements for submitted events allow for narrative format (14,21,26). For all non-narrative data, automated validation techniques were included in the design. For example, preventing input of a future date as the date of the incident (30). As part of the agreement for system support, these validation techniques can be updated as the submission form evolves, or as additional validation techniques become available.

Component five: Standardized analysis of events. Each incident undergoing analysis is assigned a team of reviewers consisting of the operations director and a subject matter expert (SME) (31). A flow chart that outlines the process is presented in Figure 2. This chart outlines the steps involved in the analysis, including structural suggestions the operations director can make to the SME based on previous reports to the system, as well as the ability of the SME to contact the reporter for clarification before analysis is completed.

The analysis form, appended below (Appendix B), begins with a narrative section in which the analyst gives a general description of the events as they understand them. All fields of the analytical form are searchable by a system administrator. The goal is to create a system capable of more accurately and effectively collecting and distributing information with each additional report.

To summarize, analysis standardization is achieved by:

- Training analysts on standardized techniques, process, and workflow.
- Employing two experienced clinicians familiar with the equipment and techniques reported in the NRE.
- Adopting a standard report template containing event classification by modified Reason’s Error Classification System (mRECS), timing, equipment involvement, contributing factors, and recommendations for mitigation of future risk.
- Requiring both analysts to reach consensus on findings.

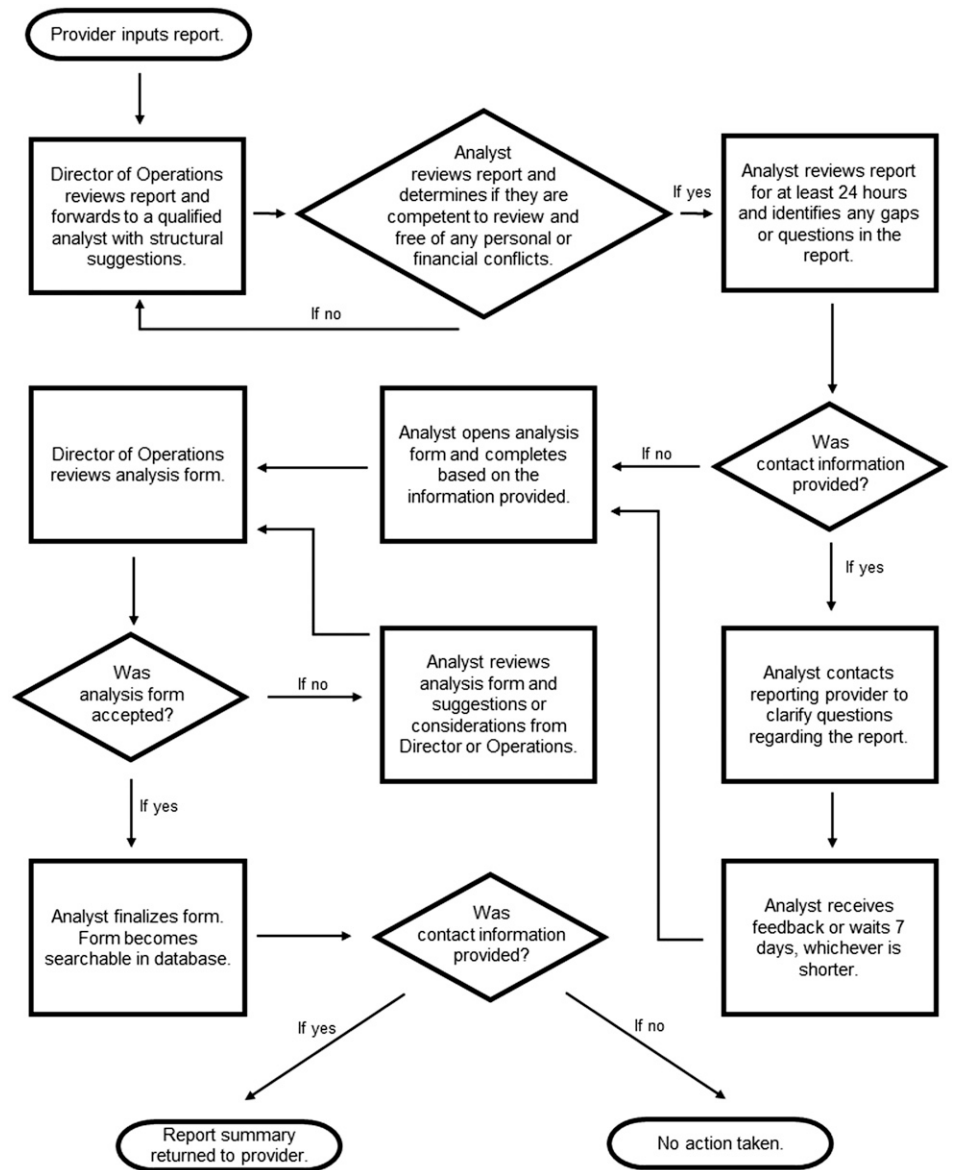


Figure 2. Non-Routine Event (NRE) Report analysis workflow.

