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Improving Cardiac Surgical Care: A Work Systems Approach

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Abstract

Over the past 50 years, significant improvements in cardiac surgical care have been achieved. Nevertheless, surgical errors that significantly impact patient safety continue to occur. In order to further improve surgical outcomes, patient safety programs must focus on rectifying work system factors in the operating room (OR) that negatively impact the delivery of reliable surgical care. The goal of this paper is to provide an integrative review of specific work system factors in the OR that may directly impact surgical care processes, as well as the subsequent recommendations that have been put forth to improve surgical outcomes and patient safety. The important role that surgeons can play in facilitating work system changes in the OR is also discussed. The paper concludes with a discussion of the challenges involved in assessing the impact that interventions have on improving surgical care. Opportunities for future research are also highlighted throughout the paper.

Keywords

Safety; Surgery; Error

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There is something compelling about open-heart surgery, something fantastic and fabulous, a mixture of dream and nightmare, all come true.

-- Michael Crichton

Significant reductions in patient morbidity and mortality following cardiac surgery have occurred since the inception of the surgical subspecialty over 50 years ago. Despite these dramatic improvements in outcomes, however, surgical errors with serious consequences continue to occur (Kohn et al., 1999). It is now estimated that one-third of all bypass deaths are preventable (Guru et al., 2008). Historically, surgical outcomes have been attributed primarily to the technical skills of the surgeon. For example, within most surgical specialties, the primacy of technical skill is the underlying assumption driving rankings of surgical

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performance across institutions or among one's surgical colleagues. In general, "once patient outcomes (usually mortality) have been adjusted for patient risk factors, the remaining variance is presumed to be explained by individual surgical skill" (Vincent et al., 2004). Hence, when things go wrong or surgical errors are made, it is logical from this "human-centered" perspective to naturally question the particular surgeon's competency or aptitude.

In contrast, a systems safety approach suggests that human error is often caused by a combination of work system factors rather than solely the ability of the individual surgeon. Specifically, the Systems Engineering Initiative to Patient Safety (SEIPS) model (Carayon et al., 2006) indicates that in addition to surgical skill (person factors), performance and outcomes are also impacted by such factors as teamwork and communication, the physical working environment, technology/tool design, task and workload factors, and organizational variables (see Figure 1). According to this perspective, errors are the natural consequences, not causes, of the systemic breakdown among the myriad work systems factors impacting performance (El Bardissi et al., 2007). Consequently, patient safety programs are likely to be most effective when they intervene at specific failure points within the system rather than focusing exclusively on the competency of the individual who committed the error (Carthey et al., 2001).

Although the work systems approach is relatively new to many surgical specialties, there is an increasing awareness of the impact that systemic factors can have on shaping surgical performance, as illustrated by the following quote:

> To put it crudely, good surgical skills coupled with basic team performance and the basic equipment may enable a surgeon to achieve a 90% success rate in a high-risk operation. However, refinements in surgical skill may be a relatively small element in the drive to reduce mortality from 10% to 1%. Optimizing the surgical environment, attention to ergonomics and equipment design, understanding the subtleties of decision making in a dynamic environment, enhancing communication and team performance may be more important than skill when reaching for truly high performance (Vincent et al., 2004, p. 481).

Historically, the majority of data concerning systemic factors that impact patient safety in the OR have come from anecdotal and sentinel event reports, which often lack details concerning the specific nature of the systemic problems that impact surgical performance (Carthey et al., 2001). However, in recent years, there have been a growing number of published studies that have used prospective data collection methods, such as ethnographic and direct observation to identify empirically the real-time dynamics of work system factors in the OR and their impact on patient safety (Healey et al., 2007; Wiegmann et al., 2007). While research still needs to be done to fully understand the complexities of cardiac surgical care, the results of these prospective studies have begun to identify opportunities and interventions for improving surgical performance and patient outcomes. Albeit, the efficacy of only a few of these interventions have actually been tested and it is unlikely that any single intervention alone will have a major impact on surgical care. Nevertheless, the majority of recommendations emerging from this body of research are grounded in empirical data. When considered together they provide an opportunity to develop comprehensive intervention strategies for addressing a wide variety of work system factors that impact surgical performance and patient safety in the OR.

The purpose of the present paper is to provide a review of previous research on the impact that work system factors have on cardiac surgical care and the subsequent recommendations that have been put forth to improve surgical performance and outcomes. A summary of some of the key references and their recommendations can be found in Table 1.While the majority of this research has been conducted in the United States and the United Kingdom, the results should be readily generalizable to cardiac surgery in general. We will frame our discussion using the SEIPS model, highlighting research and recommendations pertaining to the various

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component of the model including (1) the physical OR environment, (2) teamwork and communication, (3) tools and technology, (4) tasks and workload, and (5) organizational processes. We should note, however, that our goal is NOT to comprehensively review all pertinent data for each SEIPS component as they relate to every surgical subspecialty in the OR (e.g., anesthesiology, nursing, perfusion, etc.). To do so would result in a document of encyclopedic form. Rather, for each SEIPS component, we will detail two key issues and associated recommendations that we feel show significant potential for improving surgical care, some of which remain relatively unexploited. We will also focus *primarily* on the performance of surgeons, which is the topic that we have spent most of our research efforts attempting to understand. Nevertheless, our discussion will clearly illustrate that surgical performance cannot be understood in isolation from the actions of other members of the surgical team. For each set of SEIPS recommendations, we will also highlight their potential pros and cons, as well as the possible barriers that could hinder their implementation. We will then briefly turn to the role that surgeons can play in facilitating work system changes in the OR. We finish with a discussion of the challenges involved in evaluating the impact of safety interventions, given the availability of relevant outcome and process variables. Areas in need of future research are also highlighted.

The OR Environment

There are a variety of environmental factors in the OR that could potentially affect surgical performance. These include the general OR layout and clutter (Ofek et al., 2006), as well as ambient factors such as noise (Healey et al., 2007), lighting (Fanning, 2005), motion/vibration (Trivindi et al., 1997) and temperature (Gosbee & Gosbee, 2005). While all of these factors are important, the first two, OR layout and noise, have received most of the attention in the literature, and will therefore be our main focus here.

Standardize OR layout and Eliminate Clutter

Congestion due to the location of equipment and displays, as well as the disarray of wires, tubes, and lines (known as the “spaghetti syndrome”) is a common scenario in the OR (Brogmus et al., 2007). Consequently, movements by members of the surgical team are often obstructed, wiring is difficult to access and maintain, and the risk of accidental disconnection of devices and human error increases. All of which heighten the threat to patient safety (Ofek et al., 2006). In addition, the location of workstations and the placement of equipment relative to the surgical table can also hinder communication and coordination among team members. For example, in our previous study of designing cardiopulmonary bypass machines (CBM) for the human user (Wiegmann & Sundt, 2008) we discovered that the perfusionist’s location behind the surgeon, along with the various components of the CBM that physically separated the perfusionist from the surgical table, significantly hindered team performance. One of the main problems caused by this OR layout was that the perfusionist could not easily see what was happening at the surgical field. This made it difficult for the perfusionist to coordinate his or her actions with the surgeon. Most often, a perfusionist had to anticipate a surgeon’s needs using the passage of time and by inferences made from the movements of surgical personnel at the table. The surgeon was also unable to view and monitor the actions of the perfusionist. Consequently, this OR layout and configuration often lead to poor coordination of activities that subsequently disrupted the surgical flow of the operation.

