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Patient Safety and Human Factors in Pediatric Cardiac Surgery

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Abstract The patient safety movement and human factors studies are becoming an increasingly important part of everyday clinical practice. Pediatric cardiac surgery is a high-risk field that is very much dependent on safe practices and continuous research into improvement of outcomes. This article reviews the main research frameworks, methods used, and current findings in the area of patient safety and human factors within pediatric cardiac surgery.

Keywords Patient safety · Human factors · Pediatric cardiac surgery

Introduction

The patient safety movement became a forefront issue with .the publication of the Institute of Medicine (IOM) report titled *"To Err Is Human"* in 2000 [18]. The authors stated that "deaths due to medical errors exceed the number attributable to the eighth-leading cause of death." The IOM generated these numbers by extrapolating statistics from several previous incidence studies, including the Harvard Medical Practice Study I [2] and II [23], and incidence and types of adverse events and negligent care in Utah and Colorado. The report was meant to be a call to action encouraging improvement in the quality of health care over the next 10 years. This study was also met with criticism because of methodological problems that could have rendered the number of victims either too high or too low [2]. Regardless of the exact count, what is clear is that the concept of "patient safety" has now become a sort of "fifth column" that shadows every move clinicians make. This review focuses on the main research frameworks, methods used, and current findings in the area of patient safety within pediatric cardiac surgery.

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Systems and Human Factors: The Contribution of Latent Human Failures to the Breakdown of Complex Systems

The vast majority of serious adverse events are not the result of a single isolated error. Rather, it is a succession of events that, although minor in isolation, can lead to an adverse event if they occur together. Reason's [30] "Swiss cheese model" depicts an organizational accident and its contributing factors. This model suggests there are "holes" in the system (or nonexistence of systems) that are dormant elements. When they eventually line up, the patient is harmed. Since every human is fallible, the challenge facing the human factors community is to find ways of identifying and neutralizing these latent failures before they combine with local triggering events to breach the system's defenses. An ideal system should function independently of the health care providers that work within this system [37]. Successful hospital microsystems have been defined as having a core team of highly trained health care professionals, a defined population they care for, an adequate information environment, and adequate support (administration and equipment)

[28]. As patients move through the hospital experiencing different stages of patient care, they enter different microsystems. Errors are known to originate or occur specifically during handoffs, or from a breakdown in communication or coordination [22, 27].

High-reliability organizations recognize that human variability is a force to harness in averting errors, but they work hard to keep that variability in check and are constantly preoccupied with the possibility of failure [30, 35]. Each model has its model of error causation, and each model gives rise to quite different philosophies of error management. Understanding these differences has important practical implications for coping with the ever-present risk of mishaps in clinical practice. Normal accident theory asserts that errors result from system failures [37]. An important element of this perspective is the need for a system that collects, analyzes, and disseminates information from incidents and near misses as well as regular proactive checks on the system's vital signs. Four subcultures are necessary to support such an environment: a reporting culture, a just culture, a flexible culture, and a learning culture. High-reliability organization theory posits that accidents occur because individuals who operate and manage complex systems are themselves not sufficiently complex to sense and anticipate the problems generated by the system. Lessons learned from high-reliability organizations indicate that a safety culture is supported by migrated distributed decision making, management by exception or negotiation, and fostering a sense of the ''big picture.''

Why Is Pediatric Cardiac Surgery a Good Model for the Study and Development of Improved Safety Practices?

Pediatric cardiac surgery is an ideal field for human factors study because it is both complex and has a low error tolerance. It encompasses many complex procedures that are highly dependent on a sophisticated organizational structure, coordinated efforts of multiple individuals working as a team, and high levels of cognitive and technical performance. High-risk populations, particularly neonates and infants, exhibit a fragile physiology that can be very unforgiving [3, 8, 38]. Recent advances have allowed for marked improvement in outcomes and also for more successful early complete repairs, often performed during the neonatal period in low-birth neonates [6]. This has increased the complexity and low-error tolerance even further. However, although the published mortality rates for children older than 1 year undergoing open-heart surgery are in the range of 3.5%, mortality rates for neonatal repairs are still in the range of 10–40%, varying vastly by the underlying lesion and the type of repair [12, 34]. Several factors have been linked to poor outcomes in pediatric cardiac surgery, including institution and surgeon-specific volumes, complexity of cases, and systems failures [11, 32, 34].