Component six: Consistent, timely, high-quality feedback. Consistent, timely, and high-quality feedback is noted to be important to successful use of incident-reporting systems (2,8,23). To develop this component, a variety of techniques are used. First, individuals who submit an NRE report see a confirmation message once their event is successfully submitted. In addition, if a contact e-mail is provided, the person submitting receives a follow-up e-mail stating that their submission has been received and is undergoing review, incorporating closed-loop communication. If a report is started but not completed, and contact information is provided, the provider will receive a reminder e-mail after 24 hours stating that their report is still in draft form. To promote timeliness

of the feedback, a service goal has been established to begin analysis of each event no later than 72 hours after submission.

Component seven: Wide dissemination of lessons learned. As suggested in prior publications, the small size of most perfusion departments in the United States means that reviews of safety events may yield little to no benefits at the local level (8,10,13,26,32,33). For this reason, the ability to disseminate lessons learned across multiple organizations and clinical sites is essential to improving the safety of the community.

To achieve this component, we determined our reporting system would need to be organized as a Patient

Safety Organization (PSO), listed by the U.S. Department of Health and Human Services (HHS) AHRQ (34). PSOs provide enhanced access to reporting, analysis, and recommendations in a protected environment, which prohibits disclosure and ensures confidentiality. Legally, PSOs allow providers, defined as “An individual or entity licensed or otherwise authorized under State law to provide health care services” to become members of the PSO and have access to services and deliverables the PSO generates (35). In pursuit of our goal for a widely available system, with broad dissemination of lessons learned, anyone who meets the legal definition of a provider can become a member and have access to the analysis (but not identifying details) of each event. Theoretically, this structure allows all NREs and their analysis to be accessible by all clinicians and organizations in the United States.

Component eight: Protection for reporters and data.

Fear of discovery is noted as a major barrier to event reporting in several publications (6,8,23,25,28). To establish anonymity, as well as legal protection for both the reporters and the data contributed, we rely upon a combination of the PSO structure and IT system design.

Many authors note that submission to an incident-reporting system should be non-punitive (6–8,25). Though mandatory reporting was mentioned as desirable in one reference, a mandatory component has been purposefully left out of our incident-reporting system to highlight a non-punitive nature (7). To further promote this aspect of the event reporting system, we include in our PSO contracts a requirement for providers to use the information from our reporting system solely for the purposes of improving the safety and quality of healthcare delivery. We note that other uses of the information provided would be a violation of the Patient Safety and Quality Improvement Act (PSQIA) and be reportable to the Office of Civil Rights (35). In addition to legal protections, IT protection was needed. The selected IT vendor was required to show compliance with a variety of security standards (36–39).

System testing. Using the eight desired system components, template NRE forms were developed based on similar reporting systems in other countries and repeatedly tested in a sandbox environment for functionality (14,15). These sandbox tests were undertaken to assure the correct flow of data from reporting form to primary reviewer and SME, while remaining inaccessible to all other system users. Sandbox testing was also undertaken to confirm that the completed analysis could be correctly returned to the provider submitting the report, again, without being accessible to other system users. Before collecting actual NRE data, four perfusionists who had

no knowledge of the project were asked to complete a mock NRE submission. The perfusionists who were selected to submit reports represented a convenience sample that was in close geographical proximity to the primary author. The four perfusionists ranged in experience from less than 1 year up to 20 years. Three had bachelor’s degrees, and one held a master’s degree. Three were board certified at the time by the American Board of Cardiovascular Perfusion (ABCP). Feedback on content and clarity was requested, after which, only minor grammatical suggestions were received. These suggestions were reviewed and incorporated with the consensus of the authors.

The modified submission form was then used to generate two mock submissions that were processed by a primary reviewer and an SME to determine the content and clarity of the analysis form and process. Feedback received consisted of including or expanding selected definitions, as well as suggestions on how to orient new SMEs to the form. Following this feedback, the suggestions for modification were again incorporated into the analysis model with a consensus of the authors and an orientation process was outlined for use in orienting and training of new SMEs.

Phase Three: Creation of Legal Structure.

After our literature review but before system design, we contacted Emergency Care Research Institute (ECRI) (Plymouth Meeting, PA), one of the first and largest PSOs, to determine whether we could house a perfusion-centric reporting system inside their PSO. At the time, ECRI worked only with existing PSOs and used only the AHRQ Common Formats for reporting (40). As our system was not yet a listed PSO and we wished to create a perfusion-centric incident-reporting system that did not follow the Common Formats, this was not feasible. Additional attempts to locate resources that could act as a turnkey solution were unsuccessful. As a result, we contracted with ECRI to act as a consultant and began the development of our own PSO. Becoming a PSO is a five-step process that is overseen by AHRQ (41).