A variety of recommendations for addressing the “spaghetti syndrome” have been proposed including better utilization of ceiling space, such as ceiling-mounted columns that descend to the team upon request and return to their place after use. Others include color coding and arranging cables in unique patterns on the ceiling for easier identification (Ofek et al., 2006). The area under the operating table has been identified as an unused, vacant space for placing or storing equipment. The elimination of wiring through the use of wireless technology has

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also been proposed. A recent study of electronic medical devices in the operating theatre and intensive care environments indicated that Bluetooth communication did not interfere with or change the function of the medical devices (Wallin & Wajntraub, 2004). Ofek et al. (2006) have argued that the utilization of wireless technology would not only eliminate clutter and the potential for confusion and errors, but would also allow equipment to be arranged in a flexible manner in the different operating theatres according to the specific operation being performed or needs and preferences of the surgical team. However, such flexibility or variability in OR layout may not always be beneficial. Brogmus et al. (2007) have argued that "although the needs in ORs vary according to the procedures performed, there is a good argument to be made for making the layout of ORs consistent so that efficiency is improved. For example, a consistent OR layout will have clean-up supplies on the same shelf, communication equipment in the same location, and the information monitor on the same boom. This also will reduce wasted time and, potentially, patient-threatening errors."

While the benefits of standardization versus flexibility have long been debated, there are general principles that can be followed when determining the arrangement of components within the OR suite (Alvarado, 2007). These include the (1) Importance Principle – components and equipment that are vital to the achievement of a procedure or task should be placed in convenient locations, (2) Frequency of Use Principle – components and equipment that are frequently used during the completion of a procedure or task should be located in close proximity and be easily accessible, (3) Function Principle – components, equipment or information/displays that serve the same function or are commonly used together to make decisions or complete a task should be placed in similar locations or in close proximity to one another, and (4) Sequence of Use Principle – during completion of a procedure or task, certain tools and technology may be consistently used in a set sequence or order and should therefore be arranged in a manner to facilitate this process. These principles are not always independent and may even conflict when being used to make decisions regarding the rearrangement of components in the OR suite. For example, component location may also interfere with face-to-face communication among surgical staff or disrupt the traffic flow or movement of personnel in the OR; therefore, there may be a need to separate functionally related equipment to allow for efficient traffic flow or communication. Consequently, considerable research is needed to collect and combine appropriate sources of data, including task analysis, anthropometric, and architectural data before specific recommendations can be made for redesigning a particular cardiac surgery OR suite.

Establish Policies and Procedures to Reduce Noise

In addition to layout and clutter, the OR environment is full of noise and distractions that can hinder the ability of the surgeon and other team members to fully concentrate on the primary task at hand. "Noise" is generally defined as auditory stimuli that bear no informational relationship to the completion of the immediate task (Sanders & McCormick, 1993). In a recent study on noise levels in the OR it was found that the average maximum noise level for an operation was over 80 decibels (dB), with absolute maximum noise level observed being over 90 dB (Healey et al., 2007). These maximum noise levels equate to sounds as loud as lawn mowers, or the passing by of a subway train in an underground tunnel. Sources of noise in the OR are numerous and include the low humming of ventilation systems and other electronic equipment, alarms and feedback alerts on pumps and monitors, music from CD players or radios, telephones ringing, pagers (beepers) sounding, people entering and exiting the room, and sidebar conversations among surgical staff (Catchpole et al., 2007; Wiegmann et al., 2007). Noise can negatively affect surgical performance in a variety of ways and these effects are particularly detrimental to dynamic tasks that require flexibility or rapid changes of responses to unexpected events. In particular, sources of noise can cause distraction and hinder the ability of a surgeon to concentrate by "masking acoustic task-related cues and inner speech"

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so that surgeons cannot "hear themselves think" (Sanders & McCormick, 1993). Noise and distractions can also affect communication among the surgical team by reducing the ability to hear what others are saying or by causing statements spoken by others to be missed. Communication can also be hindered by changes in speech patterns that often occur when an individual needs to shout to overcome background noise (Proctor & Van Zandt, 1994). Excessive noise in the OR may negatively influence the surgeon's concentration on the current task or case relevant communications among team members which can lead to errors and impact patient safety during the surgical case.

Reducing noise and distractions in the OR is clearly desirable and would likely improve error management processes and surgical outcomes (Carthey et al., 2001). Policies that limit the number of observers in the operating theatre, restrict the use of radios and pagers, curb non-essential staff from entering the OR during a case and discourage non-case related conversations among the surgical team have all been recommended. Similar rules exist within the aviation industry but are generally limited to critical phases of a flight when workload is the highest and the ability to mentally focus is most critical, usually below 10,000 feet. In aviation, this policy is referred to as the "sterile cockpit rule" and was imposed by the Federal Aviation Administration (FAA) in 1981 after reviewing a series of accidents that were caused by flight crews who were distracted from their flying duties by engaging in non-essential conversations and activities during critical parts of the flight (FAA, 1981). One of the most commonly cited accidents occurred in 1974 in which Eastern Air Lines Flight 212 crashed short of the runway while attempting to land in dense fog. The National Transportation Safety Board (NTSB) concluded that a primary cause of this accident was pilot distraction due to "extraneous conversation" among the flight crew during the approach phase of the flight (NTSB, 1974).

Although policies that limit visitors, restrict the use of radios and pagers, or curb non-essential conversations may effectively reduce noise and distractions, they may not be practical in all organizations and may not be readily accepted by surgical staff. For example, during long surgical cases, the presence of background music may actually help individuals maintain levels of mental arousal needed to combat the effects of fatigue or boredom. Furthermore, the ability to engage in non-case-related conversations among surgical staff might also contribute to team cohesion and job satisfaction. Likewise the inability to communicate with others outside the OR via telephone or pager could potentially impact the safety of other patients in the hospital, who are also under the care of the surgeon, for example in the postoperative ICU, if alternative mechanisms or procedures for communication are not established. Indeed, a "happy compromise" might be the sterile cockpit rule which would only limit sources of noise and distractions during critical phases of an operation that imposes high mental workload, such as weaning the patient from the heart-lung machine. However, there are also potential "problems" with sterile cockpit rule as well. Specifically, our recent study of mental workload during cardiac surgery (Henrickson, Wiegmann & Sundt, in preparation) found tasks that impose high mental workload vary considerably across surgical staff, as well as across different phases of the surgical procedure. Consequently, identifying critical phases of the operation for applying the sterile cockpit rule may be difficult, and if applied consistently across tasks performed by all surgical staff, may result in a policy that is no different than those that impose restrictions throughout the entire operation. Additional research is clearly needed to identify and evaluate an effective method for resolving these issues.

