System Factors Affecting Patient Safety in the OR

An Analysis of Safety Threats and Resiliency

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Objective: The objective of this study is to determine the characteristics and frequency of intraoperative safety threats and resilience supports using a human factors measurement tool.

Background: Human factors analysis can provide insight into how system elements contribute to intraoperative adverse events. Empiric evidence on safety threats and resilience in surgical practice is lacking.

Methods: A cross-sectional study of 24 patients undergoing elective laparoscopic general surgery at a single center in the Netherlands from May to November, 2017 was conducted. Video, audio, and patient physiologic data from all included procedures were obtained through a multichannel synchronized recording device. Trained analysts reviewed the recordings and coded safety threats and resilience supports. The codes were categorized into 1 of 6 categories (person, task, tools and technology, physical environment, organization, and external environment).

Results: A median of 14 safety threats [interquartile range (IQR) 11–16] and 12 resilience supports (IQR 11–16) were identified per case. Most safety threat codes (median 9, IQR 7–12) and resilience support codes (median 10, IQR 7–12) were classified in the person category. The organization category contained a median of 2 (IQR 1–2) safety threat codes and 2 (IQR 2–3) resilience support codes per case. The tools and technology category contributed a small number of safety threats (median 1 per case, IQR 0–1), but rarely provided resilience support.

Conclusions: Through a detailed human factors analysis of elective laparoscopic general surgery cases, this study provided a quantitative analysis of the existing safety threats and resilience supports in a modern endoscopic operating room.

Keywords: patient safety, surgery, systems factors

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Adverse events occur commonly in the operating room (OR) and can lead to significant morbidity and mortality.[1–3] Several studies demonstrated that intraoperative adverse events were often preventable,[3,4] and occurred due to complex system factors and nontechnical aspects of surgery[5,6] including communication,[7] teamwork,[8] interactions with tools and technology,[8] and physical environment.[8–10] To prevent adverse events from recurring, it is important to better understand how system factors in the OR affect patient safety.

Human factors engineering (HFE) is a discipline that studies interactions among people, tools, and the environments within a system. While HFE has been applied routinely in the manufacturing, aviation, and nuclear power industries to analyze adverse events, it has only recently been adopted by surgical communities.[11,12] HFE can help to identify safety threats defined as deviations from an ideal course that can increase risk of harm to patients. Surgical teams often overcome unexpected events and deviations to achieve good outcomes. This process is termed resilience, which is the property of complex adaptive systems that enables them to adapt before, during, or after safety threats to be successful, despite conditions that could lead to failure.[13,14] The Systems Engineering Initiative for Patient Safety (SEIPS) is one model that helps understand the healthcare system through the interactions of 6 components: person, tasks, tools and technology, physical environment, organization, and external environment.[15–17] Our research group modified the SEIPS model to analyze the system factors that impact patient safety in minimally invasive surgery.[18]

While several studies have demonstrated that a large number of adverse events in the OR occurred due to system factors, there is a knowledge gap in the literature on safety threats and resilience in surgery. Previous studies of systems elements in surgery often focus on a small subset of factors (eg, communication breakdown and equipment failure), but did not comprehensively analyze all interactions within the system. Further, resilience in the OR has rarely been examined. To address these knowledge gaps, this observational study was performed in a single OR from a referral center, that had adopted the OR Black Box system to capture and analyze intraoperative data in an effort to implement and research quality improvement (QI) interventions. The objectives of this study are to characterize safety threats and resilience supports using a human factors measurement tool on audio-visual data obtained from elective laparoscopic operations to facilitate OR outcome analysis; and to identify the most frequently observed safety threats and resilience support codes.

METHODS

We conducted a cross-sectional study in a convenience sample of 24 adult (≥18 years old) patients who underwent laparoscopic general surgery after implementation of a multiport, comprehensive data-capturing device called the OR Black Box[19,20] (Surgical Safety Technologies Inc, Toronto, ON). Before the beginning of the study, a pilot phase consisting of 11 cases was completed, during which adjustments were made to review process and the coding of safety threats and resilience. The objective of the study was to determine the frequency and characteristics of safety threats and resilience supports in minimally invasive general surgery.

