

# Using human factors engineering to improve surgical safety: An observational study of system factors affecting risk and resilience during general laparoscopic surgery

by

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A thesis submitted in conformity with the requirements for the degree of Master of Health Science in Clinical Engineering

Institute of Biomaterials and Biomedical Engineering  
University of Toronto

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## Abstract

Laparoscopic surgery is a uniquely complex sociotechnical work system wherein surgical successes prevail despite pervasive safety threats. Characterizing intraoperative factors that thus support system resilience in addition to those that threaten patient safety is critical for optimizing surgical safety overall. In this exploratory observational study, 19 video-recordings of complex general laparoscopic surgical procedures were analyzed using a qualitative systems-based approach to identify and categorize intraoperative human factors with the potential to impact patient safety. A total of 1083 relevant observations were made over 39.8 hours of operative time, enabling the identification of 80 distinct safety threats and 68 resilience supports within the surgical system. Safety threats associated with the physical environment, tasks, organization, and equipment were prevalent, while supports for resilience were predominantly attributed to clinician behaviours. To optimize safety in the specific system observed, immediate system-level interventions to address recurring equipment malfunctions and intrusive intraoperative noise are recommended, as is the prioritization and reinforcement of resilience-supporting communication patterns.

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# 1 Introduction

## 1.1 Rationale

In the year 2000, the first national study of adverse events in Canadian hospitals found that preventable medical errors contributed to as many as 23,750 patient deaths, with more than half of all adverse events occurring in surgical settings (1). Combined with more recent reports that intraoperative threats to patient safety remain prevalent in Canadian healthcare institutions (2), these findings emphasize the urgent need for quality improvement in surgery. Proponents of surgical safety agree that laparoscopic surgery warrants particular attention, as the high level of technological integration, combined with the socio-technical complexity of the laparoscopic surgical environment, together create ample opportunity for preventable patient harm (3, 4).

To date, empirical research on quality improvement in surgery has predominantly involved the quantitative study of adverse events, while limited attention has been given to qualitatively defining the safety failures involved in these events and the characteristics of the surgical system that allow these failures to arise. However, the surgical community is increasingly recognizing the importance of qualitative research for elucidating actionable deficiencies in surgical safety, and a call has been made for the broader application of qualitative research techniques to drive quality improvement in the operative environment (5). To this end, the application of human factors engineering research methods in the surgical domain has the potential to inform targeted initiatives for practically enhancing intraoperative patient safety.

Human factors engineering (HFE) is a scientific discipline concerned with exposing and correcting areas of mismatch between people, tools, and environments within various work systems. HFE accepts human fallibility as an inescapable facet of the human condition and therefore seeks to optimize the performance of human-centred sociotechnical work systems through the design of technologies and systems that accommodate the capabilities and limitations of human beings (3, 6).

This systems-based approach to evaluation and design has important implications for surgery. Surgery is a high-risk, high workload environment with low tolerance for failure, and thus, surgical researchers have exhibited increasing interest in the application of systems-based

approaches to intraoperative analyses for uncovering latent safety threats that increase the risk of error. However, the capacity for resilience, for which surgical systems are equally renowned (7), has gone largely unexplored using a systems-based approach. Resilience is an emergent property of complex adaptive systems that enables them to produce success despite conditions that could easily lead to failure, and the work system elements that either contribute to or erode resilience are not well understood (8). Thus, by applying a systems-based approach to analyzing intraoperative factors that contribute to success *in addition to* those that increase the risk of failure, a broader understanding of the work system elements that impact patient safety overall can be gained, thereby maximizing the potential for subsequent safety improvement interventions to succeed in their goal of keeping patients safe in an unpredictable system.

Thus, with a view to addressing knowledge gaps surrounding potential preconditions to adverse intraoperative events, evaluating the capacity of surgical systems for resilience, and informing the design of meaningful safety interventions, this study adopted a multidisciplinary HFE approach to identify and characterize intraoperative factors that either threaten patient safety or support system resilience during general laparoscopic surgery.

## 1.2 Thesis Overview

In **Chapter 2** of this work, a review of the literature comprising a theoretical background of human factors engineering, its relevance to patient safety improvement in surgery, and a survey of relevant studies investigating human factors in surgical settings is presented. **Chapter 3** builds on the findings of the literature review to explicitly outline the research gaps identified in addition to the specific objectives that were developed for the purpose of addressing them. In **Chapter 4**, the observational research method employed to achieve these objectives is outlined, and **Chapter 5** presents the results obtained, both conceptual and specific. **Chapter 6** provides an in-depth interpretation of the research findings with informed recommendations for quality improvement interventions, while also elucidating the limitations of the present study and potential directions for future work. Finally, **Chapter 7** concludes this work with a summary of the contribution made to the surgical quality improvement field.

## 2 Literature Review

### 2.1 Preventable Patient Harm in Surgical Settings

In the context of patient care, safety is defined as freedom from accidental injury (9). An accidental injury, in turn, is formally known as a preventable adverse event (9). Invariably, preventable adverse events arise from medical management error: the failure of a planned medical action to be completed as intended (9) or any deviation from usual medical care that poses a risk of harm (10). Ultimately, not all medical errors lead to patient harm, but all preventable patient harm is attributed to error.

In November of 1999, the Institute of Medicine (IOM) released a historic report that brought the concept of medical error to the forefront of healthcare quality improvement. The report, titled *To Err is Human*, was the first to bring widespread public attention to the contribution of medical errors to adverse events in American hospitals, indicating that medical errors contribute to as many as 98,000 hospital deaths per year (9). The startling findings of the IOM report were mirrored by a Canadian counterpart study published one year later; in the Canadian Adverse Events Study, as many as 70,000 preventable adverse events were found to occur in Canadian hospitals, and 51.4% of all adverse events occurred in surgical settings (1).

That surgery is a particularly high-risk endeavour is well understood. The operating room (OR) has been cited as one of the most complex work environments in healthcare (11), with significant complexity arising from patient management and procedure task demands, the high level of technology, the involvement and compulsory coordination of multiple clinical specialties, and the dynamic, rapidly changing nature of the system itself (11, 12). Laparoscopic surgery, wherein surgeons use small incisions to gain access to internal organs and operate using the guidance of a laparoscopic camera and monitor display, presents an even more uniquely challenging environment; instrumentation is constrained to four degrees of freedom with limited tactile feedback, stereoscopic vision is lost due to the two-dimensional nature of conventional laparoscopic monitors, and the visual axis of the surgeon is not aligned with the motor axis of the instrument and forearm, thereby increasing the mental workload of both the surgeon and assistants (4, 13).

The mirrored findings of *To Err is Human* and the Canadian Adverse Events Study have undoubtedly brought increased attention to surgical safety improvement in recent years (14). However, more recent reports suggest that surprisingly little progress has been made in the years since their release. For example, in a rigorous study of North Carolina hospitals using methods similar to the aforementioned national adverse events studies, medical errors were found to persist in all areas, including surgical services, despite substantial attention and allocation of resources to improve the safety of care (15). These findings indicate that significant work remains to be done to eliminate systematic threats to patient safety from healthcare altogether, and experts in healthcare quality improvement insist that lasting and impactful improvements in this area will require an interdisciplinary approach (2, 5, 14).

## 2.2 Human Factors Engineering and Patient Safety Improvement

The systems approach to safety management, a foundational concept in human factors engineering, has long been employed by the manufacturing, aviation, and nuclear power industries to enhance workplace safety, quality, efficiency, and performance (3, 16). Originating in the field of systems engineering, systems theory argues that “events, objects, locations, and methods do not exist independently, but rather are intertwined as interdependent components of complex systems” (17). Systems theory is a useful tool for interpreting potential mechanisms of safety failures in a variety of complex, high-risk domains, and was built upon by James Reason to create his model of accident causation (18). According to Reason, latent conditions (i.e. dormant circumstances that predispose a system to error) and active failures (i.e. errors and violations committed at the service delivery end of a system) in a system create windows of opportunity for errors to occur (19, 20). Subsequently, adverse events arise when these windows of opportunity align across successive levels of defence, or when multiple system factors work together to yield an unsafe situation, thereby predisposing the individuals at the centre of the system to error. (20).

Arguably one of the most well known tools in human factors engineering for framing the design and analysis of healthcare research is the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety (21). The most recent iteration of this model depicts the healthcare work system as a sociotechnical, human-centred system with six

interacting components that influence system performance: person, tasks, tools and technologies, organization, internal (physical) environment, and external environment (22, 23). The “person” element at the center of this system can be a single individual (ex. a physician) or it can represent a group of individuals (ex. a healthcare team). Thus, person-related factors include individual physical characteristics (ex. strength and height), cognitive characteristics (ex. expertise), and psychosocial characteristics (ex. motivation), as well as group-level characteristics such as team cohesiveness. Task factors are attributes or characteristics of the tasks performed within the healthcare work system, including difficulty, complexity, and physical or cognitive demands. Tool and technology factors are characteristics of the objects used to complete work tasks, such as medical devices, equipment, or instrumentation, and factors associated with this element include characteristics such as usability, accessibility, familiarity, degree of automation, and functionality. The “organization” element captures structures beyond the individual that organize time, space, resources, and activity, and includes factors such as scheduling, training, management, and organizational culture. “Internal environment” refers to the physical characteristics of the environment of work, and internal environment factors include aspects of the lighting, ambient sound, temperature, physical layout, and available space. Lastly, “external environment” captures influences of macro-level societal, economic, ecological, and policy factors outside an organization that can affect the work system as a whole. Overall, this model reflects the “Structure-Process-Outcome” model of healthcare quality and suggests that clinical skill, performance, and patient outcomes are strongly affected by the various elements within the dynamic and complex healthcare work system (22, 23).

In the context of patient safety research, the SEIPS model has been most frequently applied in conjunction with Reason’s model of accident causation to frame analyses of latent safety threats in healthcare environments for the purpose reducing the risk of medical error by identifying and subsequently correcting them (22, 24). However, an alternative approach to safety management has emerged in recent years. While Reason’s model of accident causation and related safety management ideologies focus on reducing the number of adverse outcomes through eliminating opportunity for error (a concept known as “Safety I”), the emerging field of resilience engineering seeks instead to enhance the ability of a system to succeed under variable conditions (“Safety II”) (25). This field thus accepts that although adverse events are ultimately attributable to the inherent features of complex work systems, so too is the capacity for *resilience*.

A resilient system is defined as one that can adjust its functioning throughout the course of a disturbance, thereby sustaining the ability to operate as required under both expected and unexpected conditions (8). Resilient systems dynamically prevent, mitigate, or redirect failure to promote ease of recovery while diminishing the associated disruption and cost (8). According to pioneers in the resilience engineering field, resilience is a characteristic of how a system performs, and four distinct abilities make resilient performance possible: the ability to respond, to monitor, to learn, and to anticipate. These abilities subsequently rely on two crucial aspects of a work system: the presence of alternative courses of action, and the ability for actors within the system to assess situations and redirect resources towards meeting higher-priority goals (8). The presence or absence of these abilities within a system contributes to either resilience or to brittleness, the opposite of resilience, and these abilities are, in turn, either enhanced or diminished by factors throughout the system, including the design of complex equipment or information systems (26). Thus, in addition to incorporating systemic defenses against preventable error, work systems should be designed with a degree of flexibility to accommodate variations in worker performance, thereby supporting the ability of the worker to detect, evaluate, and respond to unanticipated events (8, 27).

Overall, a systems-based approach is ideal for studying the factors that promote or hinder safety in the complex, safety-critical system of the operating room. Importantly, it also has implications for the design of effective safety-enhancing interventions, as demonstrated in the hierarchy of effectiveness for risk-mitigation strategies (28). According to this hierarchy, person-based mitigation strategies, including education and information, rules and policies, and reminders, checklists, and double checks, have a significantly lower likelihood of success when compared to systems-based strategies such as simplification and standardization, automation and computerization, and forcing functions and constraints, as systems-based strategies do not rely on the fallible attention and vigilance of human beings. Thus, a systems-based approach can be useful for both identifying and addressing safety threats in surgical settings.

## 2.3 Studies of Surgical Systems using a Human Factors

### Approach

To clarify the extent to which systems-based human factors methodologies have been applied in surgical settings and to highlight pertinent findings regarding the potential role of human factors in the occurrence or recovery of intraoperative adverse events, a systematic search of the literature was conducted using PubMed. The search strategy utilized a combination of Medical Subject Headings (MeSH) and free-text terms to specifically capture human factors studies employing qualitative observational designs; the applied MeSH terms included “Surgery”, “Laparoscopy”, “Human Engineering”, “Task Performance and Analysis”, “Communication”, “Healthcare Team”, “Patient Safety”, “Medical Error, Qualitative Research”, “Observation”, and “Video Recording”, while free-text terms included “surgery”, “operating room”, “laparoscopy”, “human factors engineering”, “human factors”, “interdisciplinary”, “communication”, “patient safety”, “error”, “adverse event”, “hazard”, “qualitative”, “observation”, “video recording”, and “ethnography”. Articles with a predominant focus on competency assessment, simulation-based skills training, assessment tool validation, or technical error assessment without exploration of potential contributory factors were excluded from the search, as were non-English publications and studies lacking the necessary surgical context. Altogether, 39 articles met the outlined criteria and were subsequently reviewed.

#### 2.3.1 Surgical Systems Studied

The environments analyzed in the surgical studies reviewed spanned a variety of complex specialties. Cardiac surgery was the most predominantly observed setting (12, 24, 29-34), having been identified as particularly predisposed to error due to its involvement of multiple specialties, close coupling of complex concurrent tasks, dynamic uncertainty, and high workload (12). Other specialties included orthopaedics (35-37), neurosurgery (30, 38), surgical oncology (39), urology (40), general surgery (4, 11, 13, 27, 41-43), gynaecology (44), and anaesthesia (45). Of the surgical specialties studied, a number explored the role of human factors in surgical performance during the use of minimally-invasive surgical techniques (4, 13, 42, 43, 46, 47). However, research carried out in general laparoscopic surgery almost exclusively focused on laparoscopic cholecystectomy, the most commonly performed laparoscopic procedure worldwide (13), while



more complex procedures, such as laparoscopic Roux-en-Y gastric bypass (48), were notably absent.

### 2.3.2 Research Methodologies Applied

As the articles captured in this search demonstrate, a variety of methods have been successfully employed to identify the systemic conditions that predispose surgical systems to error. Interview, focus group, and questionnaire methodologies were utilized in a number of studies to elicit care provider perspectives on topics such as intraoperative stressors (49), safety problems in surgical settings (50, 51), intraoperative sources of distraction (52), and factors affecting situation awareness (53), among others. However, within the surgical studies reviewed, direct observation of clinicians at work in the surgical environment was the most predominant method used to uncover rich information surrounding the human factors that predispose the surgical system to error (11, 24, 29, 30, 32, 33, 40, 42, 47, 52, 54).

Direct observation, also known as ethnography, is frequently used as a starting point in human factors analyses to gain a better understanding of the environment of work, including the characteristics of the workers as well as the tasks they are required to complete. Observation is typically complemented by other qualitative methods, including interviews, such that multiple perspectives can be combined to gain a global understanding of the environment of interest (55). Using this technique, trained observers are placed within operating room environments to collect observational data. Observational notes are subsequently coded and categorized using qualitative methods such as inductive analysis, which seeks to condense the raw text notes into informative summaries, establish links between the research objective and the data obtained, and develop theories surrounding the underlying themes or constructs evident in the observations (56).

Prospective observational methods are particularly well-suited for studying contributory factors to adverse events in surgical settings. This approach is more reliable than retrospective reporting; while informative, retrospective analyses are inherently prone to hindsight bias and inaccurate recall, which limits their ability to inform the design of effective or appropriately targeted safety-enhancing interventions. By using multidisciplinary researchers to collect observational data, multiple valuable perspectives can converge to create a complete picture surrounding the etiology of an event (24, 27, 57). Furthermore, by evaluating qualitative observational data

through discussion and consensus, rather than by independently rating system performance using the Likert-type scales typical of existing global rating tools, a more nuanced understanding of events can be gained, which is essential to the development of meaningful safety-enhancing interventions.

Despite its potential for more accurately describing the nature of the operative environment, direct observations can be impractical for prospective research in the surgical domain due to the time demand of data collection and personnel constraints within the OR (58). In this regard, intraoperative video recording may provide a window into the OR through which intraoperative safety can be better studied.

Video-based analyses in the surgical domain have garnered increasing attention in recent years due to several associated benefits: prospectively recorded cases can be retrospectively reviewed, events of interest can be repeatedly assessed as needed until fully understood, and the complex interactions between the clinicians and their environment can be captured at a level of detail that exceeds the capability of a single human observer (39, 58). Several of the studies identified in the literature search employed video-based techniques for direct surgical observation, thereby acquiring detailed information around latent intraoperative safety threats (12), factors implicated in the etiology and recovery of adverse intraoperative events (27, 38), and team effectiveness (34, 59). Indeed, prospective observational studies that aim to improve safety and quality in the operating room stand to benefit from harnessing the potential of video recording technologies in the operating room.

### **2.3.3 Analyses of Intraoperative Safety Threats**

It has been acknowledged by human factors researchers in the surgical domain that simply describing the technical errors committed in surgery and reporting their frequency does not appropriately capture the complex, interdependent factors surrounding unanticipated intraoperative events (5); the explicit elucidation of these factors is necessary to design safer work systems moving forward. To this end, a number of researchers have applied systems-based approaches to uncover latent safety threats in operative environments.

Hu et al. applied a methodology for investigating the etiology of intraoperative events using audio-video recordings (27). In this study, a team of surgical researchers and psychologists reviewed transcripts of 10 complex surgical procedures. The team then reviewed the transcripts and videos together to identify all factors that contributed to the causality, mitigation, and/or recovery of previously identified intraoperative deviations or errors. Using this method, more than half of all deviations were found to be attributable to the surgical environment, and the most common problems were those related to organization, system-level communication, system-wide coordination, and surgical equipment (27).