Teamwork and Communication

Effective teamwork and communication have long been recognized as imperative drivers of quality and safety in almost every industry. Like most industries, healthcare is a team-based profession. However, as more data become available, there is increasing recognition that poor

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communication and teamwork are causal factors in a large percentage of sentinel events within healthcare systems. In fact, the Joint Commission (2006) reports “communication” as the number one root cause (65%) of reported sentinel events from 1995 through 2004. Similarly, surgical errors cannot be understood in isolation from the actions of other members of the surgical team. For example, in one of our previous studies (Wiegmann et al., 2007) we found that teamwork factors alone accounted for roughly 45% of the variance in the errors committed by surgeons during cardiac cases. Teamwork issues generally clustered around issues of miscommunication, lack of coordination, failures in monitoring, and lack of team familiarity. These findings are not specific to our study. Poor staff communication has been linked to poor surgical outcomes in general (de Leval et al., 2000; Carthey et al., 2001). For example, a study by Gawande et al. (2003) reported on the dangers of incomplete, nonexistent or erroneous communication in the OR, indicating that such miscommunication events were causal factors in 43% of errors made during surgery. Another study by Lingard et al. (2004) found that 36% of communication errors in the operating room resulted in visible effects on system processes which include inefficiency, team tension, resource waste, work-around, delay, patient inconvenience, and procedural error.

In a recent review of the teamwork literature, Salas et al. (2007) identified a large number of team effectiveness models. Each of these models, in turn, highlights a variety of key factors that presumably promote better teamwork performance. However, as a result of this review, Salas et al. (2007) concluded that there is currently no consensus among researchers as to how teamwork should be defined or the types of strategies that should be employed to improve team effectiveness. Nevertheless, the empirical research on the breakdown of surgical teams’ communication and coordination during cardiac surgery clearly indicated several possibilities for improving team performance. These include strategies that focus on team training, standardized communication, team familiarity and stability, and pre-operative briefings (Wiegmann et al., 2007; ElBardissi et al., 2008). While each has clear potential for enhancing safety, we will focus on the latter two, due to their potentially unique fit with the surgical care process.

Foster Team Familiarity and Stability

One of the key factors that impacts teamwork and communication is team familiarity. For example, we recently compared miscommunication events during cardiac surgical cases among primary and secondary surgical teams (Elbardissi et al., 2008). Primary surgical teams were defined as those in which the majority of team members (certified surgical technologist (CST), certified registered nurse (CRN), resident/fellow, perfusionist, certified registered nurse anesthetist (CRNA)/anesthesiologist) were routinely matched together during surgical cases, whereas secondary surgical teams consisted of a majority of members who had little familiarity with the operating surgeon and other team members. (This classification was made by the cardiac surgeon and confirmed by other team members.) Results revealed a significantly lower number of surgical flow disruptions including miscommunication events per case among familiar (primary) teams versus unfamiliar (secondary) surgical teams. An analysis of individual surgeon performance was also consistent with these findings, in that surgeons made significantly fewer surgical errors per case when working with their primary surgical teams than when working with secondary teams. Interestingly, there was no significant difference in the amount of overall surgical experience between primary and secondary surgical teams, suggesting familiarity as the causal factor in team performance.

Carthey et al. (2001) also found that team stability significantly improved cardiac surgeons’ abilities to perform the aortic switch operation in pediatric patients. In particular, surgeons who had a different scrub nurse for each case, or worked in institutions that utilized ad hoc assignment of staff to the surgical theatre had more difficulty establishing team coordination

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at the table than surgeons who worked with familiar teams. During conditions in which surgeons were working with less familiar team members, they experienced "repeated losses of surgical flow because the team had to stop intermittently to correct errors." Similar observations have been made during cases where changes of staff occur due to work breaks or shift turnover, which disrupts the continuity of the team and their shared knowledge of the events taken place during a case (Wiegmann, 2008).

Team familiarity and stability can also improve process variables, in addition to reducing errors and patient safety issues. For example, surgical teams who attempted to adopt a new technology had significantly shorter operating times when original teams were kept intact (Edmondson et al., 2001). Furthermore, literature in both the medical and organizational fields has found team stability to be a strong predictor of team performance (Moreland, 1999; Levine & Moreland, 1999). Within the surgical arena, the cumulative experience of the team has also been shown to significantly decrease operative times, which may be secondary to fewer surgical flow disruptions due to miscommunication (Pisano et al., 2001). In stable teams trust develops amongst team members, which in turn produces reduces the fear that others will be condemning if errors are made. Team stability also allows for the acquisition of familiarity of other team members non-verbal communication styles and the anticipation of others' actions. Additionally, as described in our previous study (Wiegmann et al., 2007), stabilizing surgical teams would likely decrease staff turnover and increase team satisfaction.

Logistically, it may be difficult within most institutions to only allow primary surgical team members to operate as a unit; however, it is important that team members acquire an acceptable level of familiarity with one another. At a minimum, team stability during each surgical case should be strived for. Team stability is important for developing and maintaining a shared mental model or awareness of the progression of the case, the potential problems that may have occurred previously during the case and/or an understanding about any problems that may arise as the case progresses. One possible way of increasing team stability during an operation would be to prohibit shift turn-over (e.g., the changing of surgical assistants or circulating nurses during a case), thereby requiring all surgical staff who began the case to remain in the OR until the operation is completed. Again, however, such a strategy may be logistically implausible due to workload issues or simply unacceptable given the culture within an organization (the topics of workload and organizational culture will be discussed in depth in later sections). However, further research is clearly required to determine the actual effect that shift-turnover might have on teamwork, as well as potential methods of remedying its impact. Further research is clearly required to determine the actual effect shift-turnover may have on teamwork, as well as potential ways of remedying its impact.

Conduct Pre-operative Briefings

Team meetings, such as preoperative briefings that are conducted prior to an operation have the potential to address a variety of communication and teamwork issues. Of note, pre-operative briefings are not synonymous with the universal protocol or pre-surgical pause to ensure the right patient, right site, and right procedure. Rather, briefings are meetings that are often conducted prior to the patient entering the OR and involve a more in depth review of the case. Briefings also allow team members to ask questions or clarify uncertainties. Thus, pre-operative briefings can be beneficial for all types of surgical teams, in terms of planning different aspects of the case, but may be principally beneficial for unfamiliar teams who may not be acquainted with a specific surgical procedure or the preferences of a particular surgeon. For example, DeFontes and Surbida (2004) developed a preoperative briefing protocol for use by general surgical teams, which was similar to a preflight briefing used by the airline industry. A six-month pilot of the briefing protocol indicated that wrong-site surgeries decreased, employee satisfaction increased, nursing personnel turnover decreased, and perception of the

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safety climate in the operating room improved from "good" to "outstanding." Operating suite personnel perception of teamwork quality also improved substantially. Within cardiac surgery, we found a significant reduction in the case frequency of surgical flow disruptions post-implementation of preoperative briefings (Wiegmann et al., 2007). Specifically, there was a reduction in the number of procedural knowledge disruptions and miscommunication events per case. On average, teams that conducted the briefing had significantly fewer trips to the core and spent less time in the core during the surgical case. There was also a trend towards decreased waste for teams that were briefed compared to teams that did not conduct a pre-operative briefing. Similar findings were also recently observed by Lingard et al. (2008). By fostering team familiarity, stability and pre-operative briefings, fewer surgical disruptions will occur, fewer surgeon errors will arise, and team communications will improve, all of which contribute to improved patient safety.