Step one: Assess eligibility. Assessing eligibility has two parts. Part one is the general assessment for eligibility. First, the mission and primary activity of the entity must be to conduct activities that improve the safety and quality of healthcare delivery. Second, the entity must not be any of the following: a health insurance issuer (or controlled by a health insurance issuer), an entity that accredits or licenses healthcare providers, an entity that enforces regulatory requirements of healthcare services, or an entity that operates a patient safety reporting system to which healthcare providers are required to report (42).

Part two of the process is determining “Full Entity PSO” vs. “Component PSO” status and determination of “Parent Organization(s).” After an extensive review of the Patient Safety Rule terms, and in conjunction with legal counsel, we determined that the appropriate status for our PSO entity would be Component PSO listing with OCA (Plymouth, MI) as the Parent Organization (42).

Step two: Assess compatibility of anticipated operations with patient safety rule requirements. In this step, we reviewed the requirements related to security, confidentiality, Health Insurance Portability and Accountability Act (HIPAA), and disclosure of Patient Safety Work Product (PSWP). We determined our IT structure, in combination with policies and procedures that ECRI would assist us in developing, would allow us to meet the requirements. The Patient Safety Rule allows for sharing of staff, information systems, and other technical tools between a component organization and its parent organization(s). The component organization, however, is required to have methods to prevent the unauthorized disclosure of PSWP to parent organization(s). We tested our IT system for proper controls and permission levels to assure that PSWP could be placed in silos to prevent access by non-PSO OCA workforce.

At the end of step two, AHRQ also recommends reviewing the application for initial listing as a PSO (43). This application requires attestation and self-certification that the entity will comply with the following seven criteria:

1. Mission and primary activity of the PSO is to conduct activities that improve patient safety and quality of healthcare delivery.
2. The workforce of the PSO must be appropriately qualified, including licensed or certified medical professionals.
3. The PSO must obtain two bona fide contracts within 24 months of listing.
4. The PSO is not a health insurer or a component of a health insurer.
5. Disclosures regarding relationships with providers that are not part of a bona fide contract.
6. Collection of PSWP from providers in a standardized manner that permits comparisons.
7. Use of PSWP for providing direct feedback and assistance to providers to minimize risk.

During the initial review of these seven criteria, we determined we met criteria one, four, and seven. During discussion with our consultants, we outlined plans to use CCPs and registered nurses (RN) with related experience to conduct event analysis, meeting criteria two. While not required at time of listing, we felt confident

we could achieve criteria three within the required 24-month period. We previously outlined our standardized collection of data based on the established PIRS-II and SCPS/CCPS Safety Committee reporting forms, and our standardized analysis based on the modified learn from defects tool published by AHRQ (13). By pairing these two standards, we were comfortable self-certifying for criteria six. Finally, criteria five requires disclosure of any relationship between a PSO and a provider that is not part of a relationship strictly based on a contract to provide services under the PSQIA. As our entity would be receiving administrative and back-office support from a provider of perfusion services (Comprehensive Care Service, Livonia, MI), and we anticipated that provider entering a PSQIA contract with the PSO, we determined we would be required to submit a disclosure at the time the contract was executed. Thus, we felt confident that we would comply with all seven criteria. After assessing the compatibility of our predicted operations against the requirements, and with endorsement of our consultants and legal counsel, we moved on to step three.

Step three: Development of policies and procedures. In step three, the entity is required to develop policies and procedures that outline the content of and methods to carry out eight patient safety activities required of a PSO (44). These eight activities are the following:

1. Efforts to improve patient safety and the quality of healthcare delivery.
2. Collection and analysis of PSWP.
3. Development and dissemination of information such as recommendations, protocols, or best practices.
4. Using PSWP for encouraging a culture of safety and providing feedback to minimize risk.
5. The maintenance of procedures to preserve confidentiality of PSWP.
6. Provision of appropriate security measures for PSWP.
7. Use of qualified staff.
8. Use of a Patient Safety Evaluation System (PSES) and feedback to participants in the PSES.

Using primarily information from our Phase Two: System and Resource Design, and with input from ECRI, we undertook the process of developing our policies and procedures. Our entity would be considered a Component PSO of OCA (45). As a result, additional policies are required to be in place regarding sharing of employees between OCA and the PSO, maintenance of PSWP separate from OCA generally, prevention of unauthorized disclosures by shared workforce members, missions that do not conflict, and written agreements regarding OCA assistance with patient safety activities (42).

Step four: Select PSO authorized official (AO). The Patient Safety Rule relies mostly on self-certification for meeting the PSO listing requirements (43). The AO must be authorized to sign the certification form that contains the self-certifications. The AO will also be required during technical assistance discussions or compliance assessments with AHRQ.

Step five: Submit certification for initial listing form. The Certification for Initial Listing form requires administrative information about the entity applying for listing as a PSO and any parent organization(s), as well as specific disclosures regarding previous PSO work if any (46,47). Having completed steps one through four, our initial application for listing as a PSO was submitted to AHRQ on 3/11/2021.