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Subjects and Setting

A convenience sample of 24 adult (≥18 years old) patients who consecutively underwent laparoscopic general surgery between May and November 2017 were observed. The cases involved 4 attending surgeons at a major academic center. We used the OR Black Box system to synchronize several intraoperative data feeds, including the audio-visual and patient physiologic data.[19] The data feeds were obtained from views of the surgical field, nursing station, laparoscopic camera, and anesthesia monitoring devices. Recording began just after patients were draped and ended after skin closure just before the drapes were removed. All patients and OR team members present during the OR Black Box recordings consented to participate in a study evaluating the use of the OR Black Box and its outcome report for benefits of team debriefing before recording. The data captured in the study were used to generate an outcome report that included video segments of each human factors event identified during the case, labeled as safety threats or resilience support codes, and also concise qualitative descriptions. This video report was promptly returned to the surgical team via a secure digital channel. The team completed a debriefing session using this video outcome report as an aid. Safety threats and resilience supports pertaining to the performances of nurses, anesthesiologists, surgeons, and their respective trainees were identified and characterized using the modified SIEPS human factors tool.

Outcomes

The primary outcome of this analysis were the characteristics of safety threats and resilience supports identified using a systems-based classification scheme for safety threats and resilience supports in laparoscopic surgery framework.[18] The SEIPS model was developed to characterize the healthcare work system and how it impacts patient safety.[15] Previously, our group modified the SEIPS model to specifically assess safety threats and resilience supports present in laparoscopic general surgery.[18] This modified version of the SEIPS framework utilizes over 100 inductively developed codes to identify safety threats and resilience supports related to each of the 6 SEIPS domains: person, tasks, tools and technologies, organization, internal (physical) environment, and external environment.[15,16,21] A safety threat is defined as any factor that could cause harm to the patient, increases the risk of harm to a patient, delays progress of the procedure, or significantly disrupts the regular work flow, and thereby reduces patient safety. A resilience support reduces the risk of harm to the patient, prevents a delay or disruption of workflow, and overall contributes to improved patient safety. The framework considers threats and resilience supports arising from the entire workflow system within the OR. They are then characterized according to the categories, subcategories, and the individual codes. For example, a safety threat can be identified by the person category, unsafe acts subcategory, and the substandard skill/technique error code. A full description of the framework can be found in Appendix 1 (http://links.lww.com/SLA/B790) of the supplementary material.

Data Collection

Six expert surgical analysts (4 surgeons, 1 physician, and 1 human factors analyst) who have undergone at least 3 months of structured curricular training to administer the protocol reviewed all OR Black Box recordings. Procedure types and duration were collected. The procedure duration was defined as the time between start of the procedure—after the patient was fully draped—to the removal of the last drape. Pairs of analysts independently identified safety threats and resilience supports in each surgical case and assigned corresponding categories, subcategories, and codes based on the framework. Resilience support and safety threat codes were identified independently to one another. Therefore while a safety threat and resilience support event may be linked (eg, a technical error causing bleeding is followed by the team working together to rapidly control the bleed), a safety threat may occur without intervention of the team or resilience support can be performed preemptively to anticipate potential errors (eg, performing a surgical timeout to achieve a shared mental model for the procedure). The intensive assessment process required double to triple the procedure duration from each analyst assessing the case to complete the analysis. After each surgical case was analyzed independently, all 6 analysts and the study investigators met as a team to have discussions about the identified safety threats and resilience supports. Then, final decisions on whether the safety events should be included and how they should be coded were reached by consensus. This process of double-coding and consensus decision-making was performed to strengthen the reliability of our results. For each event, a concise qualitative comment was provided by the reviewing team to the surgical team to provide context regarding the nature of the event. Patient characteristics and clinical outcomes were not collected in accordance with the Research Ethics Board (REB) protocol.

Statistical Analysis

Descriptive statistics including median [interquartile range (IQR)] for continuous data and frequency analysis (%) for categorical data were performed to describe the distributions of procedure types, OR duration, and frequencies and rates of safety threats and resilience supports were performed. SAS 9.4 (SAS Institute, Raleigh, NC) was used for statistical analysis.

RESULTS

Procedure Characteristics and Frequency of Safety Threats and Resilience Supports

In Table 1, we presented the characteristics and frequency distributions of the safety threats and resilience. We evaluated 24 operations spanning over 49 hours of procedure duration. The median procedure duration was 114 minutes (IQR 94–136). Laparoscopic Heller myotomy was the most frequently performed operation (12 cases, 50%) followed by both diaphragmatic hernia repair (4 cases, 17%) and adrenalectomy (4 cases, 17%).