Despite the potential benefits of preoperative briefings and the recent endorsement of briefings by the World Health Organization (WHO, 2008), their utilization remains relatively low within many surgical specialties, including cardiac surgery. This is likely due to multiple reasons. One barrier, for example, is that there are no standardized protocols for conducting preoperative briefings. Each surgical specialty has unique "issues" that may need to be addressed prior to each operation. Therefore, a generic off-the-shelf checklist may not suffice. This is not to say that the development of a common template for designing briefing protocols is unattainable, rather the specific content will need to be tailored to each surgical specialty. Other barriers impeding the utilization of preoperative briefings include individual attitudes or resistance to change by surgical staff, as well as organizational barriers such as case schedules, lack of facilities, and limited resources. As documented by DeFontes and Surbida (2004), the successful development of a preoperative briefing protocol takes several months of research and development, beginning with first understanding the needs and views of key stakeholders (i.e., surgical staff) and the nuances of the organization in which such briefings are to take place.

Tools and Technology

The practice of cardiovascular surgery demands daily interface with highly sophisticated technologies. However, few of these medical technologies have been designed with the end-user in mind, increasing the likelihood of "user error" (Ward & Clarkson, 2007). However, poor design is not the only issue that can negatively impact performance and use of medical technology. The process by which new technology is introduced and implemented can also have a tremendous impact on user acceptance and utilization, ultimately affecting the delivery of safe and efficient surgical care. Even when technology is properly designed, its implementation can have unintended consequences on the work process, some of which may be rather inconsequential while others can be rather profound. Indeed, much has been written on these topics (Karsh & Holden, 2007); therefore, we will only address some of these issues and recommendations as they pertain to cardiac surgery.

Ensure that Technology is Usable and Acceptable

New technology is often difficult to use because it differs from its predecessors in terms of the method by which information is displayed, inputs are performed, and automation is provided (Cook & Woods, 1996). Adjustment to new technology is even more difficult when systems are poorly designed. Indeed, the role that poorly designed technology can play in producing errors that cause patient harm is becoming increasingly apparent. Roughly half of all recalls of medical devices result from design flaws, with specific types of devices being associated with unusually high use-error rates, such as infusion delivery devices. For example, in a previous human factors study of cardiopulmonary bypass machines (CBMs), we identified several problems with the design and usability of these devices that predisposed surgical teams

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to make perfusion-related and other technical errors that threatened patient safety (Wiegmann et al., 2006). In particular, these design shortcomings included problems with the format, legibility, and integration of information across displays, the location, sensitivity, and shape of input controls, and problems with indistinguishable, unreliable, disarmed, or nonexistent audible alarms. Such problems are not unique to CBMs and have often been cited as factors contributing to "user error" of medical devices in anesthesia and other healthcare settings (Morrow et al., 2005).

Research also suggests that healthcare providers are not passive recipients of new technology. Rather they are active agents who will tailor technology to meet their needs, even if it is not effectively designed to do so. For example, Cook and Woods (1996) studied cardiac anesthesiologists' use of a new computer based physiological monitoring system during cardiopulmonary bypass procedures. Results revealed several characteristics of the new technology that reflected "clumsy automation." Specifically, the benefits of the new computer system occurred during low workload situations, but it also created new cognitive and physical demands that tended to congregate at times of high demand. As a result, anesthesiologists attempted to overcome these problems by adapting both the technology and their behavior to meet the needs of the patient during surgery, increasing the potential risk of errors. Other studies have found that users, rather than adapting to technology which is difficult to use, will simply discontinue its use altogether. For example, Madhavan et al. (2006) found that trust in highly reliable automated diagnostic aids diminished rapidly when the automation "behaved" in ways that were unanticipated by users and that users often opted to disregard information provided by the aids, even though the aid was significantly more accurate than the user.

Ensuring that medical devices and technology are designed to optimize their effective and safe use is clearly a priority in healthcare. In fact, the U.S. Federal Drug Administration, U.S. Department of Health and Human Services, and Center for Devices and Radiological Health jointly published the report *Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management*, which stated, "The field of human factors provides a variety of useful approaches to help identify, understand and address (medical device) use-related problems. The goal is to minimize use-related hazards, assure that intended users are able to use medical devices safely and effectively throughout the product life cycle." Performing usability testing and heuristic evaluations to ensure that medical devices meet minimal design standards is one basic approach for achieving this objective (Wiegmann et al., 2007). However, even when devices are deemed to be "ergonomically designed," ensuring that end-users have an opportunity to participate in the implementation process is vital to the acceptance of new technology (Karsh & Holden, 2007). As noted by Lorenzi and Riley (2000), "a 'technically best' system can be brought to its knees by people who have low psychological ownership in the system and who vigorously resist its implementation." Training on the use of new technology is also vitally important. For example, Lee (2006) reported that surgeons are generally slower to adopt new information technology than their colleagues even when they believed it could potentially benefit patient care, because they often lack the appropriate training to use it effectively. While many of these issues regarding technology design and training are common knowledge to human factors engineers, challenges remain with regards to how to implement these best practices within the context of cardiac surgery.

Anticipate Unintended Consequences

New technology, even if well-designed, can have complex effects on work systems and can fundamentally transform the nature of the work process in unforeseen ways and with unanticipated consequences (Cook & Woods, 1996). The introduction of new surgical technology not only changes the nature of the task of the surgeon and the required psychomotor skills to accomplish it, it can also dramatically change the dynamics among the entire surgical

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team. For example, the introduction of minimally invasive cardiac surgery systems and surgical robots has been found to change the location of information sources, the information needs of surgeons, the nature of the visual information at the surgical site, and the flow of information exchange among the surgical staff (Cao & Roberts, 2007). Even changes to seemingly "benign" tools such as the whiteboard in the OR can have significant effects. For example, Xiao et al. (2007) examined the use of whiteboards and potential impact that introducing electronic whiteboards might have on collaborative work within a trauma center operating suit. Results suggested that the advantage of an electronic whiteboard with regards to its automatic updating of information needed to be balanced against its discouragement of active interaction and adaptation by surgical staff. In particular, large electronic display boards do not necessarily replicate the social functions that the whiteboard, such as resource planning and tracking, synchronous and asynchronous communication, multidisciplinary problem solving and negotiation, and socialization and team building.

Clearly, the introduction of new technology can have unexpected interactions within the surgical team and can potentially induce new forms of error which negatively affect patient safety. New technology often requires adjustments in team communication, the development of new procedures, and altered roles of OR personnel (Cao & Rogers, 2007). Consequently, efforts need to be made to better understand how collaborative work may be affected in order to inform design and implementation strategies. Basic usability testing and heuristic evaluations described previously can help in this process. However, simulation might serve as a more effective method for identifying unanticipated changes to work processes and it can also be useful for training new procedures associated with adapting to the technology. According to Karsh and Holden (2007) simulation should be designed into the implementation process because it provides a safe and efficient means of planning, training, and learning about how the introduction of the new technology changes the current work system and what changes need to be made to allow the new work system to function safely before the technology is adopted. However, not all organizations have the resources or facilities to neither conduct elaborate simulation evaluations, nor can simulations always adequately mimic the real world scenarios surrounding the use of the technology in practice. Therefore, pilot testing of new technologies is also important because it allows for additional problems to be identified that may not have been discovered during usability or simulation testing. Nevertheless, the process of identifying unintended effects of new technology remains more of an art than science. Research is needed to develop and refine methods to reliably determine the impact of new technology before it is implemented.