Similarly, Gurses et al. used the SEIPS model of work system and patient safety as a framework for identifying and categorizing safety hazards in the cardiac operating room (24). Their observations were carried out across five distinct surgical sites and incorporated the expertise of both human factors specialists and clinical researchers. Guided by the systems-based view of surgery, considerable attention was given to factors affecting intraoperative safety beyond the clinicians, particularly technology; the researchers noted that technology-related hazards were pervasive in cardiac surgery, with usability issues arising for almost all tools employed, and 3 unique subcategories of safety hazards within the context of technology were defined based on the observations made.

A number of observational studies have investigated human-centred factors affecting safety in surgery. Wiegmann et al. used direct observation to study and characterize disruptions in surgical flow within the cardiac operating room, and found that flow disruptions primarily consisted of teamwork and communication failures, which were also the strongest predictor of surgical errors (54). Lingard et al. completed an observational study to further deconstruct communication failures in the OR, and ultimately observed communication failures defined by poor timing, inaccurate or incomplete information, failure to include key team members, or failure to resolve issues in 31% of OR communications. (60).

Beyond the characteristics and behaviours of the individuals at the centre of the system, a number of systems-based factors influencing surgical safety have been explored, such as the high level of environmental interference in the operating room (37) and the significant negative impact of poor OR layout and design on surgical workflow (31). The unique task demands of

laparoscopic surgery, such as those arising from the need to oversee frequent instrument exchanges, trocar and line management, and the management of various necessary support equipment including has insufflators, were explored by Sutton et al., as was the potential for associated task-related disruptions to predispose the surgeon to error, a human operator with a finite capacity for task management (4). Finally, with respect to surgical tools and technology, poor design leading to increased risk of patient injury (13), intrusive equipment malfunction (52), and issues of usability pertaining to cardiopulmonary bypass machines (33) and other surgical equipment (46) have been observed.

Altogether, these studies demonstrate that a wide range of systems-based intraoperative factors have the potential to threaten surgical performance and patient safety, and that an urgent need for effective system-level interventions in surgical settings exists.

#### 2.3.4 Analyses of Intraoperative Resilience

Compared to evaluations of factors contributing to adverse intraoperative events, resilience in surgical work systems has been studied considerably less. Although the terms “resilience” and “resilience engineering” were scarcely integrated into the surgical studies reviewed, several concepts with relevance to system resilience were explored, including effective teamwork, communication, and situational awareness.

In their study of error etiology and recovery in surgery, Hu et al. indicated that nearly all of the intraoperative care deviations they observed were ultimately corrected by clinicians (27). Their findings suggest that resilient performance may be predominantly attributed to the behaviour of the human care provider, and that promoting this adaptability through appropriate training is as important a safety initiative as preventing and mitigating care deviations through system redesign. Moffatt-Bruce and Ellison further reflected upon these findings by promoting the methodology employed by Hu et al. as a viable tool for identifying team factors that allow for the recovery of unanticipated events in the operating room (7).

The dominant role of the human providers observed in the recovery of unexpected intraoperative deviations led the authors to posit that this result negates the construction of excessively standardized systems with safeguards against inconsistent human performance, as over-

constraining human behaviour in complex sociotechnical systems can unintentionally erode system safety by limiting the capacity of human agents for adaptation. Instead, the authors argued that surgical safety advocates must focus on designing work systems that mitigate the risk of deviations, where possible, as well as on *training* providers to anticipate and address those that are cannot be avoided.

The notion that the variable and dynamic nature of presentations and circumstances in the practice of medicine render certain deviations unavoidable is compelling as it underscores the singularity of sociotechnical systems in healthcare and the extreme criticality of fostering *resilience* therein. However, the notion that resilient performance is hindered by high leverage systems-based risk mitigation strategies may perpetuate a potential false dichotomy placing the concept of resilience at odds with the principles of human factors engineering design. Interventions intended to enhance healthcare safety that are implemented without scientific basis undoubtedly have the potential to have negative, unintended consequences (61), but it may be argued that well-designed solutions have the potential to contribute to resilience as well. Furthermore, to suggest that adequate provider training is the key to ensuring the successful anticipation and management of unavoidable intraoperative deviations is to discount the multifaceted nature of resilience and the potential role of other systems-based factors in *supporting* resilient performance.

Other researchers have also given attention to surgical processes and factors implicated in the successful identification and recovery of adverse intraoperative events. In their prospective video-based observational study evaluating the ways in which surgical incidents are detected and subsequently corrected, Couat et al. identified knowledge, technical skill, and team effectiveness emerging from behavioural and communication competencies as critical factors for success (38). Conversely, Brady et al. used focus groups to discern that intraoperative situation awareness, as well as the identification and treatment of patient risk, is supported by team-based care and standardisation (53). Yet, of the studies that touched on resilience, a video-based observational study on event compensation mechanisms in pediatric cardiac surgery was one of the only studies to approach resilient performance from a moderately systems-based perspective (29). In this study, compensation processes were observed to arise from either human cognition, luck, established OR policies and procedures, surgical technical skill, or monitoring technology.

During major adverse events, cognitive and surgical–technical compensation, rather than prevention or policy measures, were predominantly observed, and compensation mechanisms were found to be largely reactive rather than preventive. However, the *latent* resilience-enhancing factors present within the surgical system that support these reactive compensation mechanisms remain to be explored.

## 3 Objectives

### 3.1 Knowledge Gap

Overall, research that adds to the growing body of knowledge regarding threats to quality and safety in surgery is valuable for process improvement in healthcare moving forward. At present, studies that prospectively investigate the specific human factors and contributors to adverse events in complex laparoscopic surgery are limited, as are studies of resilience in this field.

Currently, our research group is conducting an ongoing study involving the capture and analysis of audio-visual recordings in an operating room dedicated to general laparoscopic surgery. Using these recordings, our group has predominantly focused on characterizing intraoperative events in terms of *technical* errors (62) and on correlating aspects of technical performance with validated measures of non-technical performance and distraction, with the ultimate goal of informing evidence-based improvements to surgical education. However, the availability of surgical video data presents a unique opportunity to also understand intraoperative system safety from a human factors perspective in a way that is both more accurate and informative than retrospective reporting or field observations alone.

In their video-based observation study, Hu et al. presented a particularly in-depth analysis of clinician characteristics that may contribute to intraoperative errors, but their evaluation of contributory factors associated with the work environment, technology, and organization was limited by insufficient granularity. In this regard, their study may have yielded more usable insights to guide the design of real, practical interventions if a more *specialized and comprehensive* human factors framework had guided their observation of the environmental, technological, and organizational factors present. Specifically, a hazard classification system similar to that put forth by Gurses et al., if combined with the root cause analysis methodology used by Hu et al., may ultimately produce more detailed qualitative data surrounding intraoperative events, while also organizing the results such that they are easier to analyze, disseminate, and act upon.

Hu et al. also broached the concept of system resilience in their analysis of the recovery mechanisms activated in surgical care deviations and ultimately attributed all observed

compensatory factors involved in deviation recovery to the care providers themselves. However, the extent to which system-based factors *support* clinicians in activating these compensatory factors remains to be explored. Given that identifying and appropriately valuing the behaviours and resources that contribute to a system's ability to respond to unexpected events is a foundational concept in resilience engineering, analyzing healthcare systems through the lens of resilience in greater detail may be useful; identifying supports for resilience in addition to latent safety threats in a clinical environment may provide a more comprehensive picture of how vulnerable a clinical work system is to failure, while also illuminating resilience-enhancing elements that should be standardized across similar work systems.

Thus, the present work seeks to address the aforementioned knowledge gaps by characterizing work system factors that have the potential to contribute to either the origination or recovery of adverse events during general laparoscopic surgery. Through the exploratory analysis of surgical video data, this thesis looked beyond teamwork and training alone to acquire a heightened understanding of the human, environmental, technological, organizational, and task-related elements of the surgical work system that may influence surgical safety and are amenable to mitigation (safety threats) or implementation (resilience supports) via user-centred interventions and design.

## 3.2 Thesis Objectives

The objectives of this thesis are:

- (i) To identify and categorize human factors in general laparoscopic surgery that have the potential to either threaten patient safety or support system resilience
- (ii) To compile the identified intraoperative human factors into a categorization scheme that can inform the development of an intraoperative human factors observation tool for surgical process improvement
- (iii) To demonstrate the utility of a human factors approach in understanding the mechanisms through which adverse patient safety events occur and provide actionable quality improvement recommendations for the surgical system observed



## 4 Methodology

### 4.1 Study Design

The present work describes an exploratory observational study involving the retrospective review of *prospectively collected* intraoperative video recordings.

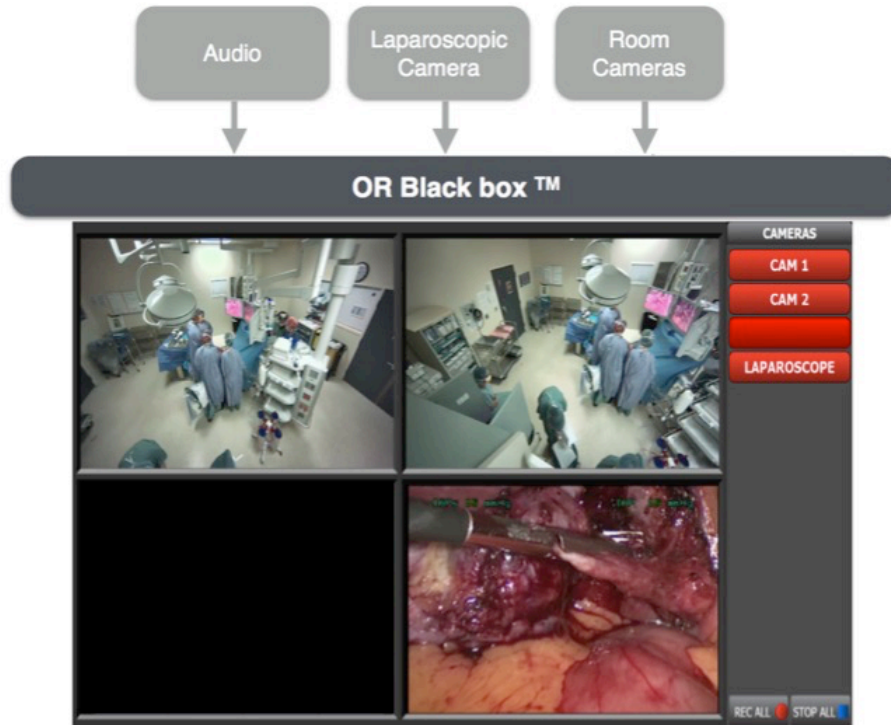
### 4.2 REB Approval

Ethics approval was granted for this study by the St. Michael's Hospital Research Ethics Board (REB) as an addendum to an overarching parent study titled "Development of strategies to identify, analyze and prevent errors in the operating room - an inter-professional approach to enhancing technical and non-technical performance and improving patient safety: A pilot study" (St. Michael's REB #12-069). The REB approval letter for this study is included in Appendix A.

### 4.3 Sample

The videos analyzed in this study were sampled from a series of intraoperative recordings that had been prospectively collected using a surgical "black-box" multi-channel data recorder. This device works to record and synchronize multiple feeds captured by cameras and microphones installed throughout the operating room to generate a holistic and detailed picture of the intraoperative environment throughout the surgical case.

Observational data collected with this device and analyzed in this study originated exclusively from a single operating room dedicated to general laparoscopic surgery at St. Michael's Hospital, a University of Toronto affiliated tertiary-care teaching hospital. Video analysis software (Studiocode V.5, Sportstec, Warriewood, Australia) was subsequently used to view the synchronized recordings side-by-side on a single computer interface, as well as to pause, rewind, and alter playback speed during the observation phase. Specifically, the recorded intraoperative video feeds included external views of the operating room from two separate perspectives as well as the internal laparoscopic camera view (Figure 1). The portion of the procedure captured in these recordings was limited to the period of time immediately following draping of the patient until the point of completion of surgical site closure.



**Figure 1.** Simplified representation of the synchronized intraoperative video display.

The surgical case recordings analyzed for this study constituted a subset of videos sampled from a pool of recordings collected for the ongoing parent study under St. Michael’s REB #12-069. As per the REB approval, black-box recordings collected for this parent study are retained on a secure server for a maximum of 30 days from the time of capture, after which all external video data is permanently deleted. Thus, rolling 30-day blocks of black-box recordings were available for analysis throughout the course of this thesis project.

The present work sampled videos from the available pool of black-box recordings over a 9-month period. Of the available case recordings, complex procedures involving multiple different surgical tasks were prioritized. For this reason, laparoscopic cholecystectomies were excluded from observation and analysis, and case codes for the remaining available videos were randomized using a list-randomizer and reviewed sequentially until the 30-day window of availability expired.

As this was a descriptive, predominantly qualitative study, the sample size was not tightly defined initially. Rather, review of the surgical case recordings occurred on an ongoing basis and was terminated once qualitative data saturation was achieved.

## 4.4 Recruitment and Informed Consent

Written informed consent to participate in this study was obtained from eligible patients preoperatively by a surgical research assistant. Written informed consent was also obtained from all surgeons, residents, students, observers, anaesthesiologists, and nurses present in the operating room immediately prior to the start of the surgical case. Black-box recordings were not collected for any case wherein written informed consent could not be obtained from every individual present. The patient and caregiver consent forms are provided in Appendices B and C, respectively.

## 4.5 Data Collection

The data collected and analyzed within this study consisted of detailed qualitative text-based observations gleaned from the selected black-box recordings by a single observer, a graduate student with a background in clinical engineering.

### 4.5.1 Preliminary Observation

To facilitate observer familiarization with the intraoperative environment as well as to enhance the observer's surgical technical knowledge, preliminary observations were carried out prior to the formal data collection phase. In this preliminary observation phase, the clinical engineering researcher directly observed 2 surgical cases within the operating room and subsequently reviewed black-box recordings of an additional 2 surgical cases.

### 4.5.2 Formal Data Collection

A single observer reviewed eligible, randomly-selected surgical videos collected under the umbrella of the parent research study. During the review of each surgical video, detailed observations were typed into textual transcripts within a spreadsheet with one distinct text-based observation per cell. Other researchers with surgical expertise who were involved in the parent

research study were occasionally called upon to clarify any ambiguous observations or to verify the accuracy of observations that were beyond the scope of the observer's clinical engineering training.

Observation of the safety threats and resilience supports within the intraoperative work system was guided by the specified research objectives through the lens of the SEIPS 2.0 work system framework. Safety threats were considered to be any element of the system that may reasonably provide the circumstances in which human errors can occur (12), while resilience supports were considered to be any work system factors with the potential to support the ability to anticipate, monitor, learn, and respond (8). Thus, specific observations collected during the video review phase included, but were not limited to, clinician actions, dialogue, body language, interpersonal interactions, characteristics of the clinical tasks, elements of the physical environment, details of the procedure progression, and features of the surgical equipment. Qualitative observations were recorded with absolute honesty and objectivity; interpretation was reserved for the coding and analysis phase.

## 4.6 Data Analysis

### 4.6.1 Qualitative Coding of Observation Data

Descriptive coding of the qualitative text-based observation data occurred simultaneously with the surgical video review phase. For each observed surgical case, coding of the data was initiated immediately after the case had been observed and transcribed in its entirety, and each observation was treated as a distinct data point. For the purpose of achieving a nuanced and highly detailed analysis of the surgical observation data, lengthy observations detailing complex events or circumstances were split into smaller text-based data points that were singular in focus and to which a meaningful qualitative code could still be applied.

Coding was performed manually using simple spreadsheet software rather than through the use of qualitative coding software as per the recommendation provided by The Coding Manual for Qualitative Researchers (63). A manual coding approach was highlighted as being particularly advantageous for researchers with limited prior experience with thematic analysis, as working

with the data in this way promotes a deeper cognitive understanding of the observation data for more effective coding.

During the coding phase, both inductive and deductive coding was applied. Inductive coding was used to assign a descriptive code to capture the essence of the observation itself. Deductive coding was used to denote the observation as either a safety threat or a resilience support, as well as to define the component of the SEIPS work system best associated with the observation. The spreadsheet setup utilized for both the observation and coding phases is given in Table 1.

**Table 1.** Sample spreadsheet setup used for both surgical observation and coding.

Case Code	Time Stamp	Observation	Code	Factor Type	SEIPS Category
1234	00:10:00	Loud door slam	Distracting workflow sounds	Safety Threat	Internal Environment
1234	00:20:00	S1 is using the LigaSure device: S1: "I like the ergonomics of the device" O1: "Yeah it's got a nice flow to it"	Ergonomic tool	Resilience Support	Tools and Technology

A working library of codes applied to the observational data was generated with corresponding definitions and edited on an ongoing basis throughout the observation and coding phase. Failure to generate new codes for an observation transcript was considered to constitute data saturation and thus substantiated the termination of the observation phase.

#### 4.6.2 Development of Intraoperative Human Factors Classification Scheme

The de novo code library developed to describe safety threats and resilience supports in the intraoperative system were inductively thematically grouped into subcategories within the major SEIPS category in an iterative fashion, resulting in the development of a multi-level intraoperative human factors classification scheme. The granularity of the codes themselves was also iteratively refined, and a high degree of detail was preserved where it was deemed potentially useful for investigating the etiology and recovery of an adverse intraoperative event. For example, the codes "not listening" and "not watching" were reconciled into the single code "active attention error", as both observations described a lapse in attentiveness on behalf of the clinician that would require similar corrective interventions; thus, the distinction between

“listening” and “watching” in this case would add little value to a root cause investigation and subsequent remediation of the intraoperative threat. However, three codes for distracting intraoperative sounds, attributed to the OR personnel, electronics, and workflow processes, respectively, were developed and maintained, as mitigating the threat to patient safety presented by each factor would require a unique remediation strategy.

#### ***4.6.2.1 Inter-Coder Agreement***

A second researcher with surgical expertise (a board-certified surgeon and surgical research fellow) was recruited to independently double-code a randomized subset of the surgical observation transcripts using the preliminary coding and categorization scheme for the purpose of affirming the validity of the observations made by the clinical engineering researcher, evaluating the reliability of the classification scheme developed, and exploring interdisciplinary perspectives on the identified intraoperative factors in relation to their potential impact on patient safety. The second researcher was blinded to the codes assigned to the textual data contained in these transcripts by the first researcher (the author of the present work).