Table 2 presents frequency per case and rates of safety threats and resilience supports by SEIPS categories. Across all categories, a median of 14 safety threats per case (IQR 11–16) was observed. The median rate of safety threats per hour of procedure time was 6 (IQR 4–9). Safety threats were most commonly classified under the person

TABLE 1. Characteristics of the Included Procedures

Total number of cases, n (%)	24 (100)
Heller myotomy and fundoplication, n (%)	12 (50)
Diaphragmatic hernia, n (%)	4 (17)
Subtotal colectomy, n (%)	3 (13)
Adrenalectomy, n (%)	4 (17)
Appendectomy, n (%)	1 (4)
Procedure duration in min, median (IQR)	114 (94–136)
Heller myotomy and fundoplication, median (IQR)	101 (90–117)
Diaphragmatic hernia, median (IQR)	128 (118–165)
Segmental colectomy, median (IQR)	204 (161–208)
Adrenalectomy, median (IQR)	121 (94–156)
Appendectomy, n	45
Number of procedures performed by surgeon ID	
Surgeon 1, n (%)	16 (67)
Surgeon 2, n (%)	3 (13)
Surgeon 3, n (%)	1 (4)
Surgeon 4, n (%)	4 (17)

TABLE 2. Frequencies of Safety Threat and Resilience Support Codes by SEIPS Category

	Cases With Any Event, n (%)	Event Count Per Case, Median (IQR)	Rate of Events Per h, Median (IQR)
Safety threat codes			
Total safety threats observed, n = 309			
All categories	24 (100)	14 (11–16)	6 (4–9)
Person	24 (100)	9 (7–12)	4 (3–6)
Tasks	12 (50)	1 (0–1)	0 (0–1)
Tools and technology	14 (58)	1 (0–1)	0 (0–1)
Physical environment	11 (46)	0 (0–1)	0 (0–1)
Organization	21 (88)	2 (1–2)	1 (1–1)
External environment	0 (0)	0 (0)	0 (0)
Resilience support codes			
Total resilience supports observed, n = 316			
All categories	24 (100)	12 (11–16)	6 (5–10)
Person	24 (100)	10 (7–12)	5 (3–7)
Tasks	2 (8)	0 (0)	0 (0)
Tools and technology	1 (4)	0 (0)	0 (0)
Physical environment	15 (63)	1 (0–2)	1 (0–1)
Organization	21 (88)	2 (2–3)	1 (1–2)
External environment	0 (0)	0 (0)	0 (0)

category [a median of 9 observations per case (IQR 7–12)], followed by the organization category [a median of 2 per case (IQR 1–2)]. The tools and technology category contributed to a small, but significant number of safety threats [a median of 1 per case (IQR 0–1)]. No safety threats were observed that were categorized under the external environment. On the contrary, a median of 12 resilience supports were identified per case (IQR 11–16). Similar to safety threats, resilience supports were the most commonly classified under the person category [a median of 9 observations per case (IQR 7–12)]. This was followed by the organization category [a median of 2 per case (IQR 2–3)] and physical environment [a median of 1 (IQR 0–2)]. There was only 1 instance in which resilience support was provided by tools and technology.

Frequently Identified Safety Threat Codes and Resilience Support Codes

A list of 10 safety threat codes identified with the greatest frequency along with their examples is shown in Table 3. Three codes from the unsafe acts subcategory within the person category of the modified SEIPS framework were observed most frequently. Examples of these codes included technical errors during surgery, deviation from standard operating procedures, and not actively paying attention to the task or team. Organizational issues such as failure to standardize procedures were also identified. Within the tools and technology category, the most frequently identified code was related to device malfunction, which resulted in delays while the device was repaired or replaced.

TABLE 3. Ten Most Frequently Observed Safety Threat Codes

Rank	Category	Subcategory	Code	Example	Observations, n	Cases With ≥1 Observation, n
1	Person	Unsafe acts	Substandard skill/ technique error	Activating energy device out of view	77	23
2	Person	Unsafe acts	Protocol violation	Violating sterile protocols, such as not wearing surgical mask appropriately	47	19
3	Person	Unsafe acts	Active attention failure	Not paying attention to team resulting in delayed task or communication	44	21
4	Organization	Suboptimal policies/ procedures	Failure to standardize	Prep not dry before application of drapes	16	13
5	Organization	Suboptimal policies/ procedures	No safety check	Settings of energy device not verified, and device not tested before use	15	14
6	Person	Communication failures	Communication absent	Team member fails to notify team of changing patient condition	13	11
7	Physical environment	Suboptimal workspace setup	Inefficient configuration/ positioning	Positioning of trocars contributes to instrument collisions	10	9
8	Tools and technology	Substandard functionality/utility	Malfunction	Energy device malfunction requires new instrument causing delay	8	7
9	Physical environment	Suboptimal workspace setup	Unergonomic configuration	Monitors not positioned ergonomically for surgeons	8	5
10	Person	Suboptimal clinician condition	Lack of situation awareness	Team member delayed identifying changing patient condition	7	6