Task and Workload Factors

Job task factors such as physical and mental workload can dramatically impact performance and safety (Gawron, 2000). Physical workload is often affected by task duration, strength requirements to complete the task, and behavioral repetition, whereas mental workload factors generally refer to a task's cognitive complexity (mental demand), time pressure, and criticality or risk (Finegold et al., 1986). Neither task dimension is completely independent of the other. Both types of workload can reduce levels of cognitive function by increasing levels of stress and fatigue, as is often the norm in complex high-intensity fields such as cardiac surgery (Hales & Pronovost, 2006). As with most work system factors in the SEIPS model (Figure 1), several recommendations have been used in other industries for reducing both mental and physical workload, including the use of new technology (e.g., automation) and the development of standardized procedures and checklists, as well as the incorporation of rest breaks into the work scheduling process (Wiegmann & Shappell, 2003). We will focus on issues related to the latter two recommendations here, given that technology and automation have already been discussed in the previous section.

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Develop Standardized Procedures and Checklists for Critical Tasks

Standardized procedures and checklists have long been used in other dynamic safety-critical environments such as aviation to decrease errors of omission (forgetting critical steps) and errors of commission (improper implementation of a procedure or protocol), and to reduce decision errors under stressful situations (Degani & Wiener, 1993). In general, a checklist is “a list of action items, tasks or behaviors arranged in a consistent [standardized] manner, which allows the evaluator to record the presence or absence of the individual items listed” (Hales et al., 2007). As a result, the use of checklists can be particularly beneficial under conditions in which there is a long sequence of operations or multiple steps in a procedure, there are critical aspects or timing of a task that cannot be missed or forgotten, there are important or mandatory tasks that must be performed, or there are multiple tasks distributed across time or personnel (Degani & Wiener, 1993). Under these conditions, the use of checklists and memory aids within critical care settings have been found to reduce errors and improve patient safety and quality of medical care through the use of best practices (Hales et al., 2007). Checklists have also been shown to be beneficial and life saving in medical situations that require rapid systematic or standard approaches to crisis management such as anesthesiology (Hart & Owen, 2005) and emergency medicine (Harrahill & Bartkus, 1990).

Despite the demonstrated benefits of checklists in improving the delivery of patient care, their integration into practice, including cardiac surgery, has not been as widespread as in other fields (Hales & Pronovost, 2006). Perhaps one reason for this limited deployment of checklists is the fear that they will reduce the autonomy and flexibility of the healthcare provider. In other words, the implementation of a checklist might imply that it must be strictly adhered to in all situations thereby potentially compromising the efficacy of the clinical process and infringing on clinical judgment (Hales et al., 2007). The design of checklists is also critical to their ultimate effectiveness. Poorly designed checklists can actually lead to errors and accidents, as has been shown in the aviation industry (Degani & Wiener, 1993). Of note, there has been no published data to date that indicates that checklists have contributed to adverse events in health care settings or delays in treatment because of lengthy or poorly designed checklists (Hales et al., 2007).

Careful consideration also needs to be taken when identifying which processes and procedures require the use of checklists so that they do not create an additional burden or layer of complexity (Wiegmann, 2007). As noted by Hales et al. (2007) “if each detail of every task were targeted for the development of a checklist, clinicians may experience ‘checklist fatigue’ whereby they become overburdened with completing these lists.” Even when checklists are well designed, interruptions and distractions can still cause steps in a procedure to be missed or skipped (Degani & Wiener, 1993). In addition, after several iterations of a procedure, complacency regarding task performance can arise, producing a perception that the checklist is unnecessary and therefore no longer used (Wiegmann, 2007). Consequently, users of checklists need to be trained on their use and committed to incorporating them into their practice. To achieve this goal, considerable human factors research is needed to understand the context and goals of checklist use, including the application of cognitive tasks analysis methods, as well as the inclusion of a multidisciplinary research team to ensure that checklists are properly designed and endorsed by users.

Incorporate Breaks into the Work Process to Reduce Fatigue

Cardiac surgical cases are generally much longer than other types of general surgery, often lasting several hours. Research suggests that simply standing for long periods of time increases lower extremity discomfort, lower back pain, and general physical fatigue (Redfern, 1995). Continuous cognitive work can also lead to increased metal fatigue and reduced vigilance, increasing the risks of errors. Conversely, long periods of low workload, such as performing

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basic monitoring tasks can also lead to boredom and reduce vigilance, resulting in lapses of attention or memory failures (Proctor & Van Zandt, 1994). For example, in one survey up to 90% of anesthesia providers admitted to at least occasional boredom while administering anesthesia which negatively affected their performance (Weinger et al., 1998). Some research suggests that altering the sequence of tasks or adding new tasks to a monotonous job can reduce boredom and improve vigilance (Sanders and McCormick, 1993). However, regular rest breaks have been shown to be effective in controlling the accumulation of both the physical and cognitive risk associated with prolonged task performance; for example, 2 hours of continuous work (Rogers et al., 2004). Nonetheless, the benefits of work breaks are transient, particularly as they relate to mental fatigue and arousal, lasting only 15 to 25 minutes following the resumption of work (Neri et al., 2002). Consequently, the frequency and timing of breaks appears to be more important than the actual duration of break periods, with shorter and more frequent breaks affording the greatest benefits for reducing fatigue and improving productivity.

Currently, work breaks are regularly employed by nursing and anesthesia staff during cardiac surgery to combat physical and mental fatigue. However, the use of work breaks is much more problematic for other members of the sterile surgical team (e.g., surgeons, scrub nurses, and surgical technicians) whose leaving the OR could jeopardize the patient's safety by disrupting the continuity of care, as well as considerably increase the duration of the operation due to the need to "scrub in" again after the break. In addition, work breaks by nurses and other non-sterile team members may also create potential threats to the safety of the surgical care process. For example, work breaks require intraoperative "hand-offs" of patients between nurses who are taking breaks and those who are temporarily relieving them. Research in other healthcare settings has produced compelling evidence that hand-offs across shifts or hospital units can significantly compromise patient safety (Paterson et al., 2004). The transfer of nursing responsibilities in the OR might have similar consequences as well. Specifically, relief nurses may occasionally lack critical knowledge of the surgical case needed to effectively support other members of the sterile surgical team or to respond to emerging critical events. In addition, the timing of hand-offs with regards to the surgical procedure can often vary across cases, due to the timing of the surgery and its relationship to the nurses work schedule. Therefore work breaks may occur at inopportune times and/or require different types of information to be shared with the oncoming nurse.

Surgeons also report being unaware of nurse turnover during an operation, due to their focused attention on the surgical procedure. Therefore, they assume that all team members are knowledgeable of events and discussions that took place prior to the hand-off; consequently surgeons may become perplexed or exasperated when team members do not recall previous conversations or respond as expected. As discussed previously, team stability is important for developing and maintaining a shared mental model of the progression of the case, the potential problems that have occurred previously during the case and/or an understanding about any problems that may arise as the case progresses. Clearly, additional research is needed to better understand the effects that work breaks and intraoperative patient-handoffs have on the surgical team's shared mental model and patient care. Research is also needed to explore effective ways of helping reduce physical and mental fatigue among the sterile surgical team members during long operations. A balance must be found between scheduling appropriate work breaks to reduce fatigue and boredom and maintaining surgical team stability so that patient safety is not compromised.

Organizational Influences

Several organizational factors have the potential to impact the delivery of safe and reliable healthcare and many of these factors have been discussed in the literature (Keroack et al., 2007). However, the topic of establishing and promoting a culture of safety within healthcare

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organizations “has become one of the pillars of the patient safety movement” (Nieva & Sorra, 2003). The general concept of “safety culture” is not new and is generally traced back to the nuclear accident at Chernobyl in 1986 in which a “poor safety culture” was identified as a major factor contributing to the accident by the International Atomic Energy Agency (Cox & Flin, 1998; Mearns & Flin, 1999; Pidgeon, 1998). Since then, safety culture has been discussed in other major accident enquiries and analyses of system failures, such as the King’s Cross Underground fire in London and the Piper Alpha oil platform explosion in the North Sea (Cox & Flin, 1998; Pidgeon, 1998), as well as the crash of Continental Express Flight 2574 (Meshkati, 1997), the Columbia Space Shuttle accident (CAIB, 2003), and the explosion at the British Petroleum refinery in Texas City (CSB, 2005).

Safety culture has also been found to be important in determining safety behavior of workers across a wide variety of organizations and industries. For example, safety culture has been associated with employees’ safety-related behavior in industries such as manufacturing (Cooper & Phillips, 2004; Griffin & Neal, 2000), shipping (Hetherington et al., 2006), chemical processing (Hofmann & Stetzer, 1996), and building maintenance (Wallace & Chen, 2006). Safety culture also appears to predict on-the-job injury and accident rates in manufacturing firms (Varonen & Mattila, 2000; Zohar, 2000), offshore oil and gas companies (Mearns et al., 2003), and also in broad cross-organizational studies of workers in general (Barling et al., 2002; Huang et al., 2006).

Accordingly, the concept of safety culture has also been applied to patient safety. Patient safety culture is defined as the enduring value and priority placed on patient care by everyone in every group at every level of a healthcare organization. It refers to the extent to which individuals and groups will commit to personal responsibility for patient safety, act to preserve, enhance and communicate patient safety concerns, strive to actively learn, adapt and modify (both individual and organizational) behavior based on lessons learned from mistakes, and be rewarded in a manner consistent with these values (adapted from Wiegmann et al., 2002). Although safety culture may not be the only determinant of safety in organizations (Smith et al., 2006), it plays a substantial role in encouraging people to behave safely and to report errors when they do occur. There is also growing evidence that interventions aimed at improving safety culture can reduce accidents and injuries (Zohar, 2002) and within healthcare settings, can reduce medical errors (Pronovost et al., 2005). Several strategies have been proposed for improving safety culture. However, as may be gleaned from its definition, the two interventions that appear to have the biggest potential are leadership engagement and accountability.

Improve Leadership Engagement

Leadership style has been shown to have a major impact on how patient safety initiatives are viewed and accepted among medical staff. Leaders who are considered engaging, transformational, and rewarding appear to have the most influence on improving safety culture. For example, Keroack et al. (2007) found that CEOs at top performing institutions tended to be passionate about improving quality and safety and exhibit a very “hands-on” style. They were frequent visitors to patient care areas, either a part of structured leadership “walk rounds” or as unscheduled observers. In contrast, CEOs at institutions that had “struggling safety cultures” were generally unsure of their leadership roles in quality and safety initiatives. In addition, staff reported rarely seeing them in care areas and indicated that they did not feel comfortable raising safety or quality concerns to CEOs directly. Others studies have also shown the benefits of improving leadership engagement through executive walk rounds. For example, monthly executive walk rounds have been shown to have a significant impact on improving safety culture among nurses in tertiary care hospitals (Thomas et al., 2005). Pronovost et al. (2005) reported that improving leadership engagement in patient safety activities within an

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intensive care unit significantly improved safety culture, reduced length of stay, nearly eliminated medication errors in transfer orders, and decreased nursing turnover.

According to the Institute for Healthcare Improvement (2008), executive walk rounds demonstrate a leaders' commitment to safety and dedication to learn about the safety issues within their organization. They also reflect an "organization's commitment to building a culture of safety." However, several issues need to be considered during the implementation of a walk rounds strategy. For example, executives generally require training on how to conduct walk rounds and how to ensure that walk rounds remain informal. They also may need to be provided with tools or scripts to help them dialog with front-line providers about safety issues and to show their support for staff-reported errors. Additionally, some organizations are rather large and provide patient care around the clock, reducing the feasibility of having senior executives perform regular walk rounds throughout all care units at different times of the day (or night). An alternative approach therefore has been to use an "adopt a unit" strategy where executives limit their walk rounds to selected sites in a hospital rather than attempting to visit all units during a given period of time (Pronovost et al., 2005).

Perhaps, even more problematic is the process of attempting to conduct walk rounds in surgical care units. In particular, a key component of walk rounds that presumably makes them effective in changing culture is the fact that leaders are seeking to actively engage front-line staff and providers on their own "turf" or care setting. However, dialoging with cardiac surgeons, anesthesiologists, nurses, and perfusionists during bypass surgery would likely prove challenging to say the least. Consequently, executive walk rounds with surgical staff may have to occur in the cafeteria or break room, or possibly in a "town hall" setting such as during monthly staff meetings. Whether such modifications to the walk rounds strategy will prove to be equally effective in changing culture within a surgical care environment, however, has yet to be determined.

Establish Accountability for Safety

Another approach that has shown some promise for improving safety culture is to establish a formal process or system of accountability for safety at both the department level, as well as the level of the individual provider. One of the key components of an organization's safety culture is the just manner in which both safe and unsafe behavior is evaluated and the consistency in which rewards or penalties are doled out according to these evaluations (Reason, 1990). A fair evaluation and reward system is needed to promote safe behavior and discourage or correct unsafe behavior (Eiff, 1999). An organization's safety culture, therefore, is reflected by the extent to which it possesses an established accountability system for reinforcing safe practices (e.g., through monetary incentives or public praise and recognition by management and peers), as well as systems that discourage risk taking and unsafe activities. However, an organization's safety culture is signified, not only by the existence of fair reward systems, but also by the extent to which the reward systems are formally documented, consistently applied, and thoroughly explained and understood by all of its employees.

In a study of average versus high quality healthcare facilities, Keroack et al. (2007) found that average organizations tended to have clinical department heads that were inconsistent in their commitment to patient safety programs. Leaders within these organizations were also generally unwilling or unable to address these inconsistencies or hold department heads accountable. Furthermore, leaders within these organizations were generally satisfied with the status quo, did not view quality and safety as a requirement for "strategic survival" of the institution, and did not consider acknowledgement for quality and safety necessary, because individuals should know ethically that these activities are simply "the right thing to do." In contrast, high performing organizations considered excellence in quality and safety, not only as the "right thing to do" but as being a strategic advantage in the competitive market place. High performing

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organizations also tended to reinforce the fact that department heads were responsible for quality and safety within their units and leaders tended to hold them accountable for performance. These organizations also provided incentives for individual providers to adopt safety and quality goals by making contract renewals and referrals contingent upon the adoption of practices that were in line with the institutional vision.