To my knowledge, no clear guidelines exist regarding the extent to which qualitative data should be double-coded during thematic analysis. Experts on the matter suggest that although double-coding a higher proportion of data is advantageous, the practical execution of thematic analysis requires the balancing of rigour with time and budget constraints (64). Based on this rationale, transcripts of the surgical observation data were double-code until a satisfactory level of inter-coder agreement was reached. Inter-coder agreement was calculated using the kappa statistic at each level of categorization using statistical computation software (SPSS Statistics Version 21, IBM) and the strength of agreement was interpreted using the guidelines provided by Landis and Koch (65). The two coders convened for consensus discussion following their independent analysis of each transcript, and results of the consensus discussion were used to refine the classification scheme.

#### ***4.6.2.2 Expert Roundtable***

The developed intraoperative human factors classification scheme for both safety threats and resilience supports was presented to a panel of surgical experts at the subcategory level in a

visual presentation. Feedback elicited during the expert roundtable discussion was documented and ultimately used to further refine the classification scheme.

#### 4.6.3 Quantitative and Qualitative Data Interpretation

Summary statistics were generated for the number of observations per case, the number of safety threats identified per case, the number of resilience supports identified per case, and the length of operative time observed. Graphical representations were used to depict the total number of observations per case as well as the number of unique observations per case. The number of observations arising from each SEIPS category was graphically depicted as a proportion of the total number of observations for both safety threats and resilience supports. Finally, intraoperative observations coded with the finalized intraoperative human factors classification scheme were contextually evaluated and qualitatively described.

Additional exploratory analyses were performed on the observation data pertaining to two surgical cases wherein adverse intraoperative events were observed. Quantitatively, the proportion of safety threats and resilience supports observed before the event were compared to the proportion observed after. Qualitatively, potential factors implicated in the occurrence and recovery of the intraoperative events were detailed by work system category.

## 5 Results

### 5.1 Development of the Intraoperative Human Factors Classification Scheme

#### 5.1.1 Summary of Reviewed Cases

Surgical video recordings were reviewed, transcribed, and coded simultaneously until qualitative saturation was reached. Nineteen successful, complex surgical cases comprising predominantly laparoscopic bariatric procedures were ultimately observed, two of which were found to contain adverse intraoperative events. Relevant details from each observed case are provided in Table 2, and summary statistics for the entire sample are provided in Table 3.

**Table 2.** Procedure details and raw data for all observed cases including case duration, number of observations, and instances of adverse intraoperative events.

Procedure Description	Duration (minutes)	Safety Threats	Resilience Supports	Total Observations	Major Event?
Laparoscopic Sleeve Gastrectomy	120	47	40	87	No
Laparoscopic RYGB	117	11	13	24	No
Laparoscopic Sleeve Gastrectomy	136	46	58	104	<b>Yes</b>
Laparoscopic RYGB	118	17	12	29	No
Laparoscopic RYGB	123	18	14	32	No
Laparoscopic Sleeve Gastrectomy	115	14	11	25	No
Laparoscopic RYGB	110	19	34	53	No
Laparoscopic Gastrectomy	116	23	21	44	No
Laparoscopic RYGB	146	11	20	31	No
Laparoscopic RYGB	198	14	25	39	No
Laparoscopic RYGB	86	10	13	23	No
Laparoscopic RYGB	114	9	9	18	No
Laparoscopic RYGB	130	19	34	53	No
Laparoscopic RYGB	125	18	13	31	No
Laparoscopic RYGB	135	72	53	125	No
Laparoscopic RYGB	107	45	49	94	No
Laparoscopic RYGB	133	57	57	114	<b>Yes</b>
Laparoscopic RYBG	161	27	71	98	No
Laparoscopic RYBG	99	22	37	59	No



**Table 3.** Summary statistics for the total sample of observation data.

	<b>Duration (minutes)</b>	<b>Safety Threats</b>	<b>Resilience Supports</b>	<b>Total Observations</b>
<b>Total</b>	2389	499	584	1083
<b>Average</b>	126	26	31	57
<b>SD</b>	24	18	19	35
<b>Min.</b>	86	9	9	18
<b>Max.</b>	198	72	71	125

A total of 39.8 hours of operative time were observed. The surgical cases reviewed involved 19 different patients as well as the participation of a staff surgeon (one of two), one surgical fellow, and a series of surgical residents, circulating nurses, scrub nurses, and anaesthesiologists. Surgeons and nurses were observed directly on the surgical recordings, while anaesthesia personnel were not captured in the camera view.

### 5.1.2 Inter-Coder Agreement and Consensus Discussion

Two interdisciplinary researchers independently coded a total of four randomly selected textual datasets. Inter-coder agreement was initially calculated following the independent coding of the first two datasets using a preliminary version of the classification scheme. The classification scheme was refined based on the results of the first two consensus discussions, and the revised version was subsequently utilized to code the remaining two transcripts.

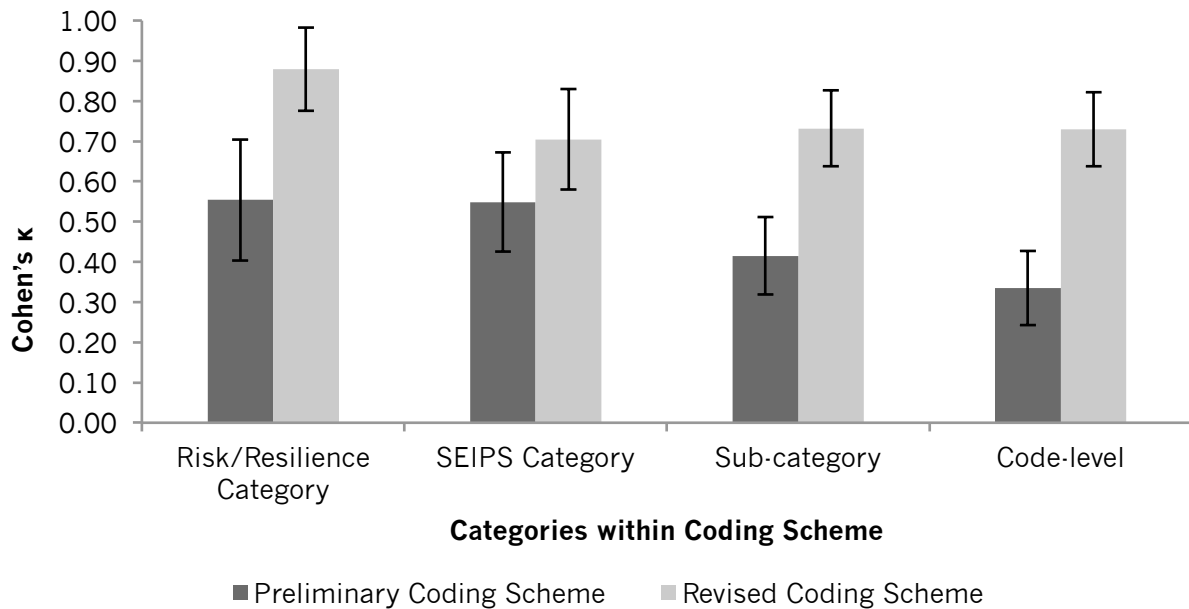
Consensus discussion was required for a total of 23 inter-coder discrepancies: 5 instances pertaining to the classification of an observation as a safety threat or resilience support, 9 at the SEIPS category level, 7 at the subcategory level, and 2 at the code level. The majority of the observed discrepancies were associated with differences in the interpretation of the situation captured in the textual data and easily clarified.

Altogether, a total of 21 codes were deleted during the revision of the classification scheme. The initial scheme comprised 169 factors impacting intraoperative safety, with 98 safety threat codes and 71 resilience support codes, while the revised version comprised 148 intraoperative factors, including 80 safety threat codes and 68 resilience support codes.

Inter-coder agreement achieved with the revised version of the classification scheme is provided at each level of categorization in Table 4, and the difference in inter-coder agreement achieved with the initial and revised versions of the classification scheme are depicted in Figure 2.

**Table 4.** Final inter-coder agreement at each level of the coding and categorization scheme.

	# Data Points	Cohen's $\kappa$	95% CI	p Value	Strength of Agreement
<b>Risk/Resilience Category</b>	91	0.879	0.775 to 0.983	<0.0005	Almost Perfect
<b>SEIPS Category</b>	91	0.705	0.580 to 0.830	<0.0005	Substantial
<b>Subcategory</b>	91	0.732	0.638 to 0.836	<0.0005	Substantial
<b>Code-level</b>	91	0.730	0.638 to 0.822	<0.0005	Substantial



**Figure 2.** Comparison of inter-coder agreement at each level of categorization for the preliminary and revised versions of the coding scheme.

### 5.1.3 Expert Roundtable and Face Validity

A total of two roundtable sessions were conducted to solicit expert feedback regarding the proposed intraoperative human factors classification scheme at the subcategory level. Each

session was one hour in duration and involved a group of surgical subject matter experts comprising practicing surgeons and surgical researchers. Specifically, those in attendance for both sessions included one staff surgeon and the primary investigator of the present work, two surgical residents pursuing graduate degrees (one Master's level, one PhD), a surgical research fellow and board certified surgeon, and three surgical research assistants with extensive experience reviewing surgical video recordings acquired from the operating room observed in the present study, including two internationally-trained physicians and one medical school graduate. The later three attendees were uniquely qualified to contribute to the roundtable as their expertise centred on the identification of surgical errors as well as the evaluation of technical skill, nontechnical performance, and sources intraoperative distraction using intraoperative video.

The expert roundtable session served to verify the face validity of the proposed classification scheme. With respect to the presented subcategories of safety threats, the experts in attendance agreed that the subcategories accurately reflected the types of safety threats they encounter (practicing surgeons) or observe (surgical researchers) within the operating room studied. Similarly, although the concept of resilience was relatively unfamiliar, the surgeons acknowledged the importance of the presented types of resilience supports with respect to their ability to respond to unanticipated surgical deviations.

The expert roundtable discussion elicited constructive feedback regarding both conceptual and practical aspects of the classification scheme. Specific suggestions were made regarding adjusting the proposed categories for the purpose of more appropriately differentiating between different underlying constructs, such as the separation of workplace design and setup into two distinct subcategories. Other suggestions centred on refining the terminology used within the categorizations scheme to increase its potential generalizability and ease of interpretation by clinician users. Finally, additional comments appraised the structure and utility of the proposed classification scheme. The size of the classification scheme was identified as a potential barrier with respect to usability and applicability to surgical observation and quality improvement initiatives on a broader scale. However, the experts agreed that the granularity of the classification scheme would provide potentially valuable detail for understanding the root causes of surgical deviations. Further, the researchers responsible for evaluating surgical performance

via surgical video review indicated that the classification scheme, particularly the categories detailing tool and technology factors, would enable them to account for system-level factors that other currently available global rating tools do not adequately capture.

## 5.2 Finalized Intraoperative Human Factors Classification Scheme

The finalized coding and categorization scheme for safety threats and resilience supports within the general laparoscopic surgical environment was developed through inductive categorization of the qualitative observation data and refined via consensus discussion during the inter-coder agreement and expert roundtable phases. The classification scheme developed for intraoperative safety threats and its constituent subcategories are provided in Table 5 accompanied by subcategory descriptions, and the equivalent classification scheme for intraoperative resilience supports is provided in Table 6. The complete classification scheme, including codes and associated definitions, is provided in Appendix D.

**Table 5.** Description of safety threat subcategories included in the classification scheme.

<b>Person</b>	<i>Unsafe Acts</i>	Actions committed by surgical clinicians that have the potential to result in preventable patient harm
	<i>Suboptimal Clinician Condition</i>	Clinician attributes or physical/physiological states that inhibit optimal clinical performance
	<i>Inadequate Experience/Knowledge/Skill</i>	Specific deficiencies in knowledge, training, experience, or skill impeding clinical task execution
	<i>Leadership Failures</i>	Characteristics of ineffective team leadership
	<i>Team Effectiveness Issues</i>	Factors that inhibit the capacity of the team as a whole to execute required tasks effectively
	<i>Communication Failures</i>	Aspects of ineffective team communication
<b>Tasks</b>	<i>Suboptimal Task Demands/Workload</i>	Features of the clinical tasks that impart a negative effect on clinician/team performance
	<i>Preventable Secondary Tasks</i>	Tasks relevant to the present surgical case that inappropriately divert clinician attention away from a higher-priority/essential task
	<i>Patient-Related Challenges</i>	Disadvantageous task features arising from the physical characteristics of the patient
	<i>Disruptions</i>	Disruptions/diversions that are unrelated to the present surgical case

**Table 5 (continued).** Description of safety threat subcategories included in the classification scheme.

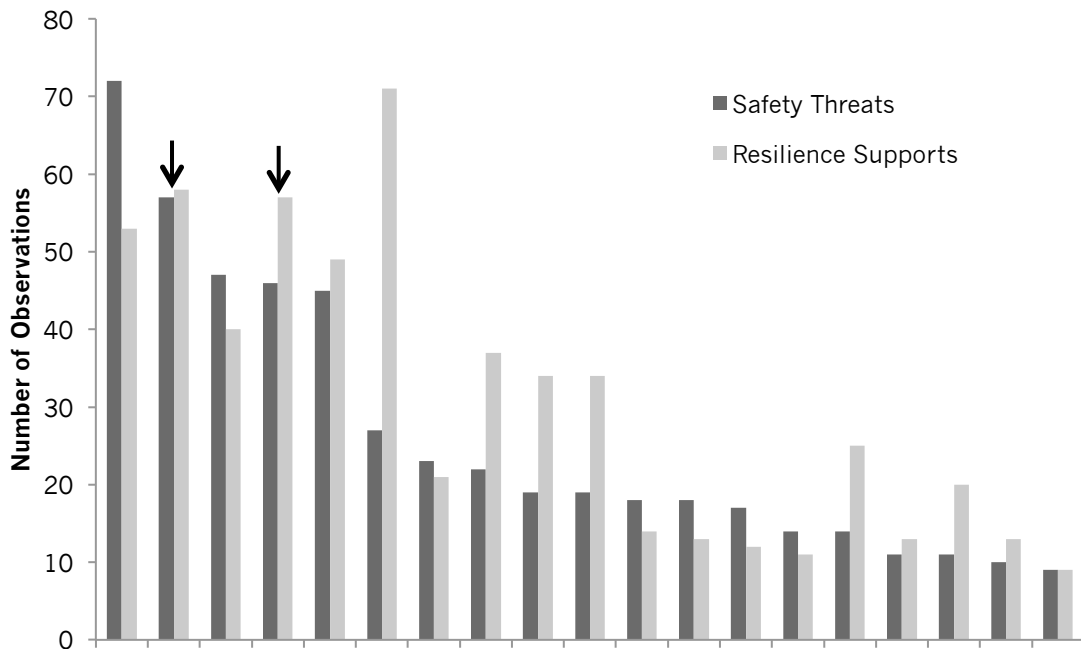
<b>Tools and Technology</b>	<i>Lack of Familiarity</i>	Lack of familiarity with surgical tools and technology or their configuration
	<i>Substandard Functionality/Utility</i>	Failures or deficiencies in the functionality of key surgical equipment or instrumentation
	<i>Safety/Reliability Issues</i>	Characteristics of unsafe or unreliable surgical equipment/instrumentation
	<i>Usability Issues</i>	Features of surgical equipment/instrumentation that threaten ease of use/correct use/user satisfaction
	<i>Inadequate Availability</i>	Factors associated with the condition/location of surgical equipment/instrumentation that inhibit user access when needed
<b>Organization</b>	<i>OR Resource Mismanagement</i>	Failures in the procurement or allocation of critical surgical resources
	<i>Safety Culture Deficiencies</i>	Deficiencies in the intraoperative manifestation of the organizational attitude towards surgical safety
	<i>Perioperative Process Failures</i>	Failures in the management/oversight of preoperative and intraoperative processes
	<i>Suboptimal Policies/Procedures</i>	Intraoperative factors indicating organization failure to enforce or implement policies or procedures that support surgical safety
	<i>Ineffective Staff Management</i>	Characteristics of ineffective organizational scheduling of surgical personnel
	<i>Inadequate Provision of Training</i>	Failure at the organization level to provide surgical personnel with appropriate training
<b>Internal Environment</b>	<i>Suboptimal Workspace Design</i>	Factors associated with ineffective large scale design of the physical intraoperative environment
	<i>Suboptimal Workspace Setup</i>	Factors associated with ineffective positioning of people and equipment within the operating room
	<i>Suboptimal Ambient Conditions</i>	Sensory stimuli present in the intraoperative environment that are not conducive to clinical tasks
<b>External Environment</b>	<i>Latent External Threats</i>	Macro-level economic or policy factors outside the present organization that diminish surgical safety

**Table 6.** Description of resilience support subcategories included in the classification scheme

<b>Person</b>	<i>Effective Guidance/Instruction</i>	Factors pertaining to the presence and effectiveness of clinical teaching and guidance
	<i>Advantageous Clinician Condition</i>	Clinician attributes or physical/physiological states that promote effective clinical performance
	<i>Anticipatory Action</i>	Behaviours associated with anticipatory planning
	<i>Effective Teamwork</i>	Factors that enable or characterize effective teamwork
	<i>High-Performance Behaviour</i>	Novel behaviours that support the execution of high quality work
	<i>Effective Communication</i>	Defining features of effective intraoperative communication
	<i>Strong Leadership</i>	Characteristics of strong intraoperative leadership
<b>Tasks</b>	<i>Optimal Task Demands/Workload</i>	Aspects of intraoperative tasks that impart positive effects on clinician/team performance
<b>Tools and Technology</b>	<i>Adequate Availability</i>	Factors that support adequate accessibility or availability of necessary tools
	<i>Optimized Usability</i>	Tool features/characteristics contributing to ease of use, correct use, or user satisfaction
	<i>Effective Functionality</i>	Factors that characterize or support effective and reliable tool functionality
<b>Organization</b>	<i>Effective Training Program</i>	Organizational factors that characterize or support trainee learning
	<i>Strong Safety Culture</i>	Intraoperative factors indicating organizational prioritization of surgical safety
	<i>Effective Policies/Procedures</i>	Standardized policies/procedures that contribute to the ability to anticipate/learn/monitor/respond
	<i>Effective Resource Management</i>	Factors associated with effective organizational management or procurement of surgical resources
	<i>Effective Scheduling/Staffing</i>	Characteristics of effective organizational scheduling of surgical personnel
<b>Internal Environment</b>	<i>Optimal Workspace Design</i>	Factors associated with effective large scale design of the physical intraoperative environment
	<i>Optimal Workspace Setup</i>	Factors associated with effective positioning of people and equipment within the operating room
	<i>Optimal Ambient Conditions</i>	Sensory stimuli present in the intraoperative environment that are conducive to clinical tasks