TABLE 4. Ten Most Frequently Observed Resilience Support Codes

Rank	Category	Subcategory	Code	Example	Observations, n	Cases with ≥1 Observation, n
1	Person	Effective communication	Communicating progress	Surgeon updates team on estimated procedural time remaining	25	15
2	Person	High performance behavior	Surgical quality control	Surgeon identifies and rectifies loose suture	24	15
3	Person	Effective guidance/ instruction	Sharing knowledge	Surgeon identifies anatomy for trainee	18	14
4	Organization	Effective policies/ procedures	Timeout	Standardized timeout performed at correct time	18	18
5	Person	Advantageous clinician condition	Good situation awareness	Anaesthetist identifies patient laying on IV line	16	10
6	Organization	Effective policies/ procedures	Instrument count	Surgical counts performed at correct time	14	14
7	Person	Effective guidance/ instruction	Skills coaching	Surgeon teaches trainee suturing technique	12	11
8	Physical Environment	Optimal workspace setup	Efficient positioning	Team takes care to optimize patient position to facilitate next surgical step	12	11
9	Physical Environment	Optimal workspace setup	Layout optimized	Team optimized layout of monitors before start of procedure	12	11
10	Person	Effective communication	Communicating changes	Anaesthetist communicates change in patient condition to team	12	9

We also presented 10 resilience support codes that were observed most frequently in Table 4, along with their examples. The majority of the resilience codes were within the person category. Subcategories such as effective communication and effective guidance/instruction were frequently identified. One example of effective communication was demonstrated when surgeons updated anesthesiologists of the estimated procedural time remaining so that they could modify drug doses accordingly. A recurring example of effective guidance/instruction was shown when attending surgeons shared their knowledge of procedural steps, anatomy, and surgical techniques with trainees. While resilience support codes were occasionally found within organization and physical environment categories, they were rarely found within the tools and technology. The description and frequency of all 309 safety threats and 317 resilience supports observed in our study is available in the supplementary material.

DISCUSSION

A detailed human factors analysis of 24 elective laparoscopic surgery cases from a referral center using audio-visual data obtained through the OR Black Box identified a median of 14 safety threats per case and a median of 12 resilience supports per case. Among the 6 SEIPS categories, both safety threats and resilience supports were the most frequently related to the interactions with "persons." Safety threat and resilience support codes were attributed to the organization second most frequently. Tools and technology were responsible for a small, but significant number of safety threats; however, they did not provide resilience supports.

The study of system elements contributing to risk to patient safety often focus on a specific subset of factors such as technical errors,[22] communication failure,[7] tool malfunctions,[23] and disruptions.[23,24] Using the modified SEIPS framework, we identified a wide spectrum of safety threats from across the surgical system. The nature of safety threat codes identified in our study was diverse, with 38 total codes across 5 SEIPS categories. The greatest number of safety threats resulted from the interactions of people with each other and the system. In recent years, there has been increasing number of studies examining safety threats in the OR from a systems perspective.[6,8,12,25] However, system resilience has not been investigated as widely.

The present study showed that while the interface between the person and the system introduced several sources of risk to patient safety, the person category also contributed nearly 75% of the resilience support codes, thereby providing the ability to prevent and respond to safety threats. In a study published in 2012, Hu et al video-recorded and transcribed 10 operations and investigated factors that contributed to intraoperative deviations and mitigated their impact on patient safety. This study suggested that people were most frequently responsible for overcoming safety compromises, whereas the organization and environment did not have a direct impact.[13] The findings in our study suggest that there is a need for further HFE research to examine safety threats and resilience supports provided by people to reduce adverse events in surgery.

A goal of studying patient safety and human factors in surgery is to apply the knowledge to develop interventions that improve outcomes. Interventions should be designed based on the system factors needs of individual clinical setting to reduce safety threats and increase resilience. There are several interventions available to reduce human errors and increase capacity for people to provide resilience within the system, including simulation-based educational tools and structured debriefing to improve technical and nontechnical skills.[26–29] One advantage of these interventions is that they target the greatest source of safety risk in the system. They also utilize the inherent adaptability of humans to respond to dynamic changes in the OR. It is more difficult to achieve the same level of adaptability in other system elements. One disadvantage of interventions that target the surgical team is that they place greater responsibility on the team members and potentially create stress and cognitive overload. Another challenge of relying on the surgical team as the greatest source of resilience in the OR is that the potential for human errors remains.

There is opportunity for developing interventions targeting system factors beyond the person category. Our study demonstrated that 31% of safety threat codes identified were due to nonhuman system elements. For instance, 7 of 24 cases (29%) had at least 1 malfunctioning device required for operation. Further, in 9 cases (38%), laparoscopic monitors were placed in unergonomic positions before the start of a case. These threats might have created stress among surgical team members and caused delay in operation. An organizational intervention, such as the WHO surgical safety checklist[30] to ensure that all required equipment and tools are optimally functional and placed before the start of a case, may provide resilience support and prevent safety threats from recurring. Organizational interventions to ensure adherence to safety protocols like the surgical checklists have shown to reduce errors and adverse events.[30] On 26 occasions across 15 cases (63%) energy devices were activated out of view during operation. This type of safety threats can cause inadvertent tissue injuries that may be missed, leading to patient harm. While educational interventions to train individual surgeons on unsafe surgical techniques may be beneficial, designing the energy device with forced function to prevent activation when out of view will likely provide a greater reduction in safety threats. In our study, we identified a small but significant number of safety threats associated with tools and technology category, but resilience support was rarely provided. Interventions targeting nonhuman systems elements to increase resilience supports will relieve some of the burden placed on surgical team to adapt and respond in the face of adversity.

The findings in this study were collected with a goal to implement an innovative educational intervention to improve patient safety in a study involving postoperative surgical team debriefing.[31] The goal of the study was to use structured debriefing supported by video reports containing clips of safety threats and resilience supports. Audiovisual clips of intraoperative events identified by the surgical analysts were anonymized and compiled into a video report for each case that included on-screen text explaining the analysts observations. This was returned to the surgical team within 1 week of the operation. A structured debriefing session was then performed with the video report as a resource to facilitate discussion. Initial observations from the study identified meaningful changes in practice following debriefing. For example, team members altered handling of an instrument to prevent breaks in sterility identified in video reports. The full analysis of the results of the intervention is in progress and will be reported in a future publication. It does, however, provide an early example of how patient safety requires the continued leadership and commitment of organizations, and the surgical community to be transparent. By collecting and analyzing intraoperative data we can better design educational and quality improvement initiatives to achieve more impactful results. These principles should be adopted by all high-reliability organizations to improve surgical quality.

Limitations

This study has a few limitations. First, it was challenging to assign category, subcategory, and code for safety events using the framework as there were 80 safety threat and 67 resilience support codes to choose from. To minimize inaccurate or inconsistent coding, a team meeting to reach consensus on how each event should be coded was required. To feasibly and reliably identify safety threat and resilience support codes in future studies, the measurement framework should undergo reduction strategies to reduce the number of codes—the subject of future studies by our group. Second, as with any study design where an intervention is implemented to observe individuals, there is a concern for possible intentional alteration of behavior and performance—a phenomenon known as the Hawthorne effect. To minimize this possible effect, a pilot phase involving 11 surgical cases was conducted to allow surgical teams to familiarize with the study design and environment. Further, the recording devices were strategically installed in nonconspicuous locations, which has shown to reduce impact of the Hawthorne effect. Third, this study was conducted in a single center, and therefore, our findings may not be generalizable to other clinical settings. Finally, this study did not collect patient level characteristics due to the restraints of the REB protocol. Thus, potential relationship between safety events and patient-level variables was not examined.

CONCLUSIONS

Through detailed analysis of the OR Black Box data using a human factors framework, this study identified a median of 6 safety threats per procedure hour and a median of 6 safety resilience support per hour. While most of the safety threats were related to human interactions, there was also a significant number of threats that occurred due to tools and technology, organization, and environment. Resilience supports in response to threats were heavily dependent on surgical teams. To reduce the burden of safety threats and increase resilience support, educational and quality initiative efforts should continue to aim at training and helping surgical teams. Creating an even safer OR will involve new tools and technology, organizational change, and environments that provide systems-level support to prevent safety threats and provide resilience support to mitigate the risk to patients.

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