Two highly-publicized landmark inquiries occurred in pediatric cardiac surgical departments: the British Bristol Affair and the Canadian Manitoba Inquiry [16, 24]. The Manitoba pediatric cardiac surgery inquest found that ''serious organizational and personnel problems experienced by the Health Sciences Center's Pediatric Cardiac Surgery Program during 1993 and throughout 1994 contributed to the deaths of some of the operated children.'' The Bristol Royal Infirmary inquiry (October 1998–July 2001) focused on 30–35 deaths that occurred after pediatric cardiac surgery between 1984 and 1995. It also found that systems failures were the root cause for many of the preventable deaths. The Bristol Royal Infirmary inquiry and the Manitoba inquiry reports both recognized the importance of human factors and systems research in improving pediatric cardiac surgical outcomes. The Bristol inquiry in particular had far-reaching consequences. Its widely publicized results were reported in gruesome details in the lay press and tabloids. Many facts were published out of context, some even erroneously. The two surgeons were initially blamed for the entire disaster, but once the final analysis was made, the blame was spread across all perioperative disciplines. The British National Health Service was permanently changed after this. Many decisions were taken at the highest political levels, resulting in new mandates such as mandatory reporting of surgical results into centralized systems and yearly mortality audits.

Studies Examining Human Factors in Pediatric Cardiac Surgery

Marc de Leval initiated the movement of safety in cardiac surgery [4]. More important than technical or statistical discoveries in safety or quality improvement was his honest debate about patient deaths. His argument was that the pressure to perform faultlessly can lead to intellectual dishonesty by covering up mistakes rather than discussing them openly. This results in missed opportunities for improvement. A series of studies examining human factors in pediatric cardiac surgery (PCS) were initiated. The first study used real-time intraoperative observations employing trained human factors researcher as observers [5]. A series of 243 arterial switch operations performed by 21 surgeons at 16 British institutions during an 18-month period were studied. Major and minor human failures were extracted from the observations. Major negative events were potentially life-threatening failures, whereas minor events were failures that, in isolation, were not expected to have serious consequences. Major events were significantly related to death. However, appropriate, compensation sharply reduced the risk of death. The total number of minor events was also closely related to both death and near misses. Minor events were shown to have a multiplicative effect on outcome. This study highlighted the role of human factors in negative surgical outcomes. However, even in the most eventful circumstances, appropriate human factors defense mechanisms can lead to a successful outcome.

Another study examined behavioral markers of surgical excellence [3]. The concept of behavioral markers of performance, previously used to understand the characteristics of the most successful aviation crews, was used. A framework of "behavioral markers" of excellence was developed based on existing research. This framework was used to explain the differences in "procedural excellence scores" among a group of 16 UK pediatric cardiac surgeons who had participated in the multicenter study described previously. Procedural excellence scores were derived from multivariable logistic regression models of the number of major and minor events per case, adjusted for known patient risk factors. Two outcomes were predicted: death and death and/or near miss. Behavior markers belonged to three categories: individual, team, and organization. For the individual there were seven markers: technical skill, mental readiness, cognitive flexibility, anticipation, team adaptation, situational awareness, and safety awareness. Behavioral markers at the team level were experience, technical skill (of team members), redundancy, adaptation, team leadership, communication, and coordination. Behavioral markers at the organizational level were policy, planning and scheduling, learning mechanisms, culture, communication interfaces, and resources. Results showed that those surgeons with the best scores were characterized by more of the behavioral markers than surgeons with lower scores. It is concluded that although behavioral markers have proven to be a useful method to explain performance differences between surgeons, further research is needed to validate and quantify the markers developed in this study and to test their applicability in other medical domains.

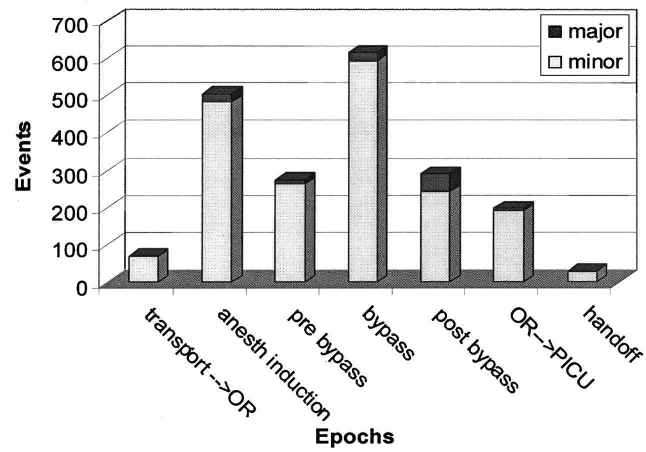

Fig. 1 Real-time observation studies: Major and minor events by epochs [Bognor A, et al. (2005) AHA meeting, Miami, FL, USA, January]

The most recent study to use intraoperative real-time observations was performed between 2002 and 2004 at the University of Chicago [8]. This American Heart Association- sponsored study encompassed 82 patients undergoing complex PCS. Adverse events were analyzed by severity (major vs minor), timing of occurrence (epoch; Fig. 1), and whether they were compensated or not (compensation mechanisms; Fig. 2). Higher case complexity and longer surgery duration were both significant predictors of major events. Cognitive compensation was the most common defense mechanism for major events.

