DEVELOPING A NOVEL 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 (U.S.). In this paper, we describe the development of a novel, prospective incident reporting system for use by perfusionists in the U.S. The system consists of eight components that were identified following an emergent literature review and include; (1) standardized definitions, (2) prospective, anonymous, online reports, (3) capture of “good-catch” and “near-miss” incidents, (4) automated validation techniques, (5) standardized analysis, (6) consistent, timely, high-quality feedback, (7) wide dissemination of lessons learned, and (8) legal and technical protections for reporters and data. After pilot testing and subsequent revisions, the system was submitted for listing with the U.S. Department of Health and Human Services Secretary and received listing status on April 6, 2021, as a Patient Safety Organization (PSO). Once all processes were re-checked, the system began collecting reports on May 24, 2021. It is anticipated that the knowledge gained from the analysis of events contributed to this PSO 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.

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INTRODUCTION

Cardiopulmonary Bypass (CPB) and related extracorporeal systems have been developed over the past half-century allowing for the correction of a wide range of conditions previously deemed inoperable. In the United States (U.S.), 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 that has been described as the riskiest 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).

Given these data, the concept of a perfusion-centric incident reporting system has long been discussed. In 2003, Journal of ExtraCorporeal Technology (JECT) editor and former American Society of Extracorporeal Technology (AmSECT) president Jeff Riley wrote that “Perfusionists frequently call for a national database to collect and report perfusion-related events, equipment failure and accidents” (4). He later stated the time for prospective reporting of perfusion incidents had come and that there was “Little reason to ever publish another retrospective perfusion incident survey” (5). Simultaneously, Kurusz summarized data on incidents during cardiac surgery by suggesting that “Prospective registries should be implemented in all cardiac surgery centers for ongoing quality control purposes” (6).

While perfusion-centric incident reporting systems are in use outside of the U.S., the development of a perfusion-centric U.S. based incident/near-miss reporting system has been elusive, with nearly 20 years since the first calls for its adoption (4, 7, 8). Single-center or local systems have been developed previously but the widespread use of a prospective incident reporting system has not been available or utilized (5, 8, 9).

The purpose of this paper is to describe the process used at Orrum Clinical Analytics (Plymouth, MI) to develop the legal, technical, and clinical components of a Non-Routine Event (NRE) reporting system for use in the United States.

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MATERIALS AND METHODS

System Design.

An emergent literature review was conducted to identify components that were cited as desirable for a perfusion-centric NRE reporting system. The initial Medline search was confined to journals known to focus on perfusion and cardiovascular surgery. The searches were conducted from February 1, 2020, through October 1, 2020. Subsequent articles were added for review based on citations in an included paper. Additionally, to capture system components described outside of peer-reviewed literature, a Google search was conducted. Select papers from this search were included in the review on an ad-hoc basis with the consensus of the majority of the authors, as has been done in other reviews (10). In this expanded Google search, the emphasis for inclusion was placed on review literature which would encompass industry-wide knowledge, as well as position papers and statements from governmental and non-governmental organizations with missions related to safety in healthcare.

An examination of the included literature produced eight components that were repeatedly mentioned as desirable. The collection is summarized in table one, with the number of references for each component in the third column: Once these components were established, the authors began the development of a system that would incorporate all eight into a single NRE reporting structure.

Standardized definitions.

Standardized definitions of safety or incident events in perfusion have not been well established. To standardize definitions and encourage the capture of “good-catch” and “near-miss” events, the previously published verbiage of a “Non-Routine Event” (NRE) was adopted (9). Integrating suggestions on defect reporting from the Agency for Healthcare Research and Quality (AHRQ), an NRE was defined as any “Event…you would not want to have happened again” (11). This definition was in-line with suggestions from other authors (7, 12, 13, 14, 15). Thus, any Non-Routine Event (NRE) can be reported to the system, which allows clinicians wide leeway in reporting.

For classification of errors, we adopted a modified structure based on the work of Reason, incorporating suggested changes from Runciman, et al. and AHRQ (11, 16). Where needed, definitions were modified to be specific to perfusion

practice. The following definition tree was thus developed (Figure 1). Errors may fall primarily into one category but have multiple categories which may be applicable. This issue is addressed in the analysis component of the system.

Reporting: Prospective, anonymous, online, secure, and encrypted.

The level of sophistication present in today's Information Technology (IT) prevented the development of an in-house solution to the technical design of the reporting system. A list of IT requirements was developed based on the literature review. These requirements were: Secure and encrypted online reporting. Secure, encrypted transmission, and data storage from across the country (17).

The ability to develop and customize the workflow for report analysis (7, 8, 9, 12, 15,17).The ability to submit anonymous reports and still receive feedback (7, 8, 9, 18).

Several vendors were then interviewed to determine if they were able to meet these system requirements. After review, Origami Risk (Chicago, IL) was chosen to contract for the development of the system based on their ability to meet these design requirements.

Capture "good-catch" and "near-miss" events.

Previously published reports have highlighted the increased knowledge and power from the capture of near-miss events (7, 8, 9, 13, 14, 15, 19, 20). To maximize the reporting of these events to the system, a three-part approach was developed.

First, standardized definitions were adopted which were broad and intended to follow published definitions which include "good-catch" and "near-miss" events (8). Second, the reporting form had defined data entry points to allow for the capture of what was included as part of a good catch or near-miss event (12, 14, 21). Finally, the reporting form avoided having the reporter 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?) (8).

Automated validation techniques.

In following established practices for similar reporting systems, most data entry for submitted events is in narrative form (12, 14, 21). For all non-narrative data, automated validation techniques were included in the system design, for example, preventing input of a future date for the date of the incident (10). Technology in the system allows for validation of a human inputting the data by using mouse tracking and other automated validation techniques. 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.

Standardized analysis of the event.

The ability to have a standardized analysis of an event was mentioned in a variety of publications (7, 8, 9, 12, 15, 17, 21).

To promote this goal, two processes were incorporated into the system design. First, each incident is assigned a core team for analysis/review which consists of a primary reviewer and a subject expert (22). Thus, the event will be reviewed in whole by two independent clinicians, each trained in a standardized analysis workflow. The subject expert is selected for each submitted event based on familiarity with the techniques and/or equipment involved.

Secondly, for analysis the system adopted a set of standards published by the AHRQ which guide the analyst through establishing variables associated with the event and weighing them according to their contribution. Following the analysis, the same tool uses a similar set of standards to determine suggestions for future prevention, along with the likelihood of deploying such suggestions (11). Following analysis, the event is classified using the modified version of Reason's Error Classification system, as described previously.

In summary, at least two experienced clinicians who are familiar with the equipment and techniques in use during the event, and who have received training on how to analyze similar events, proceed through a standardized workflow in reviewing the submission. They then produce a list of contributing factors, suggestions for mitigation, and classification of the event. Finally, to complete the analysis of the event, the primary reviewer and the subject expert must be in consensus when determining the underlying causative factors, suggestions for mitigation, and classification.

Consistent, timely, high-quality feedback.

Consistent, timely, high-quality feedback was noted to be important to the successful use of incident reporting systems (2, 7, 18). To develop this component, a variety of techniques were employed. First, individuals who submit an NRE report see a confirmation page once their event has been successfully submitted. In addition, if a contact email is provided, the person submitting receives a follow-up email stating that their submission has been received and is undergoing review, incorporating closed-loop communication.

For all reports, the use of a standardized analysis by experienced clinicians trained in the chosen approach is used to promote high-quality feedback. For each event, the reporter will receive the analyst's summary of the events of the NRE, a comparison of the NRE to published standards and guidelines, categorization of what happened, and suggestions for future mitigation (11, 23). Reviews of the event will be directed toward subject experts who have experience with the techniques or equipment used.

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

Wide dissemination of lessons learned.

As has been suggested in prior publications, the small size of most perfusion departments in the U.S. means that reviews of safety events may yield little to no benefits at the local level (7, 9, 11, 14, 24, 25). For this reason, the ability to disseminate lessons learned across multiple organizations and clinical sites is essential to improving safety.

To achieve this goal, our reporting system was organized as a Patient Safety Organization (PSO), listed by the United States Department of Health and Human Services Agency for Healthcare Research and Quality (26). The use of the PSO structure allows organizations and providers that join to have access in a non-identified way to the data gathered from all types of incident submissions across the country in a cumulative fashion. The legal protections the PSO offers were designed by the federal government to supersede all less stringent regulations that may exist at the local level. Thus, knowledge about incidents can be distributed in a non-identified fashion across city, county, and state lines without concern for differing laws regarding the exchange of such information

(27). As a result, the members have access to the analysis (but not identifying details) of each event, such that they can see the types of incidents, underlying causes, and suggested steps for future mitigation. Theoretically, this structure could allow all NREs and their analysis to be accessible by all clinicians and organizations in the U.S.

Protection for reporters and data.

Fear of discovery has been listed as a major barrier to event reporting in several publications (7, 8, 13, 18, 20). To establish anonymity, as well as legal protection for both the reporters and the data contributed, we relied upon a combination of the PSO structure and IT system design.

As outlined, the PSO framework provides legal protection for the reporter of an event as well as the data submitted. Data submitted to a PSO is both privileged and confidential (28). This legal structure also requires the PSO to maintain systems for continual training and attestation by employees of the requirements for non-disclosure, protection, and confidentiality. This legal framework, in addition to providing protection from discovery, creates substantial penalties for the release of identified information (28).

Many authors also noted that submission to an incident reporting system should be non-punitive (4, 7, 8, 13). Though mandatory reporting was mentioned as desirable, a mandatory component has been purposefully left out of our incident reporting system to maintain its non-punitive nature (4).

In addition to legal protections, IT protection was needed. The selected IT vendor was required to show compliance with a variety of security standards, including Authorization to Operate (ATO) under the Federal Information Security Management Act (FISMA) Moderate System Authorization and Accreditation, compliance with NIST 800-53, known as the HIPPA Security Rule, self-certification to the U.S. Department of Commerce that it adheres to the E.U.-U.S. Privacy Shield Principle, and independent audits confirming compliance with the American Institute of Certified Public Accountants (AICPA) Trust Services Security and Confidentiality Principles and Criteria.

The system also tracks users who are conducting analysis by date, time, records viewed and edited, and logs of previous values. In addition, there is continuous monitoring for unauthorized access attempts, as well as other intrusion attempts.

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 (29, 30). Prior to collecting actual NRE data, select perfusionists who had no knowledge of the project were asked to complete a mock NRE submission. Feedback on content and clarity was requested, with suggestions for modification reviewed and incorporated with the consensus of the authors.

The modified submission form was then used to generate two mock submissions which were processed by a primary reviewer and subject expert to determine the content and clarity of the analysis form and process. Following feedback, suggestions for modification were again incorporated into the analysis model with a consensus of the authors.

RESULTS

After appropriate legal and policy development, and after testing the technical components of the system, an initial application for listing as a Patient Safety Organization was submitted to AHRQ on 3/11/2021. Following additional communications with AHRQ, the system achieved PSO listing status with the Secretary of the Department of Health and Human Services on April 6, 2021. The Orrum PSO listing information was published on the AHRQ website on April 9, 2021 (31).

Once all processes were re-checked, the system went live on 5/24/2021 and began collecting and analyzing NRE reports.

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 simulations and training that address the specific scenarios they are likely to face, instead of those based on textbook knowledge or simulator design (19). 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 (33). 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 (7).

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 (34). Such a system would affect the culture of perfusion in a "shift from case-based, retrospective reporting to trend-based, prospective reporting" (7).

The value in large numbers of reports, including those which are categorized as "good-catch," "near-miss" and those which do not result in patient harm has been well described (9, 35, 36). These types of no-harm NREs have been suspected of initiating a cascade of complications that result in larger process failures (9). This cascade is understood to be present in other high-risk industries, such as aviation and nuclear power (7). Voluntary reporting of these types of events is understood to lower the incidents of more serious adverse events by helping to understand how existing defenses fail (8, 21). In line with this thinking, Kuruz speculated that French perfusionists had been able to achieve a low SAE rate despite a lack of safety equipment in part because of the use of an event reporting system (6).

The concept of shared learning from accidents and near misses has long been established in health care. Many institutions have local systems for capturing SAEs, but most perfusion departments in the U.S. are small in size (7, 32). This has led some authors to suggest that single-institution systems offer no benefits because they are limited in both analyses of the event and distribution of lessons learned (7). Because of these characteristics, these systems may perceive events as random occurrences instead of part of a larger collection of data (7).

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 (FEMAs) and Root Cause Analysis (RCA) are currently in widespread use in healthcare generally and perfusion specifically (37). These techniques, under the

current system, only help patients retrospectively and locally (7). 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 (7). Because of these differences, FMEAs and RCAs should be implemented in an additive fashion to an NRE reporting system (4). 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 (4, 5, 6, 7, 9, 19, 20, 24, 38). Professional societies outside of the U.S. have officially adopted this position and AmSECT has an initiative underway (17, 39, 40, 41). Many authors have also noted a moral and ethical obligation to report harmful and near-miss incidents in perfusion (42, 43, 44).

After the creation of a conceptual outline, Orrum Clinical Analytics has developed a novel, perfusion-centric NRE reporting system. The system allows perfusionists, physicians, and other providers access via an anonymous, secure, online portal from anywhere in the U.S. The data submitted and analysis generated are confidential and privileged, protected by the Patient Safety Act of 2005 (26, 27, 28). 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 to add a more granular examination of NREs, moving the focus from management of risk to improvement in training, equipment, and system design.

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Component No.	Description	No. of References
1	Standardized definitions of safety or incident events in perfusion.	9
2	The ability to make prospective, anonymous, online reports which are secure, and encrypted during transmission from anywhere in the country.	7
3	The ability to capture “good-catch” and “near-miss” events.	10
4	Validation techniques built into the reporting platform.	1
5	A standardized analysis of events.	9
6	Consistent, timely, and high-quality feedback.	5
7	Wide dissemination of lessons learned.	8
8	Protection for reporters and data.	7

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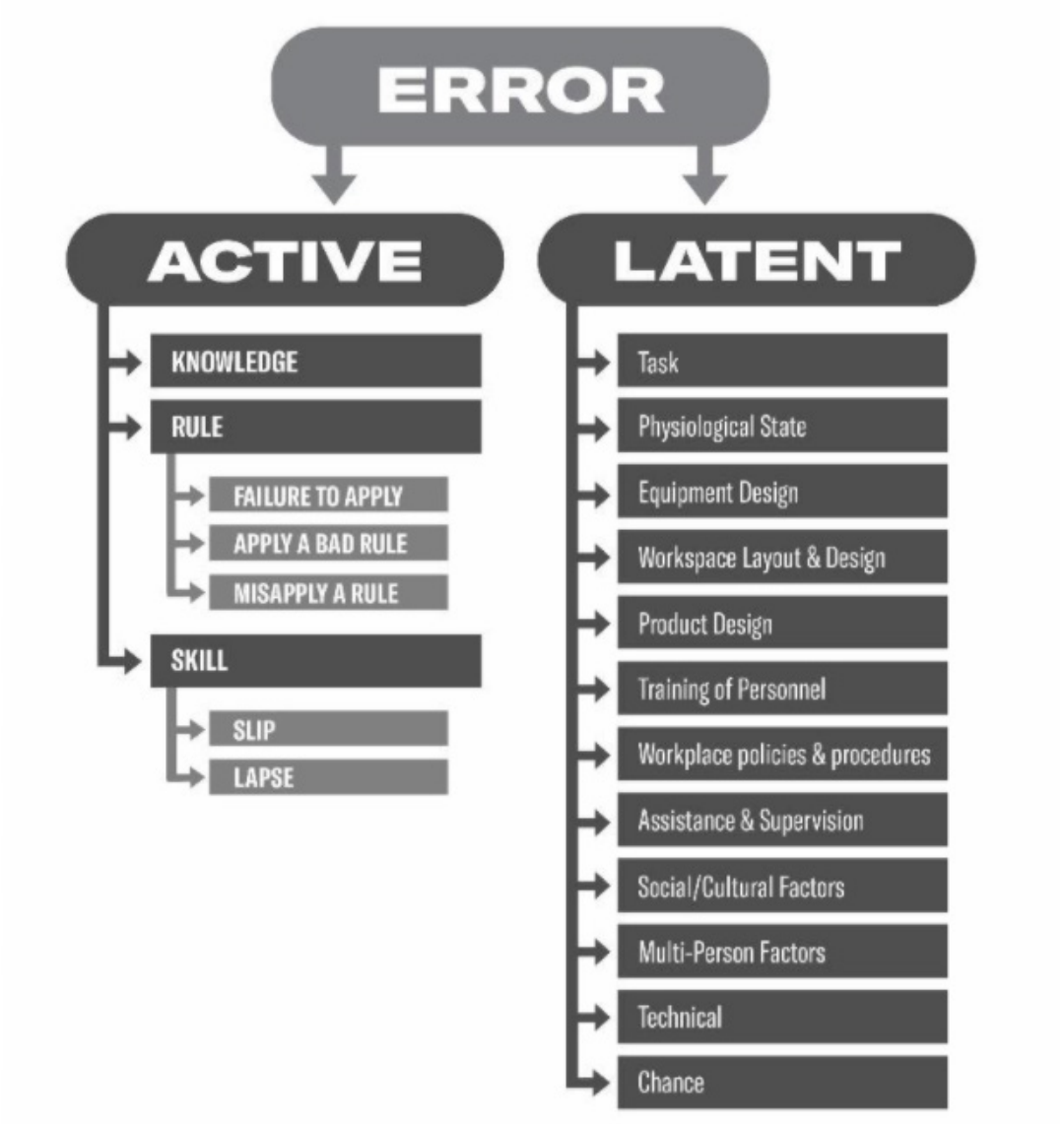

LEGENDS

1. Table 1. Incident Reporting System Desired Components.
2. Figure 1. Modified error classification system.

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