RESULTS

After the initial application for listing was submitted, AHRQ contacted us for a post-submission call. After these additional communications, the system achieved PSO listing status with the Secretary of the Department of HHS on April 6, 2021. The Orrum PSO listing information was published on the AHRQ website on April 9, 2021 (48).

The first contract for providing services under the PSQIA was executed on May 1, 2021. As this contract was with a provider whom the PSO had a relationship that was outside the PSQIA services, a disclosure was filed with AHRQ (42,43,49). After review by the secretary of HHS, our PSO was given permission to operate without restriction (50).

Once all processes were re-checked, the system went live on May 24, 2021 and began collecting and analyzing NRE reports through our portal, which requires log in to enter. In September 2021, we opened a portal to allow event submissions via a world wide web site perfusionsafety.org. This site allows non-members to submit an NRE report to the PSO without the need for a log in or password.

Through the first 11 months of operation, the PSO has received and analyzed 46 unique incident reports. The standardized analysis to which these reports are subjected has been completed and returned to their respective providers, if disclosed. The process has yielded 11 recommendations for best practices, none of which are included in the AmSECT standards and guidelines. In addition, the analysis has generated multiple opportunities to develop high-acuity simulations and training for previously undescribed NREs.

Exhaustive analysis of these reports is beyond the scope of this article; however, general review of the reports indicates that, of the reports received, 21 were

submitted anonymously, and 25 were submitted with confidential contact information provided. When the submissions are divided by calendar quarter, the trend is for an increased number of submissions, with each quarter showing a higher number of reports than the one that preceded it.

LIMITATIONS

The development of a perfusion-centric incident-reporting system that is part of a PSO and allows for the incorporation of the eight desired components commonly noted in the literature has not been undertaken before and presents several limitations.

First, while the ANZCP PIRS-II and SCPS/CCPS Safety Committee systems created an established reporting standard for us to follow, neither system appears to use a standardized analysis. As a result, the development of our analysis was done *de novo* using non-perfusion-centric nomenclature that was modified during adoption. This analysis design, being untested for extracorporeal support procedures, presents inherent limitations.

Second, the desire to allow voluntary, anonymous reports creates two important limitations. Primarily, the rate of incidents can never be determined. Voluntary reporting, by definition, means that some providers will decide not to submit reports. This may occur in an additive fashion to those who would choose not to submit reports even if reporting were mandatory. The net effect is that the rate of incidents with our system or provider groups is unknowable, despite the number of incidents submitted or the period in which they are received. This has been noted as a limitation in other healthcare-related reporting systems (51).

In addition, anonymous reports provided without return contact information mean that some analyses that would normally be undertaken via additional queries to the reporter are not carried out. To some extent, all aspects of these reports will be affected, including categorization of the event (e.g., by equipment used, procedure type, and time of occurrence), understanding of underlying causative factors, and suggestions for future mitigation. Thus, the absence of mandatory contact details creates limitations in that some reports will be submitted that both need clarification and do not have contact information provided. As a result, these reports must be analyzed cautiously and may not produce actionable knowledge. When considering this limitation, we judged that a larger number of reports received under an anonymous reporting structure would be more beneficial than a smaller number we expected to receive using a fully identified system (24).

Another limitation present with our system is that most reports will be submitted without an on-site investigation conducted, either by members or our PSO or local providers. While follow-up contact with the reporter can help to limit or eliminate inaccurate, unverified, or biased information, it is possible that some information will be incorporated into the reports that are not substantiated by facts.

When considering research access, we note that the PSQIA was designed primarily to increase safety and quality in healthcare using a translational approach. Access to identifying information for research purposes is permitted only if the research is sanctioned by the U.S. Department of HHS Secretary (52). Internal analysis conducted by PSOs is permitted under the PSQIA, and researchers can be hired as temporary employees of a PSO when desirable analysis is identified. A PSO employee, having completed training and meeting all legal requirements, can undertake the analysis of data inside the PSO. Using this technique can assist in additional analysis and dissemination of lessons learned, while stopping short of allowing open access for research purposes. This limits widespread access to identified data strictly for research purposes.

Finally, while several systems are in place in the United States to assist with reporting of different types of events in healthcare, we have opted not to include them as part of our reporting form. It has been noted that strong cultural barriers may still exist to U.S. perfusionist reporting to an incident-reporting system, thus we aim to have the reporting form be succinct to provide the least possible friction to submitting (53). For this same reason, we do not include most components of the Common Format for reporting in the United States (40). This means reports made to our system would require substantial modification if they were to be included in the Network of Patient Safety Databases (NPSD) (54). We also do not address reporting of the incident to other bodies, including local risk management, state authorities, manufacturers, or the Manufacturer and Users Device Experience (MAUDE) registry (55). These decisions, while presenting a system limitation, were again undertaken to assist in establishing a succinct reporting form.