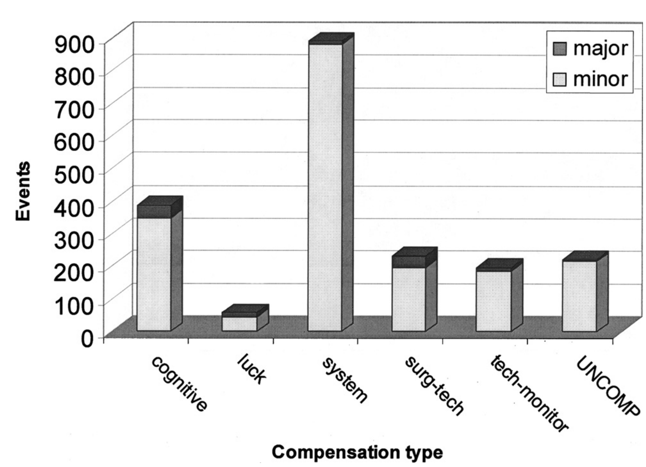

Fig. 2 Real-time observation studies: Type of compensations [Bognar A, et al. (2005) AHA meeting, Miami, FL, USA, January]

Monitoring of Technical Performance in Pediatric Cardiac Surgery

Although several studies have demonstrated that drug-related complications are the most common type of adverse event, technical complications are usually a close second, along with infectious complications [7]. Surgical performance is usually measured indirectly by means of risk-adjusted outcomes, or postoperative mortality [13, 14, 19, 20]. This data can then easily be integrated in a cumulative sum analysis to monitor surgical performance over time [1, 10, 31, 33, 36]. Although these techniques are important to assess performance and to compare outcomes among individuals or institutions [15], they cannot alone determine what is considered acceptable performance [19, 34]. It is somewhat deceptive to judge an individual surgeon's performance using postoperative outcome data such as 30-day or in-hospital survival. A poor outcome can be the result of a technical error, but it can also result from a nursing mistake, a drug error, or substandard intensive care monitoring. Intraoperative technical performance is one of the most important, if not the most important, parts of the therapeutic process and is a critical component of postoperative outcome.

A pilot study was conducted at Children's Hospital, Boston to evaluate a process for developing a tool to measure the adequacy of repair after congenital heart surgery [21]. Four common surgical procedures were examined: repair of ventricular septal defect, tetralogy of Fallot (ToF), complete common atrioventricular canal, and the arterial switch operation. Each of these procedures was divided into its component subprocedures based on the specific anatomic region of repair (e.g., ToF repair was subdivided into an atrial level, a ventricular level, a right ventricular outflow tract, and a pulmonary artery repair). A technical scoring system was then created, defining three possible categories for each subprocedure: optimal, adequate, and inadequate. These categories were defined by consensus within a group of cardiologists and cardiac surgeons based on post procedure echocardiographic assessment. Outcome categories for conduction disturbance were also created; regions with limited postoperative echocardiographic yield, such as the aortic arch, were not scored. All patients undergoing one of the four procedures at a single large institution in 2004 were identified, and each subprocedure was assessed. Overall surgical procedures were scored as optimal if all attempted subprocedures and conduction were graded as optimal, and they were scored as inadequate if any subprocedure was inadequate. A total of 138 surgical procedures were included in this pilot study; procedures were performed by four attending surgeons. Overall, optimal technical score was found in 20%, adequate in 77%, and inadequate in 3% of patients (Table 1). Outcomes for individual subprocedures, independent of the procedure in which they were performed, are shown in Table 2. The investigators concluded that despite procedural diversity and complexity, technical adequacy of repair can be assessed for congenital heart surgery.