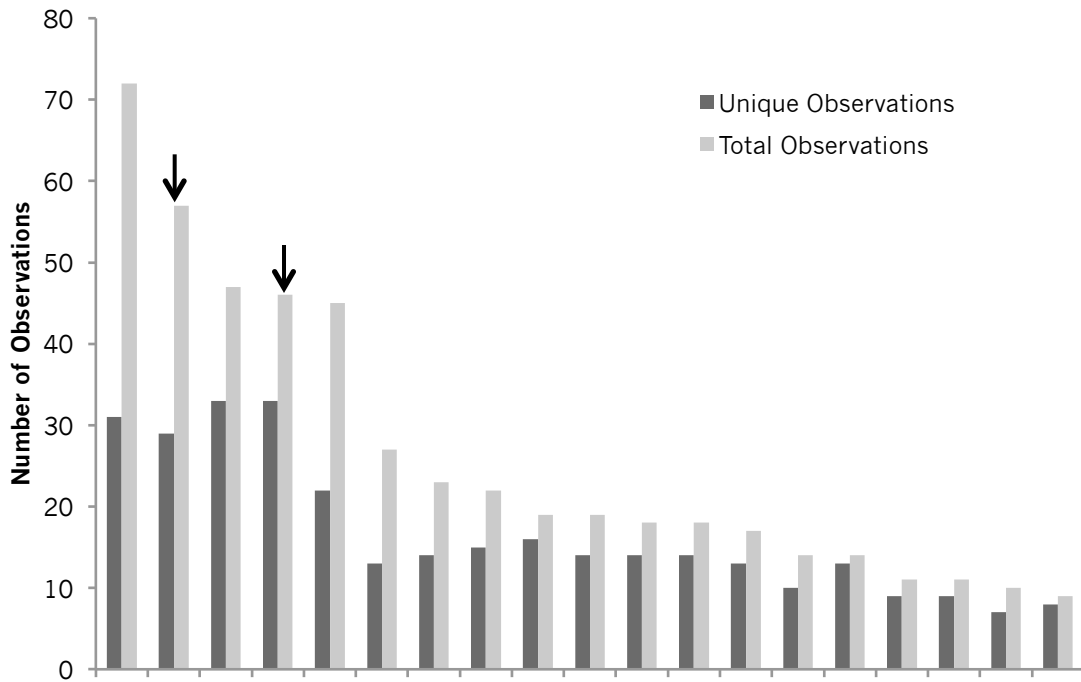
### 5.3 Quantitative Analysis of Intraoperative Observations

Safety threats and resilience supports were observed in all 19 of the surgical recordings reviewed. To discern whether safety threats and resilience supports were observed in proportional numbers for each case reviewed, the total number of factors of each type were plotted together for each case in Figure 3. In this and all subsequent figures, arrows denote the surgical cases wherein adverse intraoperative events were observed.

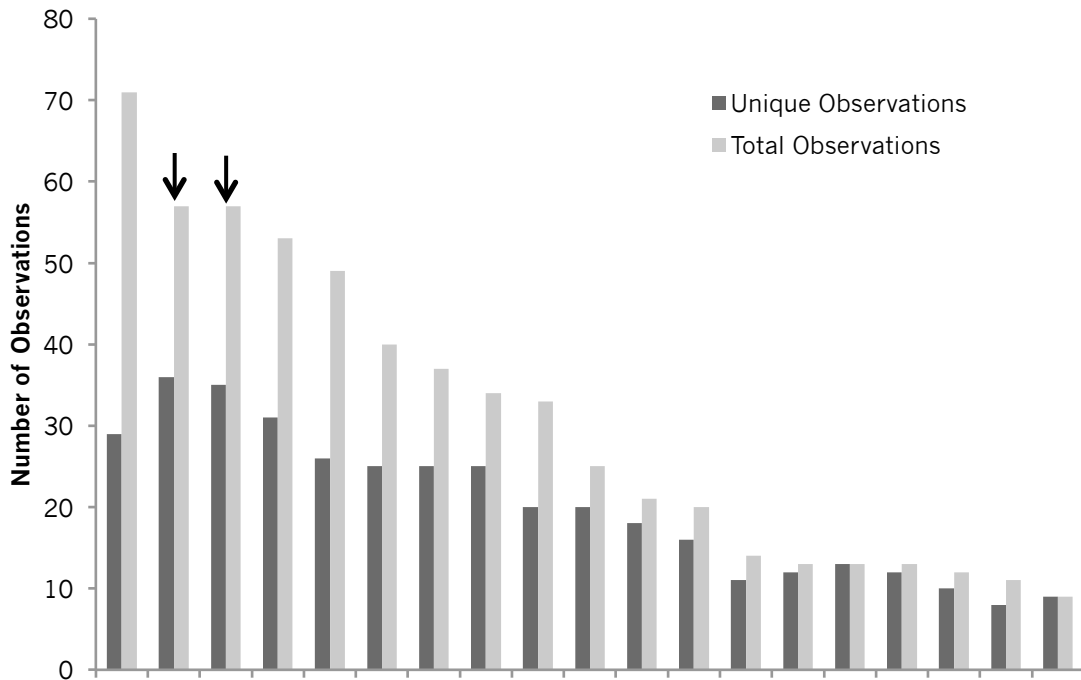


**Figure 3.** Number of safety threats and resilience supports observed for all cases, ordered from highest number of safety threats to least.

The relative contribution of unique intraoperative factors to the total number observed was explored in Figure 4 and Figure 5. Finally, Figure 6 and Figure 7 depict the distribution of the observed safety threats and resilience supports, respectively, across the SEIPS work system categories. Intraoperative safety threats were found to span all 6 categories of the SEIPS 2.0 framework, while intraoperative resilience supports were observed in all categories except for the External Environment.

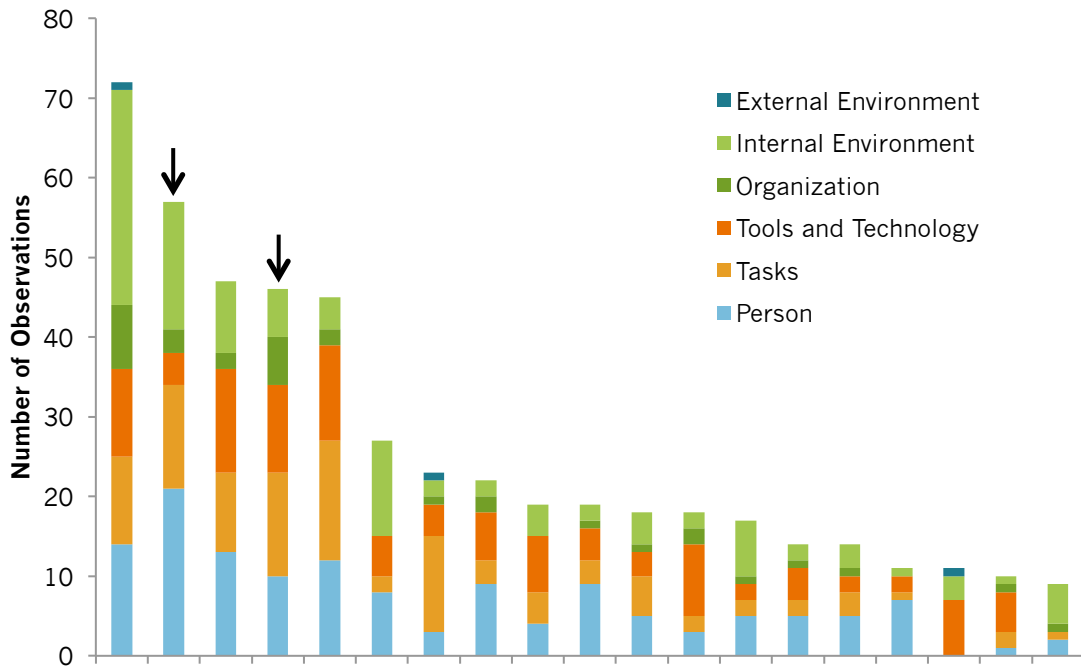


**Figure 4.** Comparison of the number of unique safety threats to the total number of safety threats observed per case, ordered from highest number of observations to least.

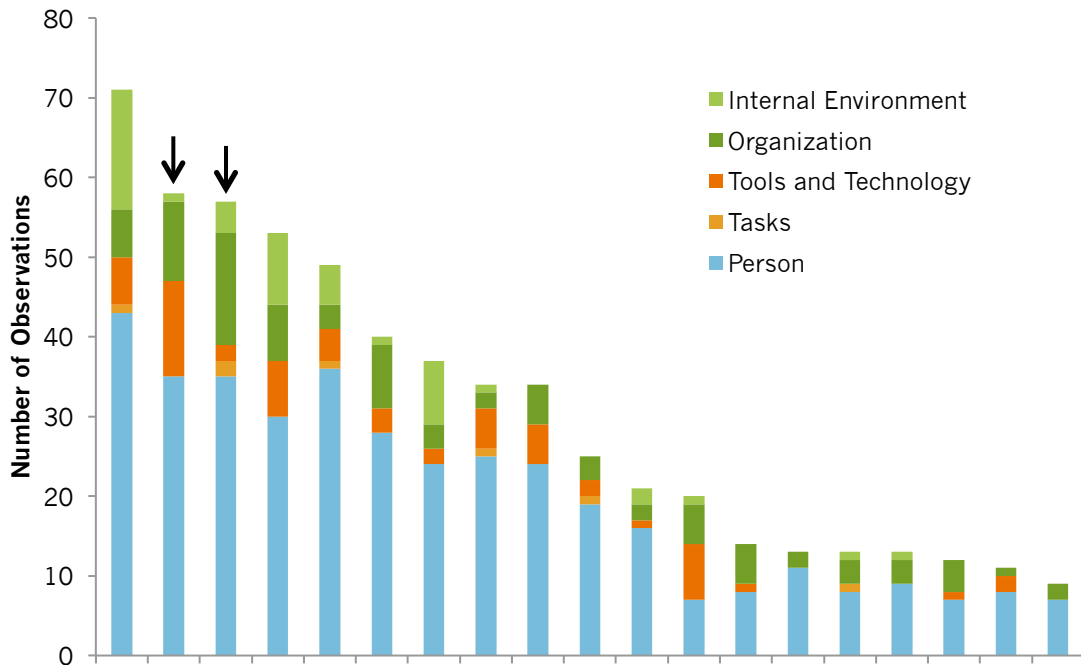


**Figure 5.** Comparison of the number of unique resilience supports to the total number of resilience supports observed per case, ordered from highest number of observations to least.





**Figure 6.** Number of safety threat observations per case, stratified by SEIPS category and ordered from highest number of observations to least.



**Figure 7.** Number of resilience support observations per case, stratified by SEIPS category and ordered from highest number of observations to least.

## 5.4 Qualitative Analysis of Intraoperative Observations

### 5.4.1 Intraoperative Safety Threats

Safety threats observed in the general laparoscopic surgical environment were diverse in nature and spanned each of the SEIPS 2.0 work system categories. Generalized examples of safety threats observed in each SEIPS category are provided in Table 7.

**Table 7.** Examples of safety threats observed in each SEIPS category.

SEIPS Category	Safety Threats
Person	<ul style="list-style-type: none"> <li>• Unintentional errors related to memory, perception, technique</li> <li>• Intentional protocol violations</li> <li>• Team professionalism issues (Ex. Lateness, poor team dynamics)</li> </ul>
Task	<ul style="list-style-type: none"> <li>• Avoidable diversions (Ex. Managing personnel or tool/technology issues)</li> <li>• Elevated task demands (Ex. Poor task ergonomics, cognitive load, time pressure)</li> </ul>
Tools and Technology	<ul style="list-style-type: none"> <li>• Technological malfunction</li> <li>• Dangerous design elements, unintended/uncontrolled effects</li> <li>• Poor device ergonomics, unintuitive use, unclear labelling</li> <li>• Absence of backup tools or compromised availability</li> </ul>
Organization	<ul style="list-style-type: none"> <li>• Inadequate allocation of surgical resources</li> <li>• Lack of effective organizational oversight of OR processes</li> <li>• Inadequate communication of surgical staff changes</li> </ul>
Internal Environment	<ul style="list-style-type: none"> <li>• Insufficient space attributed to the physical design of the operating room</li> <li>• Inefficient configuration of equipment within the operating room</li> <li>• Excess auditory distractions (Ex. door slams, phone ringing, human noises)</li> </ul>
External Environment	<ul style="list-style-type: none"> <li>• Regulatory issues delaying the procurement of desired tools</li> <li>• Healthcare system-level budget constraints</li> </ul>

To facilitate a deeper qualitative understanding of the safety threats observed in the intraoperative work system, all observed factors were inductively grouped into subcategories that emerged from the observation data based on identified common themes. The first subcategory of threats attributed to the clinicians at the centre of the system, labelled “Unsafe Acts” (Table 5) in agreement with the terminology used in the human factors literature to describe the equivalent underlying construct (66), described intraoperative safety failures or errors committed by clinicians, whether intentionally or inadvertently, with the potential to put patient safety at risk. The remaining five subcategories associated with the clinicians, and all threats identified within

the remaining major categories of the SEIPS 2.0 framework, detailed so-called “latent conditions”: preconditions or circumstances that create opportunities for unsafe acts to arise. Observations of unsafe acts included errors associated with clinician memory, perception and comprehension, attentiveness, and skill as well as intentional protocol violations. An example of an unintentional error included the inadvertent deviation from sterile protocol committed by an anaesthesiologist in touching the sterile handle of one of the laparoscopic monitors, while an example of an intentional protocol violation included a resident diverting his attention away from the patient to view a message on his personal phone (presented to him by the circulating nurse).

Safety threats were found to occur with significant prevalence across several categories of the SEIPS work system framework. The most prevalent threat ascribed to the clinicians was clinician engagement in unnecessary or trivial conversation during the execution of clinical tasks, with 30 instances observed over 13 cases. Prevalent safety threats related to clinical tasks included increased task demands associated with patient complexity (n = 23), such as a thick abdominal wall, the need to troubleshoot unanticipated technological issues (n = 17), and intraoperative interruptions related to other surgical cases (n = 15). Environmental threats included distracting workflow sounds (n = 33), most predominantly associated with the loud intrusive sound emitted from the OR door slamming shut, and distracting electronic sounds (n = 32), including the phone ringing excessively and low priority alarms.

At the organizational level, the most significant safety threats were related to missed opportunities for standardized procedures. For example, several instances were observed wherein clinicians would temporarily leave the operating room and tasks essential to the forward progression of the surgical case would go unfulfilled in their absence, resulting in unnecessary delays. Thus, the absence of a standardized protocol for ensuring that essential clinical roles remain covered when individuals are required to leave the room was identified as an organizational safety threat.

Finally, the tools and technology of the intraoperative system presented a wide range of safety threats, with technical malfunction (n = 34) representing the most prevalent safety threat of all threats observed. Additional threats included the intraoperative unavailability of critical surgical resources at points in the surgical case when they were required to proceed, such as the absence

of essential cartridges of various specifications for the powered laparoscopic stapler. Lastly, a number of specific safety threats related to functionality, safety, reliability, and usability were observed in association with tools utilized in almost every surgical case, as outlined in Table 8.

**Table 8:** Specific safety threats associated with laparoscopic surgical tools, technologies, and equipment.

Surgical Equipment or Instrumentation	Intraoperative Issue Observed
Powered laparoscopic stapler	<ul style="list-style-type: none"> <li>• Partial or complete failure to fire</li> <li>• Assembly malfunction/staff difficulty in assembling tool correctly</li> </ul>
Ultrasonic energy shears & generator	<ul style="list-style-type: none"> <li>• Prompts provided on generator screen during testing/setup phase were confusing/unclear, leading to delays</li> </ul>
Hook cautery device	<ul style="list-style-type: none"> <li>• Quiet activation tone</li> <li>• Difficulty differentiating between tones for different settings</li> </ul>
Operating table	<ul style="list-style-type: none"> <li>• Inability to lower to an optimal level for the operating surgeon</li> </ul>
Trocar	<ul style="list-style-type: none"> <li>• Design of the trocars in use promote accumulation of fluid and debris, leading to smearing of the endoscopic lens and compromised internal visualization</li> </ul>
Needle grasper	<ul style="list-style-type: none"> <li>• Weak grasp of needle resulting in recurrent slippage</li> <li>• Faulty needle grasper remained in service for several cases/issue was not adequately communicated</li> </ul>

Usability was an important issue observed in relation to surgical technology and instrumentation. In particular, confusion surrounding the setup of ultrasonic energy device was observed to delay surgical progress on more than one occasion. Further, discussion of the frequently observed malfunction of the powered laparoscopic stapler during expert roundtable uncovered the possibility that these malfunctions may be stemming from the incorrect assembly of the instrument by the scrub nurses, a potential indicator of unintuitive and non-robust design.

One important emergent quality of the observation data was the multifactorial nature of potentially unsafe situations. That is, circumstances that were deemed to present a feasible risk to patient safety were often observed to arise from a series of interconnected safety threat factors. This concept is illustrated in the following segment of observation data detailing a minor intraoperative disruption. The applied safety threat codes are provided in square brackets:

*Desktop phone rings several times [Tools and technology/distracting electronic sound]. The circulating nurse had stepped out of the operating*

*room a moment ago and is not available to answer [Organization/no cover when absent]. The operating surgeon notices the phone and an observer who is present to see if it is the OR front desk calling [Task/diversion]. The observer answers the phone [Person/intentional protocol violation]. The observer communicates to the operating surgeon that there has been a change in the scheduling of his next case [Task/other case disruption].*

## 5.4.2 Intraoperative Resilience Supports

In contrast to safety threats, resilience supports were observed in five of the six categories of the SEIPS 2.0 work system framework. Generalized examples of safety threats observed in each SEIPS category are provided in Table 9.