Within cardiac surgery, the concept of accountability is not new. Throughout their training, surgeons are taught that they are the “captains” of the ship and that no matter what happens in the OR, they are ultimately responsible for surgical outcomes (Jones & McCullough, 2007). While this leadership role of surgeons may indeed be accurate and even necessary, the history of “full accountability” for patient outcomes has generally provided them free reign of the OR and the authority to dictate the process by which care is provided by the entire surgical team. Culturally, cardiac surgery values the autonomy of the surgeon and as a result, hospital leadership has generally shown them deference, assuming that surgeons will adopt new safety and quality measures because they believe it is the “right thing to do” for their patient. Consequently, the process of holding surgeons accountable when they fail to adopt new quality or safety programs or to change their practice so that it aligns with the vision of the institution has been limited. Furthermore, the practice of cardiac surgery occurs in the oft remote and isolated OR, making a surgeon’s actions and compliance with quality and safety initiatives difficult for hospital leadership to monitor. Therefore, even when best practices are adhered to by surgeons, they are seldom reinforced. As a result, a culture of accountability for errors continues to linger rather than a culture of accountability that encourages and leverages the role of a surgeon in facilitating the entire surgical team to achieve excellence.

The Role of the Surgeon

Within the current conceptualization of the SEIPS model, the central component around which all other OR work systems factors revolve is the surgeon. However, as the above discussion clearly illustrates, the SEIPS model contrasts with traditional “person-centered” approaches that focus specifically on the negative consequences of surgical errors and disciplinary reactions to address them. Rather, the model focuses on factors that foster surgical excellence, as well as work system interventions to ensure excellence is achieved and maintained. The SEIPS model clearly views the surgeon’s cognitive flexibility, adaptability, and resiliency as being an important safety barrier between the work system factors in the OR and their potentially negative impact on patient safety. For example, Carthey et al. (2003) found that surgeons who were able to cope with unexpected complications during surgery exhibited effective cognitive flexibility. Cognitive flexibility refers to the ability to consider multiple hypotheses when attempting to generate potential causes of a patient’s unstable condition. Cognitive adaptability is also an important factor that can impact problem solving during surgical cases. For example, threats to patient safety decrease when surgeons are able to change their technique or strategy in light of unexpected patient anatomy, disruptions to surgical flow, or other unanticipated changes in work system events (Catchpole et al., 2007).

When work system factors do disrupt surgical processes, a surgeon’s mental resiliency is a key factor in ameliorating their impact on patient care. Mental resilience is reflected by the surgeon’s ability to remain calm following ineffective attempts to remedy problems, as well as the capacity to maintain a belief throughout a problem that it is ultimately resolvable (Carthey et al., 2003). According to de Leval et al. (2000) a marker of surgical excellence is not “error free” performance but rather the ability to manage errors and problems events during an operation. Effective error management consists of several interdependent processes including error recognition, error explanation, and error recovery (Kanse & van der Schaaf, 2001). For example, in our previous study of cardiac surgeons, we found that surgeons made roughly 3.5 errors per hour; however, the vast majority of these errors were detected and remedied by the

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surgical team without any observable intraoperative impact on the patient (Wiegmann et al., 2007). Another study by Bann et al. (2005) found that the ability of general surgeons to detect common surgical errors during a surgical skills training course significantly predicted their surgical performance on two subsequent surgical tasks (i.e., cystectomy and enterotomy). Galvan et al. (2005) found that recovery from potentially harmful major events during pediatric cardiac surgery (e.g., bleeding, heart rhythm abnormalities, ventilation issues and myocardial protection) was predicated by timely problem recognition and mental resiliency of surgeons.

Surgeons can also play a vital role in buffering the impact that work system factors have on other members of the surgical team. For example, Carthey et al. (2003) found that surgeons who were capable of adapting their surgical and communication style when operating with new or inexperienced team members were able to foster effective team coordination in a manner that reduced errors and improved patient outcomes. A study by Pisano et al. (2001) identified several characteristics of cardiac surgical teams that predicted successful or unsuccessful adoption of new technology associated with minimally invasive cardiac surgery. Of primary importance was the surgeon’s outlook toward the new technology. Those surgeons who actively encouraged team members, created an environment of psychological safety, and viewed the technology as a fundamental change in the way surgery is performed, had much greater success compared to those who viewed the technology as simply a “plug-in” program, ultimately making no effort to challenge the surgical team.

Clearly, as the above discussion suggests, a surgeon’s ability to manage errors or adapt to dynamic changes in work system variables is vital to ensuring patient safety. However, not all surgeons are equally adept or proficient in these areas. Some authors have argued that these “non-technical” abilities are generally intractable because they reflect the inherent skills and personalities of surgeons. To the contrary, at least one study suggests that these skills can be improved with the use of a well-designed training curriculum (Rogers et al., 2002). In any case, surgeons are certainly the final safety barrier between the work system factors in the OR and the potentially negative impact they might on patient safety. Surgeons also play a pivotal role in ensuring that interventions to improve works system factors and reliability of cardiac surgical care are ultimately successful.

Measuring Success

As indicated by the SEIPS model one of the key criteria for evaluating the impact of work system interventions on improving surgical care are patient outcome variables. Within cardiac surgery, however, the impact of any intervention on reducing surgical errors that significantly impact patient safety is difficult to establish because of their relatively low rate of occurrence. As stated previously, post-operative mortality and morbidity is less than 5% for most procedures; therefore, few critical patient outcomes will likely be observed during a given time span for an individual surgeon or even an individual hospital, making the “success” of any intervention difficult to establish (Fink et al., 2007; Polk, 2006). Research in nuclear power and aviation demonstrates that these high reliability industries have generally relied on surrogate measures to evaluate an intervention’s impact. Indeed similar approaches have often been utilized in healthcare. These surrogate measures often include process of care variables as well as employee and organizational outcome measures (see Figure 1). However, data supporting their use are often better documented in the general medical literature than the surgical literature. As a result many practicing surgeons have been somewhat slow to accept and utilize alternative metrics to patient outcomes (Polk, 2006).

Recently, our research has begun to focus on identifying intraoperative risk factors (processes of care and patient variables) that are (1) known to be affected by work system factors in the OR and (2) might also logically serve as appropriate surrogates to postoperative outcomes.

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Variables that we have identified occur frequently during surgical cases, are regularly documented in most hospitals, and have been linked to postoperative outcomes (e.g., x-clamp time associated with length of stay in ICU; cerebral desaturation associated with postoperative stroke) or to increases in the cost of care. Still research needs to be done to empirically establish a relationship between work system factors and these surrogate outcomes in the OR. Tools for reliably documenting works system factors and surrogate outcomes also need to be developed and validated (Wiegmann et al., 2007; Healy et al., 2007).

Employee and organizational variables have also been used as alternatives to traditional safety and quality outcomes (Figure 1). For example, the effectiveness of teamwork training is often evaluated by assessing improvements or changes in safety related knowledge, skills and attitudes, demonstration of teamwork skills in simulated environments, and supervisor or colleague evaluations (Salas et al., 2006). Employee satisfaction, burnout, turnover and retention are also outcome variables that have been utilized by many researchers (Sexton et al., 2006). For example, as mentioned previously, a pre-operative briefing protocol for general surgery not only reduced wrong-site surgeries but also improved employee satisfaction, decreased nursing personnel turnover, and enhanced perception of the safety climate and teamwork quality in the OR (DeFontes & Surbida, 2004). Clearly there are a number of employee outcome variables that may be impacted by patient safety interventions at the work systems level. However, research is still needed to determine which ones are most important for actually improving the delivery of safe and reliable surgical care.

Organizational outcomes have generally received less attention than employee outcomes with regards to patient safety. However, there is a growing body of literature describing efforts to understand how changes in organizational behavior reflect improvements in safety (Keroack et al., 2007). For example, Pronovost et al. (2006) have proposed an "organization-wide" approach to measuring improvements in patient safety within healthcare settings. In particular, these authors suggest that there are four key organizational variables including traditional outcome measures (e.g., how often patients are harmed within an organization), process measures (how often does an organization do what it should to prevent patient harm), structure measures (how an organization knows that it has learned from its mistakes), and context measures (how well has the organization established a culture of safety). Unfortunately, many of these variables are difficult to quantify and are therefore often left to subjective interpretation and evaluation. Nonetheless, as more becomes known about organizational outcome variables, a better understanding of their importance and relationship to surgical care processes will also likely emerge.

Clearly, there are a variety of outcome and process variables that might be used as surrogates for traditional safety and quality measures. Albeit, in isolation, the use of any individual surrogate to validate the impact of a new patient safety program on improving surgical care can be disputed. Nonetheless, a consistent pattern of results across a wide variety of these measures would strongly suggest that a given intervention has improved the margin of safety. Additional research is needed, however, to identify which group of surrogate measures is most sensitive to work system factors that significantly affect the process of delivering safe and reliable surgical care.

Conclusion

Over the past 50 years, significant improvements in cardiac surgical care have been achieved. Nevertheless, considerable variability in surgical outcomes still exists across institutions and individual surgeons; moreover, surgical errors that significantly impact patient safety continue to occur. Historically, surgical errors have been viewed as being determined primarily by the technical skill of the surgeon. However, focusing only on individual skill assumes that surgeons

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and other members of the surgical team will perform highly and uniformly, regardless of the variable working conditions within the operating room environment. Alternatively, a work systems approach recognizes that surgical skill alone is not sufficient to determine outcomes, because the process of delivering surgical care involves several interdependent variables, many of which vary across hospitals, operating rooms or surgical cases and most of which are not normally under the control of the surgical team. In this paper we have used the SEIPS model to highlight the nature of many of these work system factors that affect surgical performance including the OR environment, teamwork and communication, technology and equipment, tasks and workload factors, and organizational variables. Clearly, if further improvements in the success rate and reliability of cardiac surgery are to be realized, interventions need to be developed to reduce the negative impact that work system failures can have on surgical performance. Some recommendations have been proposed here; however, several challenges remain.

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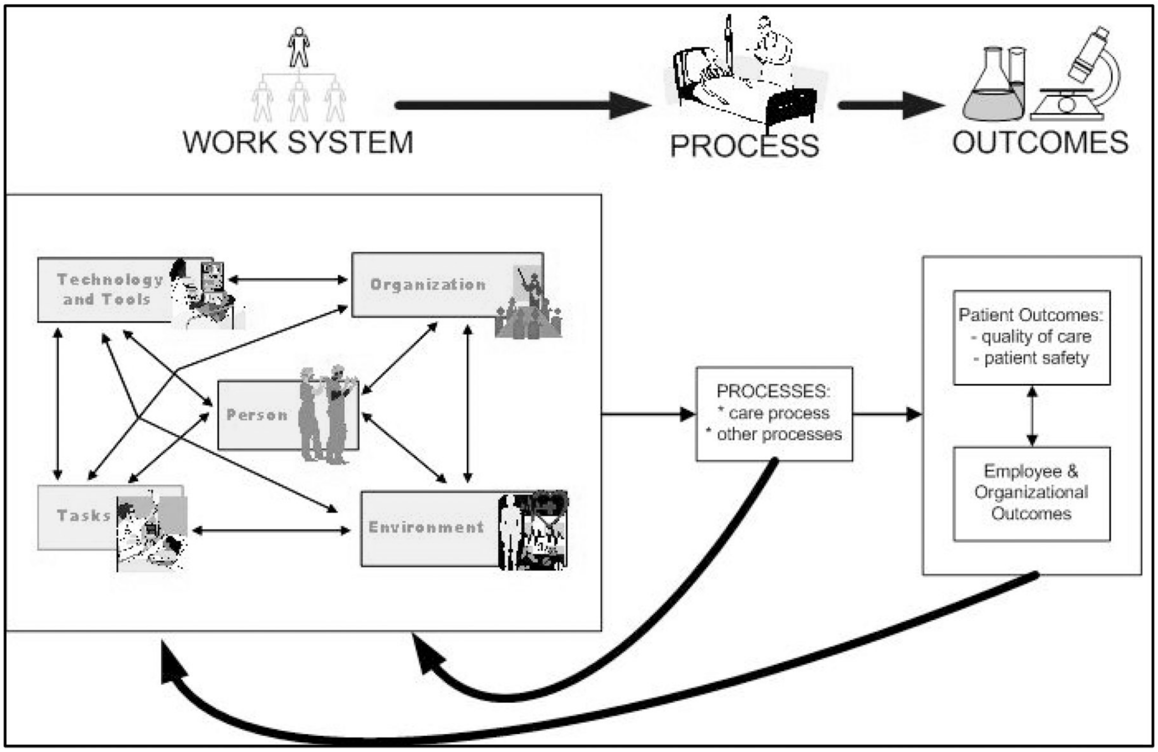

Figure 1.
The Systems Engineering Initiative to Patient Safety (SEIPS) model (Carayon et al., 2006)

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Table 1

Work System Factors Summary

Work System Factor	Potential Interventions	Key References
Physical Environment	• Standardized OR layout • "Sterile Cockpit" Rule	Brogmus et al., 2007 Ofek et al., 2006 Healey et al., 2006
Teamwork and Communication	• Foster team familiarity • Pre-operative briefings	Lingard et al., 2004 Carthey et al., 2003 Wiegmann et al., 2007 DeFontes & Surbida, 2004
Tools and Technology	• Usability testing • Anticipate unintended consequences	Morrow et al., 2007 Cook and Woods, 1996 Karsh and Holden, 2007
Task and Workload Factors	• Develop standardized procedures/checklists • Incorporate breaks to reduce fatigue	Degani & Wiener, 1993 Hales et al., 2007
Organizational Influences	• Improve leadership engagement • Establish accountability for safety	Thomas et al., 2005 Keroack, 2007 Pronovost et al., 2005 Reason, 1999 Eiff, 1999
Role of Surgeon	• Error management • Adapting surgical and communication styles	Bann et al., 2005 Carthey et al., 2003

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Table 2

Measuring Success

Type	Examples	References
Patient Outcomes	• Mortality • Morbidity • Stroke	de Leval et al., 2000 Vincent et al., 2004
Process Outcomes	• X-clamp time associated with length of stay in ICU • Cerebral desaturation associated with postoperative stroke	Fink et al., 2007 Polk, 2006 Wiegmann et al., 2007 Healy et al., 2007
Employee/Organization Outcomes	• Improvements in safety-related knowledge • Employee satisfaction/burnout • Decrease in nursing personnel turnover • Enhanced perception of safety climate and teamwork quality in OR	Salas et al., 2006 Sexton et al., 2006 DeFontes & Surbida, 2004