Table 1 Overall technical score for selected procedures

Procedure	Overall score		
	Optimal	Adequate	Inadequate
VSD repair	18 (39 %)	26 (56 %)	2 (4%)
ToF repair	4 (12%)	28 (85%)	1 (3%)
CAVC repair	5 (14%)	31 (86%)	0 (0%)
ASO	1 (4%)	21 (91%)	1 (4%)
Total	28 (20%)	106 (77%)	4 (3%)

ASO, arterial switch operation; CAVC, complete common atrioventricular canal; ToF, tetralogy of fallot; VSD, ventricular septal defect

Table 2 Technical score for sub-procedures

Sub-procedure	Score		
	Optimal	Adequate	Inadequate
ASD repair	60 (62%)	19 (20%)	0 (0%)
VSD repair	45 (42%)	59 (56%)	2 (2%)
Conduction	131 (97%)	4 (3%)	0 (0%)

ASD, atrial septal defect; VSD, ventricular septal defect

Improving Safety via Common Nomenclature, Large Databases, and Risk Stratification

Databases are an essential cornerstone of patient safety. The IOM report focused on provider errors and sentinel events, which for surgery meant wrong site/wrong side, retained foreign bodies, medication errors, transfusion mismatch, etc. Thus, patient safety was defined in terms of safety from avoidable errors. Since the publication of the IOM report, a large number of initiatives to reduce errors have been implemented, with no demonstrated evidence of efficacy in any. On the other hand, surgeon-driven databases such as the National Surgical Quality Improvement Program defined patient safety in terms of safety from all adverse outcomes and focused on obtaining validated, outcome-based, risk-adjusted, and peer-controlled reliable data prior to analyzing them [17]. Within this framework, sentinel events and avoidable errors (the ones the IOM report focused on), although very important, are only a small fraction of adverse outcomes that impact patient safety. Patient safety is defined as quality of care and quality of the systems within which care is being delivered. Consequently, measures that improve quality of systems of care will improve patient safety. An important database within PCS is the relatively recent Society for Thoracic Surgery (STS) National Congenital Cardiac Database [12]. It follows in the footsteps of the older adult cardiac surgery STS database. However, for databases to provide real benefits, auditing and independent data validation need to be an essential component. Experience from the central cardiac audit database in the United Kingdom showed that volunteered data failed to report 42 of 194 deaths occurring within 30 days after PCS or therapeutic catheterization [9].

Perhaps the best example of cardiac surgeons applying human factors and safety principles to their practices is the Northern New England Cardiovascular Disease Study Group. They found that collaborative site visits were superior to benchmarking in improving outcomes. Not only did the centers with the worst outcomes improve but also the center with the best outcome improved [29]. A similar effort is now under way for congenital heart surgery (Pamela Jenkins, MD, PhD, Dartmouth Hitchcock Medical Center). Four primary requirements exist that allow multi-institutional databases to facilitate meaningful outcomes analysis after PCS: a common nomenclature, a uniform core data set, mechanisms for auditing and validation (verifying completeness and accuracy of data), and riskadjustment (evaluate complexity of cases). Because a myriad of conditions and procedures exist in PCS, any evaluation of treatments must take into account important differences that increase the risk for poor outcomes among some children but not others. It is therefore inadequate to analyze outcomes based on mortality data alone. No method of risk adjustment for congenital heart disease is currently accepted. Two methods of risk adjustments have been developed, the Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) and the Aristotle score. There are currently efforts under way to join both methods into a single comprehensive method. Development of this new complexity-adjustment method will be based on both judgment and empirical evidence, with assistance from a panel of experts with representation from pediatric cardiology and cardiac surgery. It will include features of both the existing Aristotle basic score and the RACHS-1 method into a single methodological framework. The method will be validated using multiple data sets. The goal will be creation of a methodology that will allow benchmarking of individual center outcomes.

The successful effort by the International Congenital Heart Surgery and Database Project to create a common nomenclature and database for congenital heart surgery culminated in the publication [12, 25, 26] of defined and cross-mapped diagnoses and procedures. Thus, the European Association for Cardio-Thoracic Surgery (EACTS) and STS now both utilize the same nomenclature and data set. Most PCS procedures carry a low mortality. Other measures related to quality of life and morbidity may be better measures of quality for PCS. However, only a minimal list of basic complications was included in the basic data set requirement [25, 26]. In August 2005, representatives of the societies and groups listed in Appendix 1 formed a Multi-Societal Complications Committee, the task of which consists of creating an exhaustive list of clearly defined pre-, intra-, and postoperative complications. This complications long list will then become part of the International Pediatric and Congenital Cardiac Code (www.ipccc.net). This complications long list will be mapped to a manageable complications short list that can be used in multiinstitutional databases.

The complications long list is subdivided by organ system and includes columns for the organ system, the complication name, definition, epoch during which the complication occurred, severity, harm (yes/no), and cross-mapping fields to Society of Thoracic Surgeons ID, complication short list ID, and ICD-9 codes.

Conclusions

Many advances have been made during the past decades in the high-stress, high-risk, and low-error tolerance field of pediatric cardiac surgery. However, more remains to be done. In order to be able to control their own future, self-regulate, and improve patient outcomes, physicians need to become familiar with the language and methods of human factors and outcomes analysis.

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