When considering other reporting systems, we also note that the content of a PSO report generally cannot be shared to or referenced by other systems (56). While the information submitted to a PSO may be present in other locations, the copy inside the PSO, as well as all analyses and conclusions that exist inside the PSO, remain confidential and privileged, and can only be returned to the provider group that made the submission. This can allow sharing back to select local (i.e., hospital based) risk management or quality departments, but

prohibits virtually all other bodies. This helps to create clear silos of protection for the data submitted but prevents sharing of data between systems (e.g., a MAUDE report generally could not be linked to PSO data). While this creates a limitation for PSOs, the PSQIA was designed primarily to create strong protections for the data to encourage detailed examination of patient safety events without fear of liability, and not for widespread investigation by various government entities (56).

As with other reporting systems, we anticipate that the design of the reporting form and analysis of the contents will evolve over time as a more comprehensive understanding of the number and types of events emerges. Likewise, potential collaboration with professional associations, industry partners, and international societies may contribute to a more finely tuned reporting, analysis, and classification system.

DISCUSSION

The potential benefits of an NRE reporting system are many. Initially, quantifying the number and type of incidents would allow both practicing clinicians and educators to understand the risks they face with respect to frequency and type. If this knowledge can be quantified, stakeholders could develop clinical simulations and training that address the specific scenarios they are likely to face, instead of those based on textbook knowledge or simulator design (27). Ginther et al. found that perfusion students who simply thought about a potential problem before dealing with it performed approximately 20% better than those who did not (57). Thus, it is possible that reviewing a collection of NREs could significantly improve performance in crisis situations. Another benefit is that these data would be available in near real-time, allowing rapid identification of equipment, disposable, and personnel trends that are associated with higher risks. This contrasts with published incident surveys, which are intermittently available at significant lag after data collection (8).

From a perfusion-centric perspective, an NRE reporting system may assist the development of national standards and guidelines, in part using empirical experiences and not solely consensus standards. Aggregation of data from large numbers of incidents could assist in understanding what safety initiatives are working and which ones might need revision or redeployment of resources (24). Such a system would affect the culture of perfusion in a “shift from case-based, retrospective reporting to trend-based, prospective reporting” (8).

The value in large numbers of reports, including those that are categorized as “good-catch,” “near-miss,” and

those that do not result in patient harm has been well described (10,58,59). These types of no-harm NREs have been suspected of initiating a cascade of complications that result in larger process failures (10). This cascade is understood to be present in other high-risk industries, such as aviation and nuclear power (8). Voluntary reporting of these types of events is believed to lower the incidents of more SAEs by helping to understand how existing defenses fail (6,29). In line with this thinking, Kuruz speculated that French perfusionists had been able to achieve a low SAE rate despite lack of safety equipment in part because of the use of an event reporting system (60). Thus, another potential benefit of this system may be to decrease the number of no-harm NREs that occur. This decrease should then bring down the number of failure cascades that result in SAEs.

The concept of shared learning from accidents and near-misses has long been established in healthcare. Many institutions have local systems for capturing SAEs, but most perfusion departments in the United States are small in size (8,61). This has led some authors to suggest that single-institution systems offer no benefits because they are limited in both analysis of the event and distribution of lessons learned (8). Because of these characteristics, these systems may perceive events as random occurrences instead of part of a trend in a larger collection of data (8).

In addition to the opportunities for improvement that an incident-reporting system offers, PSOs possess other potential benefits. Conduct of simulations, training, and clinical competency assessments can be done inside a PSO, making them privileged and confidential. Peer-to-peer assessment, as described by Mort et al., also allows significant opportunities for learning and improvement inside a PSO (62). This type of assessment encourages facilities to seek out input on their weakest components without fear of incrimination. Typically, institutions are incentivized to showcase their strengths and hide their weaknesses from accrediting bodies. With a peer-to-peer assessment, in contrast, no punitive action is possible, and the results of the assessment remain privileged and confidential. Thus, rigorous review of weaknesses becomes possible without concern for legal discovery or citation by accrediting bodies. Finally, recommendations for interventions or best practices that arise from PSOs are considered PSWP and as such are not discoverable or admissible in court.

In conclusion, it should be noted that a variety of models exist, which can help to reduce errors, improve performance, and increase safety. Failure Mode Effects Analysis (FMEAs) and Root Cause Analysis (RCA) are currently in widespread use in healthcare generally and perfusion specifically (63). These techniques, under the current system, only help patients retrospectively and locally (8). It has further been suggested that the size

and case volume of North American perfusion departments means that no benefit would be garnered from an SAE report limited to a single institution, independent of RCA results (8). Because of these limitations, FMEAs and RCAs should be implemented in an additive fashion to an NRE reporting system (7). In this way, clinicians will not be limited to one route with which to improve the quality of care.

SUMMARY

It has been widely suggested that cardiac surgery centers should participate in prospective registries of good-catch, near-miss, and SAEs related to perfusion or extracorporeal circulation (7–10,27,28,32,60,64). Professional societies outside of the United States have officially adopted this position and AmSECT has an initiative underway (20,65–67). Many authors have also noted a moral and ethical obligation to report harmful and near-miss incidents in perfusion (68–70).

After the creation of a conceptual outline, we have designed and built a widely available prospective NRE reporting system for use by perfusionists in the United States. The system allows perfusionists, physicians, and other providers access via an anonymous, secure, online portal from anywhere in the world. The data submitted and analysis generated are confidential and privileged, protected by the Patient Safety Act of 2005 (34,71,72). A standardized analysis of NREs delivers timely, high-quality feedback to reporters, and the PSO structure permits wide dissemination of lessons learned to the larger perfusion community.

As with other benchmarking and database systems developed previously, we anticipate that future versions of data collection and analysis will evolve with the addition of other providers, stakeholders, and professional societies to add more granular examination of NREs, moving the focus from management of risk to improvement in training, equipment, and system design.

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APPENDIX A

NON-ROUTINE EVENT

- **Notice: The form below submits information to the Orrum PSO, a Patient Safety Organization listed by the United States Secretary of Health and Human Services. The information submitted is protected by Patient Safety and Quality Improvement Act of 2005.**
 1. Would you like this submission to be anonymous?
(Providers will be able to select one of two answers)
 - A. Yes
 - B. No
 2. *Was the incident a ...
(Providers will be able to select one of four answers)
 - A. Good catch/near-miss—An incident that did not reach the patient
 - B. Good catch/no harm—An incident that reached a patient but no discernable harm resulted
 - C. Harmful incident—An incident that reached the patient and resulted in harm or an unknown level of harm
 - D. Unknown
 3. *Full and detailed description of the incident or variance (please include brand of equipment used): (Providers will be able to enter an unlimited amount of narrative text into a free text box).

4. *What went well “GOOD CATCH”? (Providers will be able to enter an unlimited amount of narrative text into a free text box).
5. What could we have done better? (Providers will be able to enter an unlimited amount of narrative text into a free text box).
6. Future preventative actions planned or instituted? (Providers will be able to enter an unlimited amount of narrative text into a free text box).
7. May we contact you for follow-up analysis of this event? (saying yes can still allow your submission to remain anonymous)
 - A. Yes B. No
 - (If this is answered yes, then the option to enter any one or all of the fields below appears)
 - i. Confidential Contact Name _____
 - ii. Confidential Contact E-mail _____
 - iii. Confidential Contact Number _____
8. Is your institution a subscribing member of the Orrum PSO? (Not required to submit a report)
 - A. Yes B. No
 - (If the provider answers YES, a drop-down menu appears and allows them to select their institution from a list of subscribing members)
 - Here, an option to upload a video, photograph, or electronic health record (EHR) data log of the event is present in the form of a submission button labeled “Save and Continue” appears.
 - Additional Optional Fields Below:
9. Was this an error made by yourself?
 - A. Yes B. No
10. Was an additional perfusionist or specialist available in-house to assist during this incident?
 - A. Yes B. No
11. Timing of incident: (Provider can select one answer from the following list)
 - A. Setting up/Pre-prime
 - B. Prime
 - C. Post-Prime/Pre-cannulation
 - D. Post-Cannulation/Pre-CPB
 - E. CPB Hypothermic
 - F. CPB Normothermic
 - G. Post-CPB
 - H. ECMO/VAD/IABP Extra Corporeal Membrane Oxygenation (ECMO), Ventricular Assist Device (VAD), Intra-Aortic Balloon Pump (IABP)
12. Procedure acuity
 - A. Elective B. Emergent
13. How was the incident FIRST detected? (Provider can select one answer from the following list)
 - A. Observed by self
 - B. Alerted by monitor or alarm
 - C. Change in monitor sound, trend, or display
 - D. Third party
14. Duration of the incident: (Provider can indicate the number of hours, minutes, or seconds the event lasted, each in a separate and labeled box)
15. Impact on patient: (Provider can select one answer from the following list)
 - A. None
 - B. Mild (transient variance not extending LOS)
 - C. Significant (injury prolongs intensive care unit [ICU]/hospital stay)
 - D. Serious (injury lasting > months and expecting to resolve)
 - E. Unknown
16. Hours of sleep in last 24 hours: (Provider can enter a number up to two digits in a free-text box)

17. Hours since last sleep:
(Provider can enter a number up to two digits in a free-text box)

Required questions indicated by *after submission for publication, the ANZCP requested the following citation to be added to the bottom of this appendix:

"Note: Portions of this form have been adapted from the Australian and New Zealand College of Perfusionists (ANZCP) Perfusion Improvement System 2 (PIRS2) Incident Report form and have been reproduced here with the express written permission of the ANZCP. Further reproduction prohibited without permission. For more information on the ANZCP and the PIRS2 system, please visit <https://anzcp.org/pirs-ii/>. "

APPENDIX B

PSO ANALYST EVENT ASSESSMENT FORM

1. Please provide a written summary of the event. Include your understanding of what likely happened during the event.
2. Would following the current AmSECT Standards and Guidelines have prevented the event from occurring? If yes, please provide the specific standard or guideline that is applicable.
3. Were you able to ascertain if the host facility had existing policies and procedures that should have prevented the event from occurring or lessened the chances that the event occurred?
 - a. I was not able to ascertain.
 - b. I was able to ascertain they did NOT have policies and procedures that should have prevented the event from occurring.
 - c. I was able to ascertain they DID have policies and procedures that SHOULD have prevented the event from occurring, but the policies and procedures were not followed.
 - d. The provider was unsure if they had policies and procedures.
4. When did the error that caused the event (the primary error) happen:
 - a. Long before the procedure (i.e., equipment was not properly maintained, equipment was stored improperly, equipment was damaged at some remote time, etc.).
 - b. During the setup/initial checklist period (i.e., during the time when the perfusionist should have properly conducted a pre-CPB or pre-ECMO checklist).
 - c. In the peri-initiation period (i.e., during heparinization, cannulation, or initiation or first few minutes of CPB or ECMO).
 - d. During the maintenance of CPB (i.e., after the first few minutes of CPB but before the period where weaning would begin).
 - e. During the weaning period (i.e., the period during weaning of CPB or ECMO and immediately after CPB or ECMO is discontinued, including protamine administration, if applicable, and adjustment of vasoactive drips)
 - f. After the weaning period.
5. When was the event discovered by the clinician?
 - a. Long before the procedure (i.e., equipment was not properly maintained, equipment was stored improperly, equipment was damaged at some remote time, etc.).
 - b. During the setup/initial checklist period (i.e., during the time when the perfusionist should have properly conducted a pre-CPB or pre-ECMO checklist)
 - c. In the peri-initiation period (i.e., during heparinization, cannulation, or initiation or first few minutes of CPB or ECMO).
 - d. During the maintenance of CPB (i.e., after the first few minutes of CPB but before the period where weaning would begin).
 - e. During the weaning period (i.e., the period during weaning of CPB or ECMO and immediately after CPB or ECMO is discontinued, including protamine administration, if applicable, and adjustment of vasoactive drips)
 - f. After the weaning period.
6. Please categorize the event using the algorithm below: (a two-step question where they select all that apply and then need to make a decision about the PRIMARY cause)
 - 6b. Please select the primary cause from the items selected above:

Please mark all categories that contributed to this event:

Mark

The clinician formulated an inappropriate or bad plan to deal with the situation due to lack of knowledge or experience.
 The clinician carried out an action that was a mistake because their attention was imperfect. The clinician had an “attentional failure.” Example: Administered phenylephrine when intended to administer heparin (both syringes labeled correctly). Do not choose this category if the clinician forgot to execute an action.
 The clinician forgot to carry out an action that was intended or that they would normally do in this situation. The clinician had a “memory failure.” Example: The clinician forgot to give mannitol at the appropriate time.
 Equipment Design: Alarms of similar sound, alarms allowing permanent override or not allowing override, lack of a battery backup for critical components.
 Product Design: Poor or identical labeling or packaging, different product components too similar in appearance, components designed to stay together which disconnect too easily.
 Technical Error/Chance: Plan and technique was appropriate, correct rules were followed, but intended outcome was not achieved. Includes failure of properly maintained equipment.
 The workspace layout did not allow needed equipment to be within reach, the vitals or lab results were not able to be reviewed, clutter, or poor workspace design resulted in event.
 Clinician failed to apply a rule (either national or local) designed to avoid this specific event.
 Clinician applied a “bad” rule. Example: Clinician applied a personal rule that is not consensus or evidence based and is not supported by standards, but which they erroneously felt would prevent this event.
 Clinician misapplied a rule. Example: Clinician applied a rule for increasing potassium in case of electrocardiogram (EKG) activity but did not realize interference from pump was causing a noisy EKG tracing.
 Workplace processes: Use of different rules or equipment between operating rooms. Example: Different pumps or alarm settings in adjacent odds ratios (ORs).
 Inadequate assistance available in case of emergencies or inadequate assistance available to provide breaks. Inadequate supervision of subordinate clinicians.
 Sociocultural Factors: Clinician overconfidence, reluctance to seek help, reluctance of a subordinate to assert themselves. Desire to uphold reputation.
 Physiological State: Clinician was fatigued or under chemical impairment.
 Multi-Person Failures: Communication or coordination between people, problems with handoffs, belief that someone else executed task when in fact they did not.
 Training of Personnel: Personnel were not trained to a level expected in the field. Example: Simulation or drills of “common” errors not conducted.
 Other

7. Was this event dependent upon the type of equipment used (i.e., could this event have happened using any similar device or is it specific to this device).

A. Yes B. No

7b. If yes, please select the type(s) of equipment involved from the drop down list (select all that apply).

a. Capital Equipment

i. Heater/Coolers

1. LivaNova 3T
2. Cincinnati Sub-Zero Hemotherm
3. Cardioquip without ice maker
4. Cardioquip with ice maker
5. Alpha-Omega Heater Cooler
6. Other _____

ii. Pumps

1. LivaNova S5
2. LivaNova S3
3. Terumo System 1
4. Sarns 8000
5. Cobe Centruy
6. Quantum Perfusion System (by Spectrum)
7. Maquet Heart Lung Machine
8. Other _____

iii. Stand Alone/Modular Pumps

1. Sarns 8000
2. LivaNova SCPC
3. Maquet Rotoflow
4. Medtronic Biomedicus 550

- 5. Medtronic Biomedicus 560
- 6. Other _____
- iv. VAD/ECMO Devices
 - 1. Impella
 - 2. Tandem heart/tandem lung
 - 3. Cardiohelp
 - 4. Centrimag
 - 5. Other _____
- v. Misc.
 - 1. Quest MPS
 - 2. Terumo CDI 500
 - 3. Terumo CDI 550
 - 4. Adapter Plates (for centrifugal pumps)
 - 5. Other _____
- b. Disposables
 - i. Tubing Packs
 - 1. Terumo
 - 2. Medtronic
 - 3. Maquet
 - 4. LivaNova
 - 5. Other _____
 - ii. Oxygenators
 - 1. Terumo FX models
 - 2. Terumo SX models
 - 3. Medtronic Affinity
 - 4. Medtronic Affinity Pixie
 - 5. Medtronic Fusion
 - 6. Maquet Quadrox models
 - 7. LivaNova Inspire
 - 8. LivaNova EOS PMP
 - 9. Other _____
- c. Equipment not listed
 - i. Other _____

8. Please complete the modified Learning from Defects assessment below (step one):

Below is a framework to help you review and evaluate the event. Please read each contributing factor and evaluate whether it was involved. If it was involved, did it negatively contribute (increase harm) or positively contribute (reduce impact of harm) to the incident?

Contributing Factors	Negatively Contributed	Positively Contributed	N/A
Patient			
Patient was acutely ill or agitated.			
There was a language barrier.			
There were personal or social issues.			
Task			
Was there a protocol available to guide therapy?			
Were test results available to help make the care decision?			
Were tests results accurate?			
Provider			
Was the provider fatigued?			
Did the provider's outlook or perception of his or her own professional role affect this event?			
Was the provider's physical or mental health a factor?			

(continued)

(cont.)

Contributing Factors	Negatively Contributed	Positively Contributed	N/A
Team			
Was verbal or written communication <u>during handoffs</u> clear, accurate, clinically relevant, and goal directed?			
Was verbal or written communication <u>during care</u> clear, accurate, clinically relevant, and goal directed?			
Was verbal or written communication <u>during a crisis</u> clear, accurate, clinically relevant, and goal directed?			
Was there a cohesive team structure with an identified and communicative leader?			
Training and Education			
Was provider knowledgeable, skilled, and competent?			
Did provider follow the established protocol?			
Did the provider seek supervision or help?			
Information Technology or Computerized Physician Order Entry			
Did the computer or software program generate an error?			
Did the computer or software program malfunction? <i>Equipment problems not related to information technology are not entered here, see first line in "Local Environment"</i>			
Did the user check what he or she entered to make sure it was correct?			
Local Environment			
Was there adequate equipment available and was the equipment working properly?			
Was there adequate operational (administrative and managerial) support?			
Was the physical environment conducive to enhancing patient care? Extra supplies/equipment available and easy to access.			
Were there enough staff on the unit to care for patient volume?			
Was there a good mix of skilled with new staff?			
Did workload affect the provision of good care?			
Institutional Environment			
Were adequate financial resources available? Does not include pay for clinicians but does include resources to support staffing models that have the appropriately licensed clinicians at the appropriate staffing levels, if requested.			
Were clinicians involved in care adequately in-serviced or educated on equipment, procedures, or processes?			
Was there adequate staffing in the facility to perform the procedure?			
Were clinicians adequately in-service or educated?			
Did the departments involved have a good infrastructure (e.g., policies and procedures)?			
Was there adequate staffing?			
Does hospital administration work with the units regarding what and how to support their needs?			

Step 2: Please list, in order of importance, the three most important contributing factors from the list above (if less than three, list all):

- 1.
- 2.
- 3.

9. If the risk of this event could NOT have been completely eliminated by following a previously established local policy or procedure, or an AmSECT standard or guideline, please list any interventions you can think of that would reduce the risk of this event re-occurring. For each intervention, please note your perception of the ability of the intervention to mitigate the risk for this event in the second column. For each event, also note your perception of the feasibility of the intervention (its implementation and execution in real day-to-day care) in column three.

Interventions to Reduce the Risk of the Defect	Ability to Mitigate the Contributing Factor, 1 (Low) to 5 (High)	Belief That the Intervention Will Be Implemented and Executed, 1 (Low) to 5 (High)