**Table 9.** Examples of resilience supports observed in each SEIPS category.

SEIPS Category	Resilience Supports
Person	<ul style="list-style-type: none"> <li>• Effective teaching (Ex. Advising caution, teaching tool safety)</li> <li>• Calmness, good situation awareness</li> <li>• Preference for effective surgical technique</li> <li>• Effective interdisciplinary communication (Ex. Surgical staff communicating progress to nurses and anaesthesia staff)</li> <li>• Providing positive feedback, avoiding criticism</li> <li>• Informal intraoperative briefing/debriefing (pre/post case)</li> </ul>
Task	<ul style="list-style-type: none"> <li>• Absence of time pressure</li> <li>• Optimized task ergonomics (Ex. Well-placed trocars)</li> </ul>
Tools and Technology	<ul style="list-style-type: none"> <li>• Availability of backup instrumentation, extras, multiple options within the OR</li> <li>• Good device ergonomics, intuitive design, ease of adjustability</li> <li>• Forced functions</li> </ul>
Organization	<ul style="list-style-type: none"> <li>• Staff continuity throughout case</li> <li>• Availability of surgical support services</li> <li>• Standardized double-check procedures, surgical timeout</li> <li>• Informative features (Ex. Audible alarms, different energy activation tones)</li> </ul>
Internal Environment	<ul style="list-style-type: none"> <li>• Lighting optimized for task at hand</li> <li>• Quiet in OR during key surgical steps</li> <li>• Efficient positioning of tools within reach of users</li> </ul>

Although resilience-enhancing factors were observed throughout various elements of the work system, the highest number of observed supports was attributed to the clinicians themselves. The most prevalent person-related resilience supports included the provision of skills coaching (n =

38) and the proactive delegation of tasks to team members in advance of their required completion (n = 36). The verbalization or narration of essential tasks was also a particularly impactful and prevalent resilience support, such as measuring segments of bowel aloud during a laparoscopic Roux-en-Y gastric bypass to enable teammates to verify the accurate completion of the procedure step. Overall, all of these resilience-enhancing factors appear to align well with the four constituent components of resilience, namely the ability to anticipate, monitor, learn, and respond, while a select few, such as the presence of forced functions on certain surgical instrumentation, specifically support the potential to respond *appropriately*.

Interesting qualitative associations were observed between a number of resilience supports and safety threats, such as the tendency for resilience-enhancing factors to be observed immediately following an observation of a safety-threat, as demonstrated in the following segment of observation data. The relevant applied codes are provided in square brackets

*Surgical fellow uses the “coag” setting of cautery device, rather than “cut”, to create a small hole in one section of bowel, resulting in significant spray/thermal spread [Person/substandard technique error]. The difference in the activation tone between the two settings was faint and difficult to distinguish [Tools and technology/not robust]. The staff surgeon recognizes the error and explains the rationale for and importance of using the “cut” setting for this procedure step [Person/teaching tool safety].*

Finally, while some factors were initially identified as potential resilience supports, many of these observations were flagged during interdisciplinary discussion as having inappropriate or unsafe timing. That is, certain behaviours, such as sharing medical knowledge, were potentially beneficial, but unless the behaviour was immediately relevant to the care of the patient, it was deemed extraneous, potentially distracting, and, therefore, hazardous to patient safety.

## 5.5 Exploratory Analyses for Adverse Intraoperative Events

Of the 19 cases observed in this study, the two wherein serious adverse intraoperative events were observed were deemed to warrant deeper exploratory analyses. The first observed intraoperative deviation (Event 1) involved the accidental transection of an internal temperature

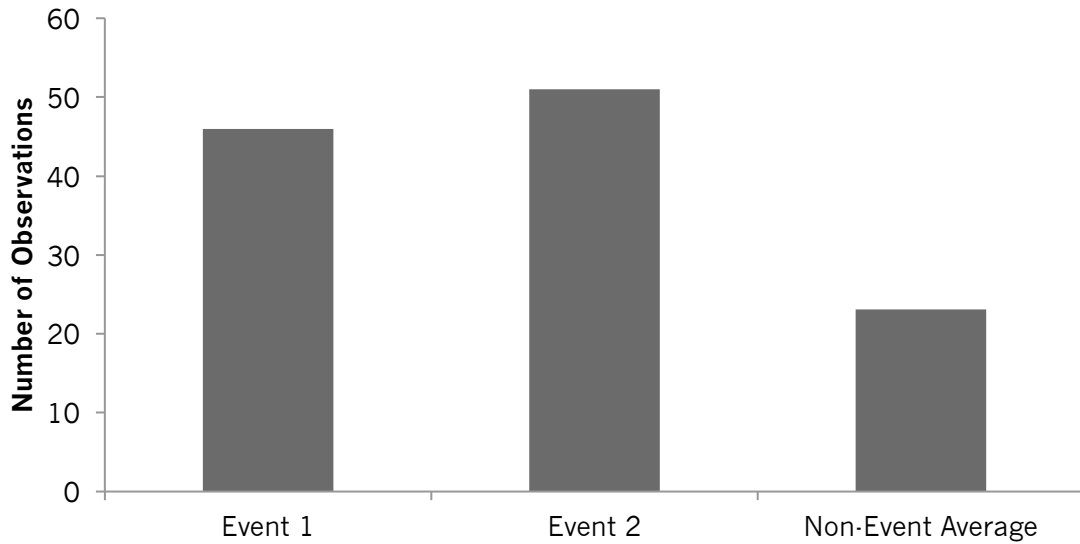
probe during the stomach transection step of a sleeve gastrectomy procedure. The temperature probe had been originally placed in the patient's nasal cavity, but the introduction of the bougie caused the probe to migrate into the stomach unbeknownst to the surgical or anaesthesia staff. The stomach was transected using a powered laparoscopic stapler resulting in a portion of the temperature probe being enclosed in the extracted specimen and the remainder being secured in the gastric staple line. This deviation went unrecognized until the attempted removal of the temperature probe following completion of the sleeve gastrectomy procedure. Upon discovery, the deviation was quickly corrected through surgical revision of the gastric sleeve without adverse consequence to the patient.

The second observed intraoperative deviation (Event 2) involved the creation of an anastomosis with the incorrect limb of the small bowel during the jejunojejunostomy step of a laparoscopic Roux-en-Y gastric bypass as a result of an unperceived twist in the bowel. The deviation was recognized by the operating surgeons upon preparation for the execution of the subsequent gastrojejunostomy step and immediately rectified via surgical revision of the jejunojejunostomy without adverse consequence to the patient.

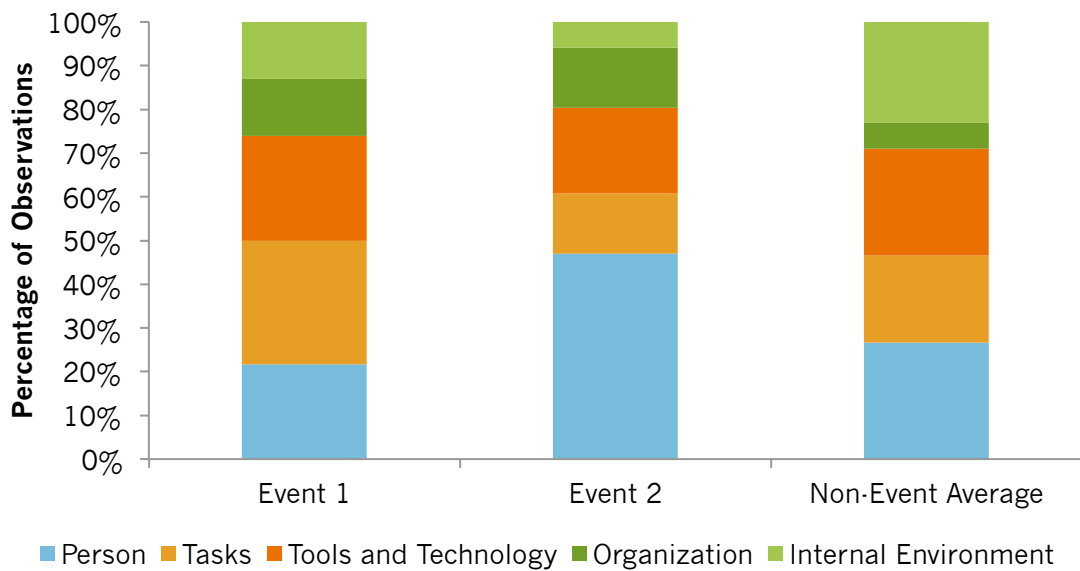
### **5.5.1 Comparison of Cases with Intraoperative Events to Those Without**

To explore whether the quantity and breadth of intraoperative safety threats and resilience supports observed in the cases with adverse intraoperative events differed from those wherein an adverse event did not occur, the observations made for the cases involving Events 1 and 2 were quantitatively compared to the observation averages from the cases without adverse events.

With respect to observed safety threats, the total number of observations made for Events 1 and 2 are compared to the average number of observations made per non-event case in Figure 8, while the proportion of safety threats observed in each major category of the SEIPS 2.0 work system framework are compared to the average proportions of observations made per non-event case in Figure 9.



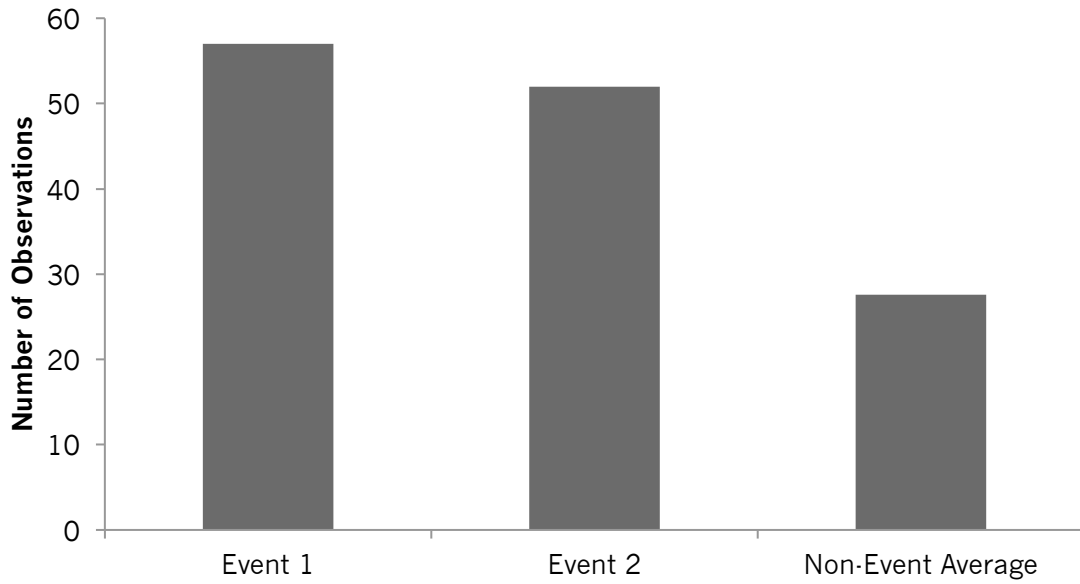
**Figure 8.** Comparison of the total number of safety threats observed for cases with observed adverse intraoperative events vs. those without.



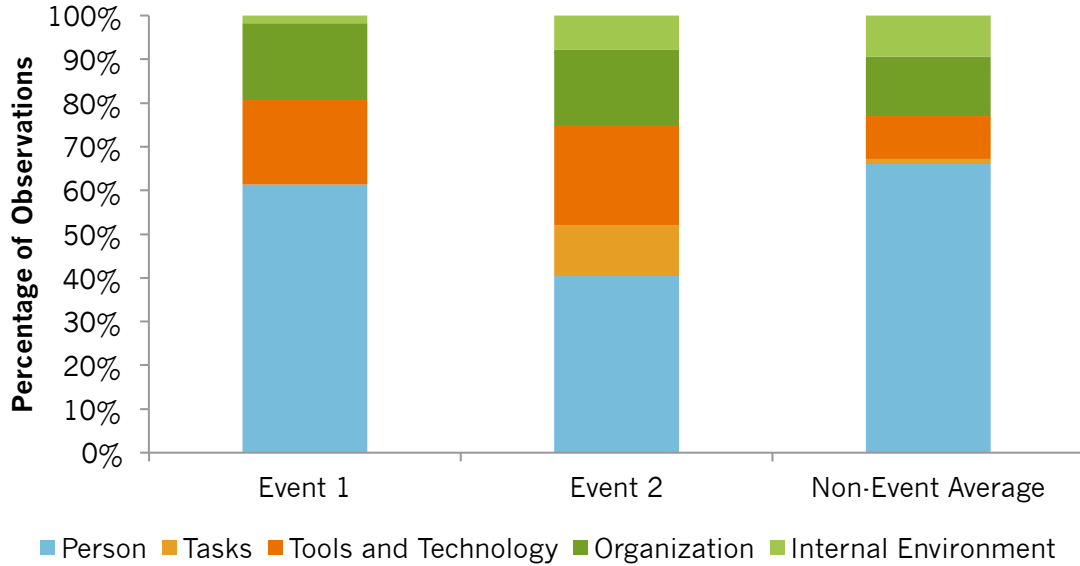
**Figure 9.** Comparison of proportion of safety threats observed in each SEIPS category for cases with observed adverse intraoperative events vs. those without.

Similarly, the total number of resilience support observations made for Events 1 and 2 are compared to the average number of observations made per non-event case in Figure 10, and the proportion of resilience supports observed in each major SEIPS category are compared to the average proportions of observations made per non-event case in Figure 11.





**Figure 10.** Comparison of the total number of resilience observed i for cases with observed adverse intraoperative events vs. those without.



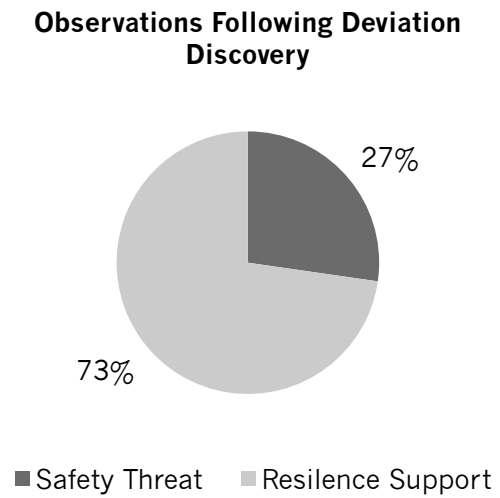
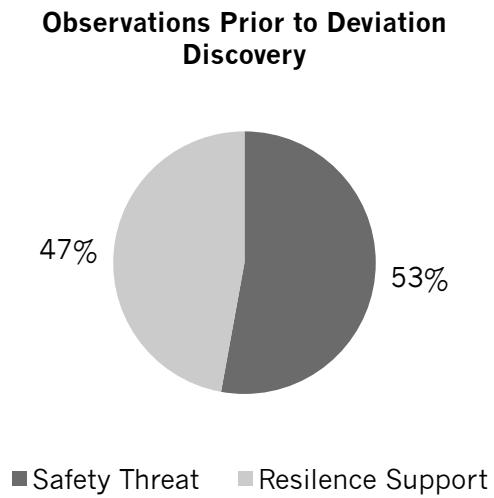
**Figure 11.** Comparison of proportion of resilience supports observed in each SEIPS category for cases with observed adverse intraoperative events vs. those without.

## 5.5.2 Factors with Potential Involvement in the Occurrence and Correction of Observed Adverse Intraoperative Events

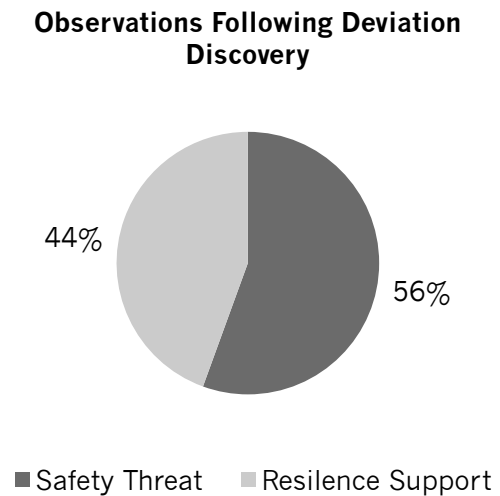
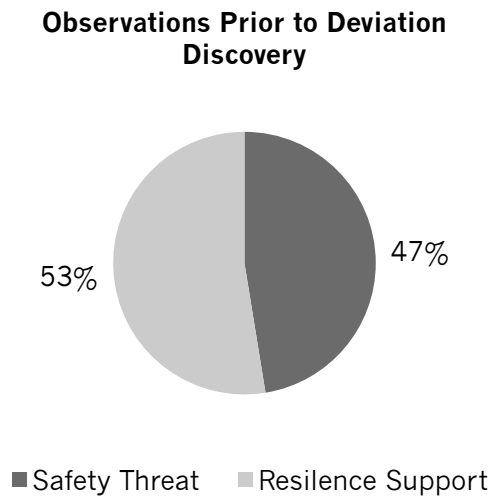
The two surgical cases within which serious intraoperative deviations were observed were further analyzed for the purpose of qualitatively exploring the potential factors implicated in their occurrence and recovery as well as to demonstrate the utility of the proposed human factors categorization scheme in exposing these factors as a prerequisite to the development of meaningful interventions.

To elucidate whether the prevalence of salient intraoperative safety threats and resilience supports was altered upon discovery of the intraoperative deviation by the operative team and the subsequent initiation of a remedial response, the relative proportion of safety threats and resilience supports observed prior to the point in time at which the team discovered the deviation was compared to the proportion observed afterwards for both cases. These proportions are presented in Figure 12 and Figure 13, respectively.

The codes applied to the observation data surrounding both intraoperative events were then contextually and qualitatively examined to facilitate the exploration of potential factors involved in event occurrence and recovery. Potential contributory safety threats observed for both events are described in Table 10, while resilience supports utilized in the recovery of the events are described in Table 11.



**Figure 12.** Comparison of the type of factors observed prior to and following the discovery of the adverse intraoperative event in Event 1.



**Figure 13.** Comparison of the type of factors observed prior to and following the discovery of the adverse intraoperative event in Event 2.

**Table 10.** Factors implicated in the occurrence of the observed adverse intraoperative events.

SEIPS Category	Event 1	Event 2
Person	<ul style="list-style-type: none"> <li>• Staff surgeon preoccupation with coaching the relatively inexperienced operating fellow during the dissection step preceding the creation of the gastric sleeve</li> </ul>	<ul style="list-style-type: none"> <li>• Inexperienced scrub nurse requiring frequent guidance from/correction by operating surgeon</li> <li>• Visible frustration/suboptimal team dynamics between surgeon and inexperienced scrub nurse</li> <li>• Engagement of surgical staff in unnecessary communication during critical procedure steps</li> <li>• Perception/comprehension error in evaluating bowel orientation on monitor</li> <li>• Failure of surgeons to fully explore/verify bowel orientation following verbalization of potential concern</li> </ul>
Task	<ul style="list-style-type: none"> <li>• Potentially increased task demand associated with patient complexity and challenging anatomy</li> <li>• Lack of stimulation associated with the required surgical tasks leading to potential surgeon complacency</li> </ul>	<ul style="list-style-type: none"> <li>• Operating surgeons forced to engage in secondary task of managing an unexpected staff shortage</li> <li>• Additional task of camera manipulation placed on operating surgeons in the absence of resident/surgical assist</li> </ul>
Tools and Technology	<ul style="list-style-type: none"> <li>• Absence of valuable tactile feedback during transection of temperature probe with power stapler</li> <li>• Absence of sufficient technological notification system indicating temperature probe transection</li> </ul>	<ul style="list-style-type: none"> <li>• Absence of potentially valuable equipment to secure camera in position when surgical assist is absent</li> <li>• Potential failure of the laparoscopic monitor to support the accurate comprehension of spatial orientation</li> </ul>
Organization	<ul style="list-style-type: none"> <li>• Change of anaesthesia staff once case had already begun and incomplete transfer of information regarding placement of temperature probe</li> <li>• Absence of procedure or system-level interlock to mandate communication between surgical and anaesthesia staff prior to stomach transection</li> </ul>	<ul style="list-style-type: none"> <li>• Failure of operating room management to appropriately communicate and address unexpected shortage of surgical staff</li> </ul>
Internal Environment	<ul style="list-style-type: none"> <li>• Ongoing distracting sounds associated with workflow (door opening and closing) and electronic (phone calls)</li> </ul>	<ul style="list-style-type: none"> <li>• Ongoing distracting sounds associated with workflow (door opening and closing) and electronic (phone calls)</li> </ul>

**Table 11.** Factors implicated in the discovery and recovery of the observed adverse intraoperative events.

SEIPS Category	Event 1	Event 2
Person	<ul style="list-style-type: none"> <li>• Good situational awareness (staff surgeon) enabling identification of potential abnormality at stomach staple line</li> <li>• Informal intraoperative debriefing following original completion of the procedure to discuss abnormality encountered with all present staff</li> <li>• Prompt communication of safety deviation by anaesthesia staff to surgeons upon discovery</li> <li>• Interdisciplinary problem-solving between surgical staff and anaesthesia to devise appropriate remediation of the error</li> </ul>	<ul style="list-style-type: none"> <li>• Awareness and verbalization of need for caution during anastomosis step regarding bowel orientation</li> <li>• Narration of steps taken during surgical task/counting aloud during measurement of bowel, facilitating deviation discovery</li> <li>• Non protocol-driven double-check of surgical task execution prior to gastrojejunostomy creation indicating preference for effective surgical technique and surgical quality control</li> <li>• Calm control of surgical staff upon discovery of surgical error</li> <li>• Collaborative decision-making between operating surgeons to devise appropriate remediation of the error</li> </ul>
Tools and Technology	<ul style="list-style-type: none"> <li>• Preserved accessibility of required surgical instrumentation to enable rapid surgical remediation</li> </ul>	<ul style="list-style-type: none"> <li>• Presence of extra staple cartridges within operating room to enable rapid remediation of deviation</li> </ul>
Organization	<ul style="list-style-type: none"> <li>• Strong safety culture supporting the communication of mistakes without fear of penalty and emphasis on learning from transpired event</li> <li>• Same nursing staff throughout case enabling efficient initiation of team remediation response</li> </ul>	<ul style="list-style-type: none"> <li>• Availability of backup surgical staff to compensate for unexpected staff shortage</li> </ul>

## 6 Discussion

The laparoscopic surgical environment represents a uniquely complex sociotechnical work environment with significant opportunity for error and preventable patient harm. By integrating and building upon previous methodologies put forth in the domain of healthcare human factors research (24, 27), this work sought to elucidate the system-level factors that have the potential to threaten patient safety or enhance system resilience during complex general laparoscopic surgery, as well as to expand the methodological toolbox available to surgical quality improvement researchers for identifying factors that affect both risk and resilience in the operative environment through the development of a comprehensive intraoperative human factors classification scheme.

### 6.1 Intraoperative Human Factors Classification Scheme

The intraoperative human factors classification scheme presented in this work built upon the SEIPS 2.0 work system model to provide a comprehensive framework for identifying safety threats and resilience supports in a surgical setting. The classification scheme consists of 25 subcategories of safety threats encompassing 80 distinct safety-threatening intraoperative factors, as well as 68 distinct resilience-enhancing factors grouped into 19 subcategories (Table 5, Table 6, Appendix D). These subcategories and their constituent intraoperative factors emerged from the analysis of detailed, text-based observation data collected through the review of surgical video recordings by a single clinical engineering observer (Table 2) and was refined through consensus discussion towards inter-coder agreement and roundtable discussion with surgical experts.

The incorporation of interdisciplinary input from researchers with both surgical and engineering backgrounds was deemed essential to the development of a robust and representative classification scheme for intraoperative human factors. The exclusive participation of a non-clinician engineering researcher in the observation of the surgical system and synthesis of the observation data minimized the potential for bias towards surgical care-providers and assured the identification of performance-affecting factors associated with the surgical work system at large, while the subsequent refinement of the classification scheme using the expertise of surgeon scientists provided robustness and face validity to the ultimate classification scheme obtained.

The consensus discussions carried out during the inter-coder agreement phase of the study particularly emphasized the value of integrating an interdisciplinary approach; in this phase, it was observed that the surgeon researcher tended to attribute a greater number of observations to the “person” category than the engineer, which may be interpreted as a potential indicator of the prevailing safety mindset in surgical settings. The surgeon researcher also expressed a reluctance to code observations of potentially problematic behaviours enacted by staff surgeons as safety threats. Nevertheless, the input of the surgeon researcher during this phase was invaluable. Problematic codes requiring clearer definitions, revision, or deletion were revealed, and expert insight clarified the correct interpretation of ambiguous surgical observations.

Revision of the classification scheme following consensus discussion significantly increased inter-coder agreement (Figure 2) and the level of agreement ultimately achieved with the refined version was “almost perfect” for the characterization of observations as either safety threats or resilience supports and “substantial” at all other levels of the classification scheme (Table 4), indicating that, after a period of familiarization, surgical researchers without human factors expertise can reliably apply the human factors classification scheme to text-based surgical observation data. The results of the roundtable were equally encouraging, as surgical researchers with experience in intraoperative performance assessment validated the utility of the scheme for enabling the identification of performance-affecting factors associated with work system elements beyond the care providers.

Overall, the safety threat subcategories represented in this classification scheme mirror several of those put forth by Gurses et al. in the classification scheme of intraoperative hazards they developed using observations of cardiac surgery (24), while also reflecting the nature of intraoperative safety threat observed and reported by others. However, to my knowledge, the classification scheme for intraoperative resilience supports presented here is the first of its kind to systematically highlight critical intraoperative factors with the potential to enhance the capacity for resilience from a systems perspective.

## 6.2 Intraoperative Safety Threats and Resilience Supports

Analyzing the prevalence of safety threats and resilience supports observed within the 19 surgical cases reviewed generated a number of interesting insights.

Despite the inclusion of surgical cases involving predominantly the same surgical procedure (i.e. laparoscopic Roux-en-Y gastric bypass) and of comparable complexity, the number of safety threats and resilience supports observed per case varied widely, with the number of identified safety threats ranging from 9 to 72, and the number of resilience supports ranging from 9 to 71 (Table 3). However, as depicted in Figure 3, the number of resilience supports identified was not observed to increase proportionally with the number of safety threats observed; rather, a high proportion of resilience supports was observed for several cases wherein the number of observed safety threats was low. This particular observation appears to align with established theory regarding system resilience, specifically the notion that resilience is present in a system before a disturbance arises. Given that resilient performance, made possible by the ability to anticipate, monitor, learn, and respond, depends on the system's configuration and the opportunities it provides (8), it follows that resilience-enhancing factors may be observable in a system while it is functioning normally with little apparent risk.

The relative contribution of unique safety threats and unique resilience supports to the observed totals per case were graphically explored in Figure 4 and Figure 5, respectively. As shown in Figure 4, a higher observed proportion of unique safety threats corresponded to a higher total number of observed safety threats (comprising unique instances as well as multiple instances of the same threat). However, as the total number of observed safety threats increased, the number of unique safety threats observed did not increase at the same rate, and it was found that the number of unique safety threats comprised less than half of the total number observed for the cases with the highest observed frequency of threats overall. Thus, this result indicates that significant risk is introduced to the operative work system by *recurring* safety threats, a finding made more significant by reports in the literature suggesting that adverse events in surgery are likely to be associated with a number of recurring and prospectively identifiable issues (12).



As shown in Figure 5, a similar pattern emerged for the prevalence of unique resilience supports compared to the total number of resilience supports observed per case; that is, as the total number of observed resilience supports increased, so too did the proportion of unique resilience supports. However, the highest proportions of unique resilience supports were notably observed for the two cases wherein adverse intraoperative events were found to occur. As the use of video recordings for the observation of the surgical system enabled observed intraoperative events to be examined repeatedly as desired, the number of unique resilience supports identified for these two cases may have been artificially increased as a result of increased vigilance on behalf of the observer in looking for compensatory factors surrounding the identified event. However, an alternative explanation for this result, as highlighted by Schraagen et al. in their study on teamwork in pediatric cardiac surgery, is that certain teamwork processes are adaptive mechanisms that emerge primarily when operations become more difficult, and increased team effectiveness during difficult situations is characteristic of high-performing teams (67). Thus, to successfully manage the remediation of the difficult and unanticipated events observed in these two instances, it is possible that the surgical team activated or called upon an additional number of critical resilience supports that would have otherwise gone unobserved.

The respective distributions of safety threats and resilience supports observed across the elements of the SEIPS 2.0 work system framework are depicted in Figure 6 and Figure 7. As indicated in Figure 6, safety threats were observed in 5 of the 6 the major SEIPS 2.0 categories in relatively equal proportions across the 19 cases observed. However, Figure 7 shows that the resilience supports observed were predominantly associated with clinician attributes and behaviour for all surgical cases. Within the classification scheme, person-centred resilience supports are dominant, comprising 38 of the 68 of the different factors identified, and this result indicates that these resilience-enhancing factors were also the most frequently called upon during the surgical cases observed. This result also aligns with the findings presented by Hu et al. in their study of contributory and compensatory factors associated with surgical care deviations; although they exclusively ascribed compensatory factors to the surgical care providers, while we were able to identify a number of resilience-enhancing factors in the broader surgical system, this result potentially confirms that the capacity for resilience in surgical systems is most significantly influenced by the attributes and behaviours of the care providers themselves.

Qualitatively, many of the safety threat observations made in this study corroborate findings reported for other surgical settings, including the prevalence of technological malfunction (37, 52), interdisciplinary silos and communication breakdown (11, 24, 34), distracting elements of the physical environment (49), ineffective OR design (31), and the prevalence of irrelevant or unnecessary conversation during the execution of surgical tasks (40). Similarly, the intraoperative resilience-enhancing factors reported here align with the findings reported by others emphasizing the importance of situation awareness (53), team effectiveness (42), and strong communication (34) for identifying and mitigating unanticipated surgical deviations.

### 6.3 Analysis of Adverse Intraoperative Events

Two adverse events were observed during surgical video review. Both events were subclinical in nature, meaning they were recovered successfully during the course of the operation and did not manifest in adverse patient outcomes, and a number of interesting observations surrounding both risk and resilience emerged from their observation.

The cases containing these events were associated with a greater number of both safety threats (Figure 8) and resilience supports (Figure 10) than the non-event averages, again calling into question whether this result was a by-product of increased vigilance on behalf of the observer. However, the highest number of safety threats overall was observed for a case wherein an adverse event did not occur (Table 1), thus rendering it plausible that this result is a true representation of the amount of risk present in the system at the time, and that the increased number of resilience factors was related to the activation of otherwise-latent resilience supports by high performing teams under stress (67).

The difference in the distribution of safety threats and resilience supports across the SEIPS work system between the two cases containing adverse events underscores the stark singularity of the events, each one arising from a unique combination of intraoperative factors (Figure 9, Table 10) and requiring different mechanisms and system supports for remediation (Figure 11, Table 11). For Event 1, the remediation of the intraoperative event was swift and efficient, potentially made possible by the seamless identification and activation of resilience supports during this period (Figure 12). In contrast, for Event 2, safety threats persisted during the deviation remediation

stage (Figure 13), including suboptimal team dynamics, inexperience on behalf of the scrub nurse and surgical assist, malfunction of various surgical equipment (including stapler assembly failure, loss of suction), verbalized frustration and fatigue of the surgical staff, and the recurring unavailability of necessary equipment precipitating the need to acquire surgical resources from outside the OR. The potential for suboptimal dynamics between the scrub nurse and the surgeon, arising from insufficient training or the need for correction, to negatively impact surgical performance has been observed elsewhere (44). Additionally, as illuminated by Sutton et al., the laparoscopic surgeon has a finite capacity for task management (4), and it is likely that the additional task demands imposed on the surgeon due to the inexperienced scrub nurse and absence of sufficient staff played a major role in the occurrence of the event observed.

Overall, coding the observation data arising from these cases using the classification scheme and the subsequent analysis of these codes facilitated the identification and conceptual organization of potential factors implicated in event occurrence and recovery (Table 10, Table 11) thereby highlighting viable opportunities for effective mitigation (safety threats) and widespread standardization (resilience supports) and demonstrating the potential added value of this systems-based approach in the context surgical safety improvement.

## 6.4 Recommendations

The specific safety threats and resilience supports identified in this work provide direction for the development of intraoperative safety-enhancing inventions within the surgical system observed. Given the observation that recurrent safety threats contributed significantly to the level of risk observed in the surgical system overall, prioritizing the remediation of these threats through targeted design interventions would be the most fruitful strategy moving forward.

Many of the most prevalent safety threats observed in this work were associated with non-human elements of the surgical work system and are thus amenable to high-leverage design solutions. Technological malfunction of surgical tools and equipment was the most prevalent safety threat observation overall, most predominantly in association with the powered laparoscopic stapler, laparoscopic graspers, and suction equipment. As these items were used in almost every observed case, the immediate and thorough inspection of these items by maintenance personnel

should be carried out to elucidate the underlying technological failings and facilitate their remediation. The second most prevalent safety threats were intrusive and potentially distracting sounds arising from the physical environment, predominantly the sound of the phone ringing and the sound of the operating door slamming shut. Both of these issues may be addressed through design; for example, the installation of an automated pocket-door with silent closure, a feature of operating rooms elsewhere, would mitigate the risk of environmental distraction associated with unavoidable personnel movement in and out of the OR, while assigning a portable handset with vibration notification to the circulating nurse may be a viable alternative to the conventional operating room phone.

The technological issues identified in Table 8 also represent practical opportunities for impactful design interventions. Several of these issues centre on the topic of usability, specifically the ambiguity of the prompts provided by the ultrasonic energy device generator monitor to the clinician users during device setup and the recurrent tendency for trained nursing personnel to load cartridges onto the powered laparoscopic stapler incorrectly. To address these concerns, surgical technology representatives should be engaged to facilitate user-centered adjustments to the instrumentation based on the observed shortcomings. To reduce the risk of such issues arising in the future, usability tests in high-fidelity simulation sessions should be carried prior to the procurement of critical surgical instrumentation, at best, and before their introduction into routine surgical workflow, at the least. Practically, these strategies may depend on collaboration between the hospital and the appropriate healthcare technology companies at the organizational level.

The most common person-centred safety threat observed in this study was the tendency for unnecessary conversation during the execution of surgical tasks, which serves as a source of distraction with the potential to contribute to medical error. To this end, exploring the applicability of the “sterile cockpit” concept to complex laparoscopic surgery may be beneficial. This aviation-style practice of instituting protocol-driven communication during periods of high risk and high mental workload has been previously studied in cardiac surgery, where a structured and unambiguous verbal communication protocol developed and implemented around key steps in a cardiac surgical procedure was found to reduce the number of critical communication breakdowns observed (68). In the context of laparoscopic bariatric surgery, the implementation

of protocols such as this may serve to mitigate the risk of adverse intraoperative events similar to the temperature probe transection event observed in this study.

The hierarchy of effectiveness may also be applied to appraise the reliability and effectiveness of the identified intraoperative resilience supports. The majority of the resilience supports observed in this system were associated with clinicians. As such factors integrate an inherent reliance on fallible human memory and vigilance, human-centred resilience supports may potentially be deemed unreliable from the hierarchy's perspective. However, the standardization of certain resilience-enhancing behaviours, such as interdisciplinary communication at various procedure steps, mandated surgical quality control at select procedure checkpoints, and intraoperative briefing and debriefing, would represent a moderate-leverage systems-based strategy for building an increased capacity for resilient performance into a surgical system.

## 6.5 Limitations

The present work has several limitations.

As this is an observational study, it is necessary to consider the potential influence of the Hawthorne effect on the results obtained. The Hawthorne effect describes a phenomenon wherein subjects exhibit unintentional behaviour changes in response to the presence of an observer (69). However, two distinct aspects of this study may reduce the potential impact of the Hawthorne effect. First, surgical recordings have been collected from the operating room featured in this work for over two years as part of an ongoing surgical quality improvement research study. Thus, it would be reasonable to assume that the clinical teams who routinely work in this environment have become acclimated to the presence of recording equipment, subsequently rendering them less susceptible to the Hawthorne effect. Second, due to the absence of a visible observer within the operating room and the unobtrusive nature of the video recording equipment installed, the knowledge of being observed is less likely to spontaneously enter the conscious awareness of operative clinicians throughout a surgical case, thereby further reducing the risk of the Hawthorne effect.

The observational nature of this study and the use of surgical video recordings to perform intraoperative observation may be a second limitation. As the recordings did not capture events

prior to the draping of the patient or any intraoperative processes occurring after the incision site closure, relevant intraoperative process details may have been missed. Further, these recordings did not allow for the examination of certain work system elements, such as surgical instrumentation, in granular detail, and interpersonal dialogue was occasionally inaudible, thereby inhibiting the extent to which care provider perspectives could be perceived. Thus, the supplementation of this methodology with in-person observation and interviews or contextual inquiry techniques may enhance the robustness of the presented findings in the future.

An additional limitation is the potentially unrepresentative nature of the observation data collected in this study, which thus calls into question the completeness of the intraoperative human factors classification scheme it was used to create. Although qualitative saturation was achieved during the coding of the observation data in this work, this is likely a direct result of having acquired the observation data from a single operating room featuring many of the same clinical staff for each case observed. The use of a larger sample of observation data arising from multiple operating rooms with distinct clinical teams would have undoubtedly resulted in the creation of a more robust intraoperative human factors classification scheme. However, the nomenclature incorporated into the classification scheme at the code-level was deliberately kept general enough so as to promote applicability to a wide range of intraoperative observations. Further, it is likely that any newly identified intraoperative safety threats or resilience supports would be accommodated by the subcategories that have been established in this work, and expansion of the scheme in this manner by other researchers is encouraged, if possible.

Finally, the inclusion of a single site in this study limits the generalizability of the qualitative findings reported here to other surgical settings. This work represents an attempt to gain a comprehensive understanding of the elements that contribute to the performance of a specific work system. The concept of system configuration, one aspect of the SEIPS 2.0 model emphasized by its creators, stipulates that performance is an emergent property of the interacting system components, and, importantly, these interactions are dynamic and system-specific (23). Thus, while it is possible that the contributory factors to system performance identified in this work may be mirrored in other similar surgical work systems, the contextual singularity of each system demands the re-evaluation of the relationships between these factors and their relative contributions to system performance.

## 6.6 Future Work

Moving forward, this work highlights a number of potential opportunities for further research.

To further assess the potential utility and reliability of the presented intraoperative human factors classification scheme in the context of video-based assessments of surgical systems, a formal validation study should be carried out. Specifically, the validation should involve the application of this classification scheme directly to video-clips of surgical systems without the generation of text-based observation data, as transcribing and coding surgical observations is likely to be prohibitively time-consuming for practical surgical quality improvement initiatives. Feedback elicited from surgical researchers applying the classification scheme in this manner would be valuable for refining the tool further to increase its appeal to practitioners interested in surgical quality improvement on a broader scale. Furthermore, marking observations made with this scheme on a surgical case timeline populated with observations derived from other currently available surgical rating tools capturing technical skill, non-technical performance, and distraction would illustrate the added value of a systems-based, human factors approach in the context of a larger surgical quality improvement initiative.

During the completion of this work, the 19 included cases had not yet been analyzed under the umbrella of the parent research study for observations of technical error, and thus, surgical error data was not readily available for comparison with the safety threat and resilience support data acquired in this work. However, technical error rates for these cases are expected to be available in the near future. Thus, whether the prevalence of technical error varies according to the number of safety threats or resilience supports present in the surgical system is an additional research question that merits exploration.

The identification of potential associations between systems-based safety threats, resilience supports, and patient outcomes was beyond the scope of the present work. However, preliminary results of the ongoing parent study of this work suggest that an increased incidence of surgical errors do not necessarily translate to adverse outcomes. Given the findings presented here, it is feasible that the surgical system's capacity for resilience has a role to play in mitigating the potential for surgical errors to contribute to adverse patient outcomes. Thus, a prospective study

to evaluate the potential role of intraoperative resilience supports, identified observationally through the use of the presented classification scheme, in mitigating the effects of latent safety threats on patient outcomes may provide more definitive evidence to support the integration of resilience-enhancing features into surgical systems.

Observations pertaining to the adverse events observed in this study raised additional and potentially worthwhile research questions regarding resilience. Particularly, do higher-performing teams identify and activate a higher number of resilience supports, as suggested by Schraaghen et al. and potentially observed in Event 1 (Figure 12), during the remediation of adverse intraoperative events in complex laparoscopic surgery than less effective teams? Further, do a higher number of emergent resilient supports during these situations correlate to faster or more effective event remediation?

Finally, additional research surrounding the development and subsequent implementation of targeted design interventions to the intraoperative issues identified here should be explored. For example, a study to identify high acuity procedure steps demanding optimized vigilance in laparoscopic bariatric surgery should be carried out to inform the development of a standardized communication protocol for these procedural windows, followed by an evaluation of the effectiveness of this intervention in terms of reducing the number of teamwork, communication, environmental distraction, and task-related safety threats within the surgical system.



## 7 Conclusions

A persistent need to identify and correct safety threats in surgical settings contributing to medical error, in addition to identifying and correctly valuing the factors that enhance the capacity of surgical systems for resilience in failure-prone situations, has been identified as an important area for research in the domain of surgical quality improvement. To this end, this work detailed the successful application of a systems-based observational methodology to the analysis of risk and resilience in the complex work system of general laparoscopic surgery. Through the observation of 19 surgical cases, human factors that have the potential to either threaten patient safety or support team resilience in general laparoscopic surgery were identified, categorized, and analyzed. The identified intraoperative human factors were subsequently inductively arranged into a categorization scheme that can inform the development of an intraoperative human factors observation tool for surgical process improvement moving forward. Finally, the utility of a human factors approach in understanding the mechanisms through which adverse patient safety events occur and are remediated was demonstrated in the qualitative analysis of two subclinical adverse intraoperative events using the classification scheme developed, and actionable opportunities for meaningful safety interventions that emerged from this analysis were presented. Ultimately, the significance of this work is its contribution towards expanding systems theory to the analysis of resilience in surgical setting and the development of a classification scheme to aid clinical researchers in analyzing risk and resilience in surgical systems moving forward.

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# Appendices

## Appendix A: REB Approval Letter

Research Ethics Office  
Telephone: (416) 864-6060 Ext. 2557  
Facsimile: (416) 864-6043  
E-mail: [pateld@smh.toronto.on.ca](mailto:pateld@smh.toronto.on.ca)

**St. Michael's**  
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Inspiring Science.

March 18, 2016

Dr. Teodor Grantcharov,  
Department of Surgery, Division of General Surgery,  
St Michael's Hospital

Dear Dr. Grantcharov,

Re: REB# 12-069 - Development of strategies to identify, analyze and prevent errors in the operating room - an inter-professional approach to enhancing technical and non-technical performance and improving patient safety: A pilot study

<b>REB APPROVAL:</b>	<b>Original Approval Date</b>	<b>October 09, 2012</b>
	<b>Annual/Interval Review Date</b>	<b>October 09, 2016</b>

Thank you for your communications received **13-November-2015** regarding the above named study.

I have reviewed and hereby issue St. Michael's Hospital (SMH) Research Ethics Board (REB) approval for:

1. Protocol - ver: 3/17/2016
2. Patient consent form - ver: 3/17/2016
3. Patient consent form with 3D camera - ver: 3/17/2016
4. Staff consent form - ver: 3/17/2016
5. Staff consent form with 3D camera - ver: 3/17/2016
6. Appendix 1: Letter of Information - ver: 3/17/2016
7. Appendix 5: Postoperative Human Factors Assessment Form - ver: 3/17/2016
8. Appendix 11: Visualization and Physical Symptoms Questionnaire ver: 3/17/2016
9. Questionnaire - Appendix 12: Mental Workload Questionnaire - NASA Task Load Index - ver: 3/17/2016
10. Appendix 13: Surgical Team Demographic Questionnaire - ver: 3/17/2016

Furthermore, the following documents have been received and are acknowledged:

1. Pre-Procedure Checklist - ver: 3/17/2016
2. Inclusion/Exclusion Criteria - ver: 3/17/2016
3. Appendix 2A: Patient Data Sheet - ver: 3/17/2016
4. Appendix 2B: Postoperative Follow-up Data Sheet - ver: 3/17/2016
5. Appendix 3: Objective Structured Assessment of Technical Skills (OSATS) - ver: 3/17/2016
6. Appendix 4: Error Classification Tool - ver: 3/17/2016
7. Appendix 6: Oxford NOTECHS Rating Scale and Surgeon Subteam Modifiers - ver: 3/17/2016
8. Appendix 7: NOTSS Rating Scale - ver: 3/17/2016
9. Appendix 8: Staff Consent Master Log - ver: 3/17/2016
10. Appendix 9: Patient Linking Log Template - ver: 3/17/2016
11. Appendix 10: Adverse Event Report Form (Olympus) - ver: 3/17/2016
12. Appendix 14: Pictorial Surface Orientation (PicSO) Test - ver: 3/17/2016

Dr. Teodor Grantcharov (REB# 12-069)

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Please note that no member of the St. Michael's Hospital Research Ethics Board associated with this submission was involved in its deliberation, review or approval.

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.

The St. Michael's Hospital (SMH) Research Ethics Board (REB) operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Product Regulations, and the Medical Devices regulations. Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

Good luck with your investigations.

With best wishes

\_\_\_\_\_  
Dr. David Mazer  
Chair, Research Ethics Board  
DM/PB/BJM/kt

  
Dr. Philip Berger  
Vice Chair, Research Ethics Board

\_\_\_\_\_  
Dr. Brenda McDowell  
Vice Chair, Research Ethics Board

# Appendix B: Patient Consent Form

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## **Consent to Participate in a Research Study**

**Title of Research Study:** Development of strategies to identify, analyze and prevent errors in the operating room - an inter-professional approach to enhancing technical and non-technical performance and improving patient safety: A pilot study

### **PILOT STUDY Operating Room Data Recorder**

**Principal Investigator:** **Dr. Teodor Grantcharov (MD, PhD, General Surgeon)**  
St. Michael's Hospital  
Division of General Surgery  
16-056 Cardinal Carter Wing  
30 Bond St., Toronto, Ontario M5B 1W8  
**Phone # 416-864-5748**  
**Available 8am-5pm Monday to Friday**

**Funding Support:** **St. Michael's Hospital Innovation Fund 2012-2014**

This study is being conducted as Research in the field of Education in Surgery and Patient Safety.

The study Principal Investigator Dr. Grantcharov will also be involved in this study as a study participant.

### **Introduction**

Before agreeing to take part in this research study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions, please ask a study investigator or study staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the study with your family doctor, a family member or close friend.

### **Purpose of the Research**

The purpose of this study is to develop a "Black Box", as it is known in the aviation industry, for use in the operating room (OR). The concept of the "Black Box" was introduced in aviation several decades ago to record all relevant flight data, including voice recordings from the cockpit, to help analyze airplane crashes, accidents or critical situations, in order to improve safety. The "Black Box" for use in the OR follows the same principles by recording video and audio data during an operation as well as vital signs of the patient and environmental factors such as the operating room temperature.

The data that is gathered will later be used to design customized simulation scenarios to train surgeons with respect to manual skills in critical situations during an operation, and also to train the entire OR team in important skills such as communication and problem solving during stressful situations. The goal of such training is to enhance technical and non-technical skills and improve patient safety.

Approximately 250 elective laparoscopic surgery patients and about 80 to 100 OR team members will participate in this study taking place at St. Michael's Hospital.

### **Description of the Research**

You are being asked to consider participating in this study because you have an upcoming elective laparoscopic surgery at St. Michael's Hospital. If you choose to participate in this study, you are agreeing to be video-recorded while your surgery is performed. The view of the laparoscopic camera will be video-recorded throughout the procedure as per standard of care in this unit. In addition, views of the entire operating room will be video-recorded upon the OR team entering the room. The laparoscopic video recording will show the surgery as it is happening inside your body. The video camera will be affixed on a defined position within the OR. Besides the video recordings, sound (audio) is also recorded during the procedure. Environmental factors that are recorded will be room temperature and sound level.

We will review your medical record and collect basic demographic information (e.g., age, gender) and relevant medical information, including information about your surgical procedure. We will document post-operative complications and events for a period of 30 days after your surgery. You will also be asked to complete a voluntary 36-item questionnaire that looks at quality of life (physical functioning, bodily pain, energy/fatigue, emotional well-being, general health perceptions). This questionnaire will be presented to you before your operation, and after during the follow-up appointment.

The video recordings will be assessed by expert personnel (including 2 surgeons and a human factors specialist) who will rate the operative technical and non-technical OR team performance using validated evaluation tools. The video recordings will only be linked to you by a unique code so your name will NOT be on the video recordings or on any data that is gathered in addition to it. As per standard medical practice any technical deviations or incidental findings during your surgery will be recorded in the operative note. In cases where these findings may be relevant to your health and future treatment these will be discussed with you in person by your treating team as per standard medical practice.

## **Potential Harms and Risks**

Your participation, or choice to not participate, will not have any effect on your surgery or any other part of your treatment or on the quality of medical care at St. Michael's Hospital for you or other members of your family. There are no known harms related to your participation in this study, apart from some potential risks related to your personal health information/identifying information (which are discussed in further detail in the 'Confidentiality and Privacy' section below).

## **Potential Benefits**

There are no direct benefits from participation in this study. This study will not give you any improved treatment of any kind. There is however a potential benefit for future patients and operating room teams since the purpose of this study is to improve the training of the entire operating room team with the overall intention to improve patient safety in surgery. Results from this study may further medical or scientific knowledge.

## **Confidentiality and Privacy**

All the persons involved in this study, including the study investigators and study team members (hereby referred to as "study personnel") are committed to respecting your privacy. All records will be held strictly confidential unless required by law. No other persons will have access to your personal health information or identifying information without your consent. Any records, documentation, or information related to you will be coded by a unique study number. In addition to that, for the video recording of the operating room, your face will be hidden. No identifying information about you will be allowed off site. All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study personnel will be able to access. Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices. The video recording of the laparoscopy will only capture the details on the instruments and performance of the laparoscopic surgery. The video recordings and study data will be identified only with a unique study number and will not be used for any purposes other than this research study. If it happens that any identifying information does get video/audio recorded (for example, your identity printed on any documents or if your name is spoken during the recording), this information will be removed from the recording when discovered.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. During the 30 day retention period the principal investigator will protect your records and keep confidential all the information in your study file, including the log containing your name and hospital chart number. The chance that this information will accidentally be given to someone else is small.



By signing this form, you are authorizing access to your medical records and the identifying information collected in this study to the study personnel. Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality to the extent permitted by applicable laws and regulations.

The audio and room video recordings will be securely deleted after they have been evaluated by the expert assessors and are no longer required for study purposes. This will be 30 days after your surgery. The log linking the study data to your identity will be securely destroyed at that time as well. The laparoscopic camera view will be stripped of all identifying patient information (including patient name, time and day of the procedure) and stored in an educational library on a secure hard-drive. Since the laparoscopic video is anonymized, there is no way of linking the video to any member of the OR team, or the patient. Other study data (coded with the unique study number) will be securely stored for up to 5 years after the study has been completed and published, and then those data will be securely destroyed.

In no way does signing this consent form waive your legal rights nor release the study investigators or involved institutions from their legal and professional responsibilities.

### **Study Results**

We may present the results of this study at a scientific conference and we intend to write an article about this study for a scientific journal. You can ask us to send you a copy of the article upon publication by contacting Dr. Grantcharov, Principal Investigator.

### **Potential Costs and Reimbursement**

There are no costs to you for participating in this study. You will not be reimbursed for your participation.

### **Participation and Withdrawal**

Your participation in this study is voluntary. You can choose not to participate or you may withdraw at any time. Your participation, or choice to not participate, will not have any effect on your surgery or any other part of your treatment or on the quality of medical care at St. Michael's Hospital for you or other members of your family. If you wish to withdraw early from the study (and do so within 48 hours of your surgery) the video recordings of your surgery will be securely destroyed and no evaluation of the recordings will be conducted if this has not already been done. The other study participants from your surgery (the OR team members) may also withdraw from the study at any time and request that the video be deleted if it has not yet been analyzed. If analysis is already completed or after this 48-hour time point, the information gathered from the video analysis will be retained and included in the study, as well as the

information collected up to the point of withdrawal. However no further information will be collected about you for the study. The study investigator may also withdraw you from the study at any time, including if the investigator ends the study prematurely.

### **New Findings or Information**

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner.

### **Study Contact**

If you have any questions about the study, or if you wish to withdraw from the study at any time, please contact our Research Personnel at 416-864-6060, extension 77584 (8am-5pm Monday to Friday).

### **Research Ethics Board Contact**

If you have any questions about your rights as a research participant, please contact Dr. David Mazer, Chair, Research Ethics Board at St. Michael's Hospital, at 416-864-6060 ext. 2557, during business hours. The Research Ethics Board is required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience in the research study.

**Title of Research Study:** Development of strategies to identify, analyze and prevent errors in the operating room - an inter-professional approach to enhancing technical and non-technical performance and improving patient safety

**Declaration of Consent**

The research study has been explained to me, and my questions have been answered to my satisfaction. I have been informed that I have the right not to participate and the right to withdraw without affecting my treatment or the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the investigators or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept strictly confidential and that no information will be disclosed without my permission or unless required by law. I have been given sufficient time to read the above information.

I consent to participate in this study. I will be given a signed copy of this consent form.

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Name of Participant (print)	Signature of Participant	Date
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**I, the undersigned, have fully explained the study to the above-named participant.**

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Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Conducting Consent Discussion	Date
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# Appendix C: Clinical Staff Consent Form

**St. Michael's**

Inspired Care. Inspiring Science.

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## **Consent to Participate in a Research Study**

**Title of Research Study:** Development of strategies to identify, analyze and prevent errors in the operating room - an inter-professional approach to enhancing technical and non-technical performance and improving patient safety

### **Operating Room Data Recorder**

**Principal Investigator:** **Dr. Teodor Grantcharov (MD, PhD, General Surgeon)**  
St. Michael's Hospital  
Division of General Surgery  
16-056 Cardinal Carter Wing  
30 Bond St., Toronto, Ontario M5B 1W8  
**Phone # 416-864-5748**  
**Available 8am-5pm Monday to Friday**

### **Funding Support: St. Michael's Foundation**

This study is being conducted as research in the field of Education in Surgery and Patient Safety.

You should be aware that Dr. Grantcharov will also be involved in this study as a study participant.



## **Introduction**

Before agreeing to take part in this research study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions, please ask a study investigator or study staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the study with a family member or close friend.

## **Purpose of the Research**

The purpose of this study is to develop a "Black Box", as it is known in the aviation industry, for use in the operating room (OR). The concept of the "Black Box" was introduced in aviation several decades ago to record all relevant flight data, including voice recordings from the cockpit, to help analyze airplane crashes, accidents or critical situations, in order to improve safety. The "Black Box" for use in the OR follows the same principles by recording video and audio data during an operation as well as vital signs of the patient and environmental factors such as the operating room temperature.

The data that is gathered will later be used to train surgeons with respect to manual skills in critical situations during an operation, and also to train the entire OR team in important skills such as communication and problem solving during stressful situations. The goal of such training is to enhance technical and non-technical skills and improve patient safety.

Approximately 2000 patients and about 80 to 100 OR team members will participate in this study taking place during elective laparoscopic cases performed by participating surgeons in the department of General Surgery at St. Michael's Hospital.

## **Description of the Research**

You are being asked to consider participating in this study because you are an OR team member working with one of the surgeons participating in this study. If you choose to participate, you are agreeing to be video-recorded while in the operating room. The view of the laparoscopic camera will be video-recorded throughout the procedure as per standard of care in this unit. Panoramic view cameras will begin recording after the patient had been fully protected from the camera view by sterile drapes and will stop recording before the drapes are removed. Laparoscopic video recording will show the surgery as it is happening inside the patient's body. The panoramic view camera will be affixed on a defined position within the OR. Aside from the video recording, sound (audio) is also recorded during the procedure. Environmental factors that are recorded will be room temperature and decibel level.

After each elective surgery procedure for the cases included in this study, you will be asked to fill out a questionnaire, which will take about 2 minutes each time. The

questionnaire includes questions about your opinions and observations. You may also be asked to fill out a patient safety awareness survey. You do not have to answer any questions that make you feel uncomfortable or that you do not wish to answer

The video recordings will be assessed by expert personnel who will rate the operative technical and non-technical OR team performance using validated evaluation tools. Video recordings will only be marked by a randomly assigned, unique study code. Your name will NOT be on the video recordings or on any data gathered in addition to it. During the 30 day retention period all recordings will be held strictly confidential unless required by law. Upon the completed evaluation of the video recordings by the expert assessors the recordings will be securely and permanently deleted.

### *Educational Library*

Educational library is a collection of anonymized and de-identified video materials created strictly for the purpose of future education and training of the operating room team members.

The laparoscopic camera view will be stripped of all identifying patient information (including patient name, time and day of the procedure) and stored on a secure on-site, encrypted hard-drive for future analysis. Since the laparoscopic video is anonymized, there is no way of linking the video to you or any member of the OR team.

It is also possible that a short segment of the panoramic view recording be included in the educational library for future training and. In such instances, additional video and audio filters will be applied in order to ensure full protection of all persons appearing in the recorded materials. Processed educational clips will be rendered completely

### *Hospital Survey on patient Safety Culture*

This survey is voluntary and will be offered by a Research Assistant to all healthcare providers – surgical team, anesthesiology team, nursing team and scrub technicians-involved in the Operating Room Black Box study. The goal is to prospectively measure healthcare providers' perception of patient safety during their engagement with the OR Black Box study.

### **Potential Harms and Risks**

Your participation, or choice to not participate, will not have any effect on your current or future work at St. Michael's Hospital (or on your academic standing, if you are a student). There are no known harms related to your participation in this study, apart from some potential risks related to your identifying information (which are discussed in further detail in the 'Confidentiality and Privacy' section below).

### **Potential Benefits**

There are no direct benefits from participation in this study. There is however a potential benefit for future patients and operating room teams since the purpose of this study is to improve the training of the entire operating room team with the overall intention to improve patient safety in surgery. Results from this study may further medical or scientific knowledge.

### **Confidentiality and Privacy**

All the persons involved in this study, including the study investigators and study team members (hereby referred to as "study personnel") are committed to respecting your privacy. No other persons will have access to your identifying information without your consent. Any records, documentation, or information related to you will be coded by a unique study number. In addition to that, for the video recording of the operating room, all faces of patients will be hidden from the camera view. You as an OR team member will be masked as per standard hygiene regulations during the surgery and therefore will not be readily identifiable to persons outside the operating room environment. No identifying information about you will be allowed off site. All information collected, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study personnel will be able to access. Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices. -The video recordings of the laparoscopy will only capture the details on the instruments and performance of the laparoscopic surgery. The video recordings and study data will be identified only with a unique patient study number and will not be used for any purposes other than this research study. If it happens that any identifying information does get video/audio recorded (for example, your identity printed on any documents or if your name is spoken during the recording), this information will be removed from the recordings as soon as it is discovered.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The principal investigator will protect your records and keep confidential all the information in the study file. The OR team assessment is not targeted at evaluating individual performance. Therefore these ratings will be scored based on clinical role (e.g., surgeon, nurse, anesthetist, etc.). No identifying information about you will be used in the evaluation data set. The chance that the information collected for the study will accidentally be given to someone else is small.

By signing this form, you are authorizing access to your identifying information, which consists of camera and voice recordings, to the study personnel.

The audio and room video recordings will be securely destroyed (deleted) after they have been evaluated and are no longer required for study purposes. This will occur 30



days after the initial recording. The log linking the study data to the patient's identity will be securely destroyed at that time as well. The laparoscopic camera view will be stripped of all identifying patient and OR personnel information, and stored in an educational library on a secure hard-drive. Since the laparoscopic video is anonymized, there is no way of linking the video to any member of the OR team, or the patient. As previously described all educational clips will be protected using blurring and voice altering technology rendering them completely and permanently anonymized. Other study data (coded with the unique patient study number) will be securely stored for up to 5 years after the study has been completed and published, and then those data will be securely destroyed.

In no way does signing this consent form waive your legal rights nor release the study investigators or involved institutions from their legal and professional responsibilities.

### **Study Results**

We may present the results of this study at a scientific conference and we intend to write an article about this study for a scientific journal. You can ask us to send you a copy of the article upon publication by contacting Dr. Grantcharov, Principal Investigator.

### **Potential Costs and Reimbursement**

There are no costs to you for participating in this study. You will not be reimbursed for your participation.

### **Participation and Withdrawal**

Your participation in this study is voluntary. Once you give written informed consent for participation, this consent will be valid until you withdraw it. You can choose not to participate or you may withdraw at any time. Your participation, or choice to not participate, will not have any effect on your current or future work or standing. No information about a decision not to participate or about a decision to withdraw from study participation will be communicated up the professional hierarchy. If your decision to withdraw from the study is made within 48 hours from the recording, you may request that the video be deleted. The other OR team members participating in the study may do the same. If the patient withdraws from the study within 48 hours from the recording, the videos will be deleted. In order to maintain the scientific integrity of the study and avoid bias, the recordings may not be withdrawn beyond the 48-hour timeframe, nor may be the other data collected up to the point of withdrawal. The audio and video recordings will be securely deleted at the 30 day time point as described above. The study investigator may also withdraw you from the study at any time, including if the investigator ends the study prematurely.

**New Findings or Information**

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner.

**Study Contact**

If you have any questions about the study, or if you wish to withdraw from the study at any time, please contact our Research Personnel at 416-864-6060, extension 77584 (8am-5pm Monday to Friday).

**Research Ethics Board Contact**

If you have any questions about your rights as a research participant, please contact Dr. David Mazer, Chair, Research Ethics Board at St. Michael's Hospital, at 416-864-6060 ext. 2557. The Research Ethics Board is required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience in the research study.

**Title of Research Study:** Development of strategies to identify, analyze and prevent errors in the operating room - an inter-professional approach to enhancing technical and non-technical performance and improving patient safety: A pilot study

**Declaration of Consent**

The research study has been explained to me, and my questions have been answered to my satisfaction. I have been informed that I have the right not to participate and the right to withdraw without affecting my current or future work at St. Michael's Hospital (or my academic standing, if I am a student). As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the investigators or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me will be kept strictly confidential and that no information will be disclosed without my permission or unless required by law. I have been given sufficient time to read the above information.

**I consent to participate in this study. I will be given a signed copy of this consent form.**

_____	_____	_____
Name of Participant (print)	Signature of Participant	Date

**I, the undersigned, have fully explained the study to the above-named participant.**

_____	_____	_____
Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Conducting Consent Discussion	Date

# Appendix D: Complete Intraoperative Human Factors Classification Scheme

## SAFETY THREATS

PERSON		
Sub-category	Code	Description
Unsafe Acts	Active attention failure	Clinical team member is not actively listening/paying attention/observing aspects of surgical case when they should be
	Memory error	Error/mistake due to forgetting information/steps, unintentional omission of necessary steps, or inaccurate recall
	Perception/comprehension error	Perception/comprehension errors, or errors arising from impaired ability to accurately perceive/comprehend current system state
	Substandard skill/technique error	Suboptimal/non-standardized technique, approach to task execution is atypical/diverges from the standardized/optimal method; errors related to inadequate skill/experience
	Intentional protocol violation	Clinician knowingly violates standard protocol/safe operating procedure or fails to take necessary precautions/steps (Ex. Participation of observer in OR processes, prioritizing personal tasks)
Suboptimal Clinician Condition	Lack of situation awareness	Clinician does not appropriately perceive/comprehend current system state, unusual/unsafe circumstances, or deviation/error
	Suboptimal mental state	Ex. Anger, frustration, arrogance, complacency
	Suboptimal physiological condition	Ex. Hunger, fatigue
Inadequate Experience/Knowledge	Insufficient task experience/knowledge	Individual lacks experience to execute the task correctly/safely/efficiently ( <i>potential</i> to contribute to error)
	Insufficient tool experience/knowledge	Individual lacks experience to correctly/safely/efficiently operate or handle surgical tool ( <i>potential</i> to contribute to error)
Leadership Failures	Failure to explore concerns	Clinician in leadership position does not adequately address/explore concerns raised by co-worker
	Failure to guide/supervise	Absence of supervision over less experienced team members at a critical point in time
Team Effectiveness Issues	Personnel late	Clinical team member arrives late to the OR
	Suboptimal team dynamics	Evidence of incompatibility/discord between team members as a result of personality differences, unfamiliar team, etc.
	Unnecessary conversation	Clinical team members engage in trivial or unnecessary conversation that is not relevant to the task at hand
Communication Failures	Communication unclear	Communication between healthcare professionals is not delivered clearly/adequately/effectively, not communicating with teammate directly, etc.
	Communication absent	Complete absence of team communication when communication is critical, leading to confusion/disrupted workflow
	Communication delay	Delay in essential communication (Ex. Surgical team fails to communicate care plan changes to other team members in timely manner)
TASKS		
Sub-category	Code	Description
Suboptimal Task Demands/Workload	Bad ergonomics	Task is physically demanding (Ex. Strenuous, heavy, poor ergonomics associated with task, bad angles)
	Cognitively demanding	Characteristics/complexity/difficulty of task which have the potential to increase the cognitive workload of the clinician

	Time pressure	Time pressure associated with task
	Overwhelming workload	High workload experienced due to high number of required tasks, not enough colleagues, unanticipated additional responsibilities etc.
	Unstimulating task	Clinicians express boredom with task at hand/lack of mental stimulation
	Unexpected task complication	Ex. Error/issue/complication on anaesthesia side temporarily delays surgical case progression
Preventable Secondary Tasks	Diversion, personnel issue	Clinician required to attend to secondary task that diverts attention from primary objective task/delays the completion of another task; diverts attention, interrupts action, Ex. Correcting form of inexperienced scrub nurse
	Diversion, tool/tech issue	Clinician required to attend to secondary task that diverts attention from primary objective task/delays the completion of another task; diverts attention, interrupts action; Ex. Troubleshooting malfunction
	Diversion, workspace issue	Clinician required to attend to secondary task that diverts attention from primary objective task/delays the completion of another task; diverts attention, interrupts action; Ex. Rearranging obtrusive equipment
	Diversion, organization/management	Clinician required to attend to secondary task that diverts attention from primary objective task/delays the completion of another task; diverts attention, interrupts action; Ex. Managing scheduling issues
Patient-Related Challenges	Patient complexity	Unique patient factors (ex. Implant, pacemaker) add extra layer of complexity to case (known prior to surgery initiation)
	Challenging patient management	Clinicians express difficulty in managing the patient throughout the case (Ex. airway)
	Challenging anatomy	Physical/anatomical characteristics of the patient that may exacerbate the difficulty of a task (potentially unknown to team until surgery is underway)
Disruptions	Unnecessary verbal interruption	Communication delivered to an operating surgeon/working clinician (inappropriate timing); engaging a preoccupied clinician in an unnecessary discussion
	Other case interruption	Another case requires attention of clinical team, draws attention away from present case (Ex. Clinician must leave to attend another OR); Clinicians discuss details of another patient
<b>TOOLS AND TECHNOLOGY</b>		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
Lack of Familiarity	Unfamiliar configuration/setup	Tool/instrument/tech configured in a way that is unusual/unfamiliar to user
	Unfamiliar tool	Clinicians are using a tool/instrument/equipment that is different from their usual tool/is new/is unfamiliar
Substandard Functionality/Utility	Malfunction	Unanticipated malfunction/failure of tool/equipment during use (Ex. stapler, grasper, camera, monitor)
	Assembly failure	A multi-part tool/instrument comes apart while in use
	Desirable feature missing	Laparoscopic tool/instrumentation does not possess function/feature that would be valuable/useful to user
	Notification system lacking	Absence of notification to user in the event of setup error/technological malfunction/improper use
Safety/Reliability Issues	Unintended effects	Proper use of tool results in unintended effects (Ex. Thermal spread of energy device is abnormally/unexpectedly high despite proper use/setting)
	Dangerous design elements	Elements of the tool/equipment design have the potential to place patient safety at risk
	Inconsistent functionality	Standard use of tool/tech produces inconsistent results
	Not robust	Tool design does not sufficiently protected against use error; tool/tech design allows for unintentional/accidental deployment of undesired functions; easy to mess up
	Tool/task mismatch	Available tool is incompatible with/inappropriate for the task at hand



	Workarounds/ improvisation	Clinicians rely on workarounds to bypass usability problems/achieve desired goals
Usability Issues	Tech instructions unclear	Instructions for using equipment/error messages are confusing/not easily interpreted
	Instrument differences	Differences/inconsistencies between the designs of the laparoscopic instruments force users to change/adapt their surgical approach with each change in instrument
	Unintuitive	The expected/proper usage of the equipment is not made clear by its design
	Inefficient	Equipment/tool design does not support efficient workflow/use
	Suboptimal ergonomics	Device in use is not universally ergonomic (Ex. design is biased for ease of use by wither men or women)
	Substandard packaging/labels	Design of tool/equipment packaging that contributes to drops/delays/issues during acquisition/opening, labelling (Ex. Relevant/important/useful information is missing from labels on tools)
Inadequate Availability	Item unavailable	Clinical team is unable to access/acquire required instrumentation for the present procedure
	Item missing	Required item is not available in OR when need for it arises (Ex. nurse must leave room to get other scope)
	Setup/assembly issue	Required tool was not ready for use when the need for it arose due to improper setup/not plugged in etc.
<b>PHYSICAL ENVIRONMENT</b>		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
Suboptimal Workspace Setup	Unergonomic configuration	Configuration of equipment is not optimized physically for ease of use/risk of ergonomic injury (Ex. Forces awkward positioning)
	Inefficient configuration/ positioning	Configuration of equipment/people hinders workflow/contributes to delays (Ex. Poor placement of equipment contributes to dropped tools)
	Non-standardized layout	Configuration of equipment does not conform to standard/expected layout
Suboptimal Workspace Design	Insufficient space	Physical layout of room constrains people/equipment (Ex. Equipment in the OR impedes clinician pathways)
	Valuable elements missing	Lack of seating in work area causing clinicians to compromise and use inappropriate equipment to rest
Suboptimal Ambient Conditions	Distracting workflow sounds	Unexpected noise generated by movement of equipment/door closing etc.
	Distracting electronic sounds	Unanticipated noise generated by electronics in the operating room that draw clinician attention away from tasks at hand
	Distracting human sounds	Unexpected sounds made by colleagues/individuals present in the OR that have the potential to distract from present task
	Bad lighting	Lighting in OR is not appropriate for the present task
	Uncomfortable temperature	Suboptimal ambient temperature for worker comfort
<b>ORGANIZATION</b>		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
OR Resource Mismanagement	Inadequate resource allocation	Inadequate allocation of necessary surgical resources to surgical tool sets (Ex. Tool shortage, not enough to go around)
	Inadequate resource procurement	Failure to procure necessary/preferred surgical tools/materials (Ex. Bad purchasing decisions)
	Support services unavailable	Lack of support for troubleshooting intraoperative issues (Ex. No technical support staff available when needed)
Safety Culture Deficiencies	Inadequate risk resolution	Recurrent issues arising in the OR that have the potential to compromise safety are inadequately communicated/resolved

	Unsafe staffing	Ex. Not enough staff present for current procedure; staff present are working post-call
Perioperative Process Failures	Inaccurate documentation	Preoperative documentation issues, inconsistencies/errors/inaccuracies in patient record
	Incomplete information	Information available to clinicians is insufficient for adequate case preparation Ex. Indicators used to approximate case difficulty/potential challenges do not sufficiently reflect actual difficulty
Suboