The Student Section

Can Voluntary Incident Reporting Increase Safety in Perfusion?

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Introduction

Globally, the incidence of serious adverse events (SAEs) in perfusion appears to have plateaued [1-3]. This plateau comes after a period in which improvements in techniques and technologies used in the cardiac operating room have contributed to the reduction of SAEs, while explicit attempts to reduce errors in service of reducing SAEs have been far less utilized [4]. In healthcare and other high-risk industries, voluntary near-miss reporting (a "near miss" being an event in which a mistake or error that has potential to harm a patient does not) is a proven method that has been used to lower the incidence of SAEs by exposing "low level" issues that often precipitate more serious events [5]. Implementation of a nationwide voluntary near-miss reporting system is a yet untested method that could lead to a significant reduction in the rate of SAEs in perfusion. Furthermore, data about accidents collected through this system would provide information about the actual rates of SAEs and near-misses in perfusion in real time, rather than collection of that data being relegated to surveys.

The Diffuse Epidemic

When *To Err Is Human: Building a Safer Health System* was published nearly 20 years ago, it revealed the alarming scale and cost of errors in American health systems. In two large studies discussed in the book, adverse events (actual injury to a patient caused by medical mismanagement) were found to be present in 2.9% (Colorado and Utah) to 3.7% (New York) of hospital admissions, with 6.6% and 13.6% of adverse events leading to patient death, respectively [6]. Extrapolating these percentages to the total number of hospital admissions in 1997 (33.6 million), adverse events among patients admitted to hospitals ostensibly accounted for 44,000 to 98,000 patient deaths per year, placing it as the 8th-leading cause of death in the USA at the time [6].

While *To Err Is Human* is frequently cited, many subsequent studies suggest that the death toll may be much greater, amplified by the medical community's largely ineffective action in the arena of error reduction [7]. Five years after the publication of *To Err Is Human*, an analysis of inpatient deaths associated with the Agency for Healthcare Quality and Research Patient Safety Indicators in the Medicare population alone estimated that 575,000 deaths were attributable to medical error from 2000 to 2002 [8], with an average of 195,000 deaths per year [9]. A Health and Human Services report in 2010 found that this rate had not meaningfully changed. The report found that 13.5% of Medicare beneficiaries experienced an adverse event during their stay in the hospital. Furthermore, an estimated 1.5% of Medicare beneficiaries experienced an adverse event that lead to their death. This extrapolated to 15,000 deaths per month, or 180,000 deaths per year [10]. Some studies have produced rates of adverse event leading to death that suggest over 400,000 patients die due to medical error each year [9, 11]. Some of these rates would place death due to medical error as high as the 3rd-leading cause of death in the USA today. More recently, these more extreme figures have been disputed, with estimated rates of adverse event leading to patient death closer to 25,000

[12], an estimate lower than the highest by an order of magnitude. More than anything, these estimates – while inexact – highlight the difficulty of defining the problem, while potentially indicating a growing sensitivity to medical error in American medicine.

The cardiac operating room is a locus within the hospital with a relatively high rate of adverse events. Incidence of adverse events in cardiac surgery patients is 12%, significantly higher than a rate of 3% for other surgery patients [4]. More than half of these adverse events are avoidable [13]. Guru *et al.* estimate that 28,000 CABG patients experience an adverse event each year, and one third of deaths associated with the procedure may be preventable [14].

How does perfusion contribute to these adverse events in cardiac surgery? Perfusion-related adverse events are a small subset of cardiac surgery adverse events, but, rather than decreasing, the rate of perfusion-related adverse events has plateaued over several decades [3]. In 2005, Palanzo's review of perfusion surveys from 1980-2000 revealed that perfusion -related serious adverse outcomes appeared to be in decline [15], from 1:1000 perfusions in 1980 [16] to 1:1453 perfusions in 2000 [17]. Willcox noted in 2012 that serious adverse events (SAEs) in perfusion appeared to have plateaued, based on more recent perfusion safety surveys [3]. Notable indications of this plateau are a survey conducted by Groenenberg *et al.* in 2010 among perfusion practitioners in the Netherlands, which found an SAE rate of 1:1236 perfusions [1], and a survey conducted by Charriere *et al*. in 2011 among perfusion practitioners in France, which found an SAE rate of 1:1400 perfusions [2].

Interestingly, the French have achieved a similar SAE rate with a lower usage rate of safety equipment/practices compared to perfusion in the United States. Kurusz detailed some of the more striking discrepancies: "use of an arterial line filter was 70% in France vs. 98.5% in the United States; air bubble detector with automatic pump shutdown or sense only, 28% and 32% vs. 87.8% and 63%; and one-way valved left ventricular vent, 41% vs. 83%". He also noted that the rate of pre-CPB checklist usage was only 79% in the Charriere survey, versus 94.5% of respondents in the most recent United States survey [18].

What, then, accounts for the similar rates of SAEs in France and the United States considering the disparities in practice? As a possible explanation, Kurusz points to a 2005 study conducted in Sweden by Svenmarker and Appelblad, in which 15 years of perfusion incidents were captured in a single institution registration system. SAEs were shown to be in decline, while Charriere's survey indicates that the rate of reported incidents in hospitals with registration systems (33% of responding institutions) were no different than in hospitals without registration systems [2, 19]. The implication is striking: incident registration correlates with a decline in SAEs, and that registration systems can adequately capture perfusion incidents when they are properly implemented. Upon reaching this conclusion, Kurusz recommends that "prospective registries should be implemented in all cardiac surgery centers" [18].

The Recommendations

Kurusz's recommendation reveals a path forward toward significantly increased safety in perfusion in the United States. Increases in safety in the cardiac operating room in the United States have been mostly attributable to "refined techniques, advanced technologies, and enhanced coordination of care", while "there is little evidence that much progress has been achieved in reducing or preventing errors" [4]. As noted by retrospective surveys of perfusion practice, this assessment holds true for the perfusion industry. Increasing adoption of safety technology and techniques has correlated with fewer SAEs [15-17], but now that use of these devices has become a standard for many programs [17], the rate of SAEs has plateaued [3], and retrospective studies are revealing their limitations in reducing SAEs. Prospective study of perfusion SAEs through collection of data on near-misses is a promising and under-researched area that may allow the perfusion industry to further reduce the rate of SAEs.

The case may be that the most efficient method for reducing SAEs in perfusion is through voluntary incident/near-miss reporting. Many institutions have systems for logging SAEs and near-misses and performing root cause analyses (RCA), but many of the limitations of such systems are amplified by the small size of perfusion departments within most institutions in North America. A perfusion department that performs 700 pump runs a year can expect to experience an SAE once every 2 years on average if the current rate holds. Root cause analysis may be able to detect the cause of the problem, but the analysis produced by RCA is typically limited to a single inci-

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dent and rarely disseminated outside of the institution performing the analysis [20]. The value of RCA is not in dispute, but its mechanism and scope only helps patients retrospectively and locally. Perfusion departments and interdisciplinary groups within the environment of the cardiac operating theatre are often better equipped to analyze the incident and implement relevant changes to their practice, particularly when it comes to noting and responding to near misses or "inconsequential" incidents [21].

The fact of the matter remains that perfusion departments do not experience SAEs in isolation frequently enough to use any system at an institutional level that could reduce their occurrence. Meaningful data on SAEs that are related to perfusion must include SAEs that do not originate in a hospital's perfusion department. In order to detect trends, data on SAEs that occur anywhere in the cardiac operating room need to be shared and documented, and they need to include low level events that are typically classified as near-misses [6]. Near-misses occur between 7-100 times for every SAE [5]. Furthermore, when voluntary reporting is integrated with other institutional safety systems, it is the most effective at identifying near-misses and other low level incidents [5].

The identification of near-misses not only allows for the identification of what went wrong, but also allows investigators to detect what went right in situations in which mistakes did not reach the patient, often referred to as a "good catch" [22]. "Good catch" systems are gaining traction in medicine due to the fact that they essentially double the power of near-miss reporting systems [23, 24]. They allow industries and institutions to know how resilient their safety systems are, and what components of those systems contribute meaningfully to overall safety.

To Err Is Human advocated for the implementation of voluntary near-miss reporting in any area within medicine that could accommodate it. The publication went into detail comparing a hypothetical medical voluntary near-miss reporting system with the well-established and successful Aviation Safety Reporting System (ASRS). *To Err Is Human* rationalized its recommendation by noting that these systems speed up root cause analysis, which becomes a factor of the increase in analytic power provided by the scaling up of near-miss reporting, increasing the number of "rare" events reported. Taken alone by a single entity, a "rare" event may be taken as a random occurrence, rather than as a data point within a trend. Because of this mechanism, reporting systems detect emerging problems sooner and rare problems more reliably [6].

The Institute of Medicine (IOM) publication *Patient Safety: Achieving a New Standard for Care* reinforced and expanded on the IOM's recommendation of voluntary near-miss reporting systems. This publication identified three goals for a near-miss reporting system:

- Modeling – report analyzers and clinical practitioners need "to gain a *qualitative insight* into how (small) failures and errors develop into near misses and sometimes into adverse events" [5]
- Trending – report analyzers and clinical practitioners need "to gain a *quantitative insight* into the relative distribution of failure and recovery factors by building a database of underlying root causes of a large number of near misses" [5]
- Mindfulness/alertness – report analyzers and clinical practitioners need "to maintain a certain level of alertness to danger, especially when the rates of actual injuries are already low within an organization" [5]

This publication also discussed in depth methods of organizing such a system and collecting and processing reports, as well as barriers to system implementation and how to overcome them.

In 2013, the American Heart Association (AHA) published a study that examined errors specific to the cardiac operating room and made wide-ranging recommendations based on their findings. Their recommendations may be of greater value to the perfusion industry because they are properly contextualized with respect to the unique nature of a cardiac surgical procedure. One such recommendation was the "establishment of an anonymous national multidisciplinary event-reporting system to obtain data about events and near-misses (Class IIa; Level of Evidence C)" [4].

The Failure

These recommendations have been made in the context of the diffuse epidemic of medical errors for nearly 20 years. In response, systems like the Perfusion Incident Reporting System (PIRS) were created,

but the perfusion industry in the United States does not have a system for collecting, analyzing, and disseminating incident reports in the interest of patient safety.

While case reports and surveys currently serve vital roles in the industry, perfusion needs to grow beyond a reliance on these types of publications as a method of reducing the frequency of perfusion-related accidents. In other words, we have improved our rate of SAEs as much as we can with reactive, retrospective methodologies, and the time may be right to transition to prospective methods and perspectives [25, 26] that allow perfusionists to understand the sources of problems and the systems used to prevent them [22]. The work toward transitioning to systematic analysis of incidents can already be seen in projects like the Failure Mode Error Analysis archive, which can serve as a template for exploring new ways to anticipate and plan for accidents in perfusion and the cardiac operating room, as well as for establishing connections between incidents [27].

Incident Reporting Systems

When examining voluntary near-miss reporting systems, *To Err Is Human* focused mainly on the National Aeronautics and Space Administration's (NASA) Aviation Safety Reporting System (ASRS) as a practical example [6]. The system was incepted in 1975, and is operated by NASA, rather than a regulatory body like the FAA, since the ASRS is intended to be used solely for safety and quality improvement and cannot be used for regulatory, punitive, or legal purposes [28]. In the beginning, it took in approximately 400 reports per month. Currently, it accepts over 8,000 reports per month, having accepted over one million reports since 1975 [28]. Reporters are protected by immunity policies that protect them from litigation, anonymize the data, and standardize processing [29, 30].

The ASRS near-miss data is used in several ways; the data is the backbone of aerospace safety in the United States. Based on analysis of incident reports, the ASRS issues alerts and notices to the industry on hazards it identifies. It does not provide specific solutions, nor does it enforce compliance with the alerts [28]. Near-miss data is also used to publish a monthly safety bulletin [31]. Finally, the data can be accessed for use in research. The ASRS Database Online fulfills over 1,658 queries a month, and ASRS Report Sets are downloaded an average of 4,497 times a month [28]. 64 papers using ASRS near-miss data have been published to date [32].

The success of the ASRS demonstrates the power of voluntary near-miss reporting in accumulating otherwise difficult-to-obtain error data. The ASRS has become the hub of error research and reduction in the aviation industry - all organizations within the industry intersect with it in a manner that is mutually beneficial [28]. While the ASRS cannot solely be credited, decades of study into human factors has lead the industry to "deal with errors non-punitively and proactively", and cockpit crew members have significantly different views on safety when compared to healthcare workers [33].

The ASRS model is instructive and has been used to inform near-miss reporting systems in medicine [34], but cannot be translated to the cardiac operating room readily [6]. This is due to the greater variability in expertise in the cardiac operating room, meaning that it may be more productive to cultivate an ecosystem of different albeit associated reporting systems with their own expert analyses. Analysis of incidents could be performed separately from the perspectives of perfusion, surgery, and anesthesia with input from error experts like human factors engineers and their findings synthesized for integration into the operating room or other departments their findings may affect [6].

The formation of the International Atomic Energy Agency (IAEA) Incident Reporting System (IRS) was precipitated by the Three Mile Island Accident in 1979 [35]. The partial meltdown at Three Mile Island nuclear power plant was the result of "an unrevealed fault with the power operated relief valve (PORV) [that] led operators to an inappropriate course of action" [36]. As is frequently the case, this faulty valve was not an isolated issue - the commission report following the incident found that "before the event, plants of similar design had experienced problems with the PORVs on nine separate occasions" [36].

Though the origins of the IRS are rooted in this event in American history, it has become a "global contact network and forum that enables safety experts around the world to share and review information on lessons learned from reported events" [37]. The IAEA issues safety documents that are designed to communicate hazards and concerns to the international nuclear community with a prefer-

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ence for over-reporting. The IAEA IRS, like other incident reporting systems, has illuminated the fact that every adverse event that occurs within the nuclear power industry is surrounded by a constellation of low-level events and near misses, which can reveal trends that may lead to the relatively rare instance of an adverse event [37].

The field of radiation oncology has benefited from the efforts of the IAEA as well. In consultation with the IAEA, radiation oncology researchers have initiated equipment safety standards, personnel training standards, and have developed a prototype voluntary safety reporting and learning tool called Safety in Radiation Oncology. The Safety in Radiation Oncology tool is designed for integration with other reporting systems in the medical industry [38, 39].

In 2007, the American College of Physicians New York Chapter (ACP-NY) started a voluntary near miss reporting program that helps physicians categorize near miss reports and provide education for physicians regarding incidents. The system was initially limited to internal medicine residents, but it was "expanded to include reports from all physicians in all specialties and all health related professionals" in 2010 [40]. The program is recognized as a Patient Safety Organization (PSO) by the agency for health care research and quality (AHRQ) and is protected under the Patient Safety and Quality Improvement Act of 2005 and NYS Public Health Law 206 [40]. These laws were created in part to protect incident reporters from litigation.

In a newsletter published by ACP-NY in 2011, a review of the NMR's first three years found a total of 350 reports were registered between 2007-2009. From these compiled data, it was found that two-thirds of near misses was from failure to execute a valid plan (a slip) and one-third was because the provider forgot to do something (a lapse). Miscommunication accounted for 15.7% of near-misses, incorrect patient identification accounted for 13.3% of near-misses, and drug administration events constituted 48.3% of all reports [41]. The report also found that a clear majority (97.5%) of interns and residents found it important that the surveys were done anonymously [41], revealing the indispensability of laws protecting incident reporters in systems like the ACP -NY NMR.

The Institute for Healthcare Excellence at the University of Texas M.D. Anderson Cancer Center implemented near-miss reporting by creating the University of Texas Close Call Reporting System (UTCCRS). This is a voluntary and anonymous reporting system that was initially implemented in 2005 and received nearly 26,000 reports between December 2005-July 2007. The UTCCRS was designed to facilitate friendly competition among staff, altering perceptions about near-miss reporting, renaming "near miss" to "good catch", and reframing the reporting process as "an easily understood, common, and non-threatening sporting event" [24]. The program also rewards patient safety "champions" with MVP recognition and monetary rewards.

The UTCCRS system works by allowing hospital employees to place anonymous reports that they witnessed, took part in, or heard about. Notably, the employees involved can track the progress of the report through the system. Employees can also enter suggestions on how to prevent this close call from happening in the future. This information is collected end of shift; employees are given time at the end of their shift to fill out any reports. The system also effectively showed which safety systems were working as intended, such as "Medication Administration Record (MAR) reconciliation; 8-, 12-, or 24-hour chart checks; and increasing double-checks on reported high-alert medications" [24].

The UTCCRS was developed to be a hybrid system, meaning reports it received would be confidential, but reporters are still able to view the progress of their submissions. UTCCRS is mainly web-based, due to its ease of use, time to report, and assurance of anonymity. Near-miss reporters can review their report progress using randomly generated identification numbers instead of any identifying credentials [42]. In anonymous surveys, reporters' responses to the system and its effect on safety culture to be "overwhelmingly positive" [42].

In the past two decades, the Australia & New Zealand College of Perfusionists (ANZCP) has created and iterated upon a voluntary near-miss reporting system for the perfusion industry, called the Perfusion Incident Reporting System (PIRS). Its inception was precipitated in part by the revelation that accidents in perfusion are actually more common than in related fields like anesthesia [43]. PIRS receives anonymous reports from perfusionists regarding accidents/near misses and publishes them in a de-identified form on the ANZCP website.

Recently, PIRS has integrated two new initiatives. The first is a simple shift in perspective – PIRS now uses the World Health Organization (WHO) incident definitions to more effectively delineate which incidents reached a patient and which did not. This change in perspective is in service of the goal of focusing more heavily on "good catches", like the UTCCRS system [24]. By noting the methods by which near misses did not reach the patient, the power of an incident reporting system is virtually doubled [22].

PIRS is underutilized on multiple fronts. First, in a 2014 symposium, a survey of a group of ANZCP perfusionists found that only ~25% had accessed PIRS in the past year for any reason [44]. Second, as a part of the Perfusion Down Under Database (PDUC), ANZCP perfusionists are asked to report incidents that occur in each case. Ostensibly, the incidents are under-reported to PDUC [45]. Of the incidents that are reported to PDUC, only 40% are also reported to PIRS, severely hampering the amount of data fed into the system. Furthermore, AMSECT's 2014 attempt to encapsulate PIRS in some way in order to introduce it to American perfusionists raised concerns of legal discovery of reports submitted to the system [44]. These concerns must be resolved in order to introduce a reporting system to the perfusion industry in the United States.

PIRS has been iterated on several times, and remains an under-explored and under-utilized model within perfusion and the medical community at large. The absence of a similar system in North America has not gone unnoticed as perfusionists look for more efficient ways to increase safety in the perfusion industry [26].

The Way Forward

Barriers & Limitations

The greatest barrier to successful implementation of near-miss reporting systems is fear – specifically, fear of punishment and fear of litigation [6, 46-49]. Fear of litigation presents two separate obstacles: the first is encountered when an individual chooses to report to an incident reporting system, and the second is encountered when the organization attempts to share information and analysis with key stakeholders. The fear of punishment can be addressed by altering the culture surrounding incident reporting and framing the act of reporting as responsible, appropriate, and natural [24, 28, 42]. Fear of litigation is addressed in part by assuring anonymity [41]. More importantly, fear of litigation is addressed by laws designed to insulate reporters from any legal consequences associated with incidents they are involved in, such as the US Patient Safety and Quality Improvement Act of 2005 or New York State Public Health Law 206.

Another major barrier to reporting is a misunderstanding of what constitutes an error, if an error took place, or who is responsible for submitting a report [46, 47, 49, 50]. Institutions and reporting systems can address this through careful definition of errors and efforts to assign responsibility for reporting [23, 24]. The emergence of the "Just Culture" framework for maintaining safe systems and supporting clinicians has contributed greatly to the standardization of what constitutes an error and who is responsible for an error while reducing the punitive effects of defining errors and their causes [51].

The effort and time required to create and submit a report is another factor that prevents healthcare professionals from submitting [46, 49]. The specific issues here may lie in a perception that the error was too trivial to report or that the report will have no effect because the reporter does not receive feedback for it [47, 50]. Finally, in a small industry like perfusion in the United States, will there be enough reports filed to create a body of data that can be meaningfully analyzed? Furthermore, will there be enough perfusionists willing to volunteer their time to receive, organize, analyze, and disseminate reports that are received?

Finally, emotional barriers to reporting exist. Errors can negatively affect healthcare workers' self-perception, with one study finding respondents who agreed with statements like "if I admit to an error I will feel like a failure" and "it would affect my self-esteem to admit to an error" [48]. This reveals a problem with safety culture in healthcare that is difficult to resolve: while medical errors may be inevitable, the fact that they so directly and tangibly affect others' lives makes it difficult to accept them as such.

The Future

The presence of incident reporting systems is a hallmark of high-risk, "high-reliability" organizations that is conspicuously absent from perfusion practice

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in the United States. Overall safety progress in the cardiac operating room in the United States has stalled – it is time to add another slice to the "Swiss Cheese" model of accident prevention [4, 52]. The basic methods of incident report data collection, analysis, and dissemination have been developed and refined over decades in other industries that share traits with medicine and the operating room environment. The medical community is finding ways to navigate legal and organizational barriers through PSOs, and they have explored varied models that perfusionists can assess for our own purposes.

Implementation of a perfusion incident reporting system in the United States is not without barriers, but it represents an important shift in how the perfusion industry thinks about safety and accident prevention – a shift from case-based, retrospective reporting to trend-based, prospective reporting. With SAEs in the cardiac operating room plateauing, it is time to look for a new avenue by which perfusionists can pursue improved safety outcomes industry-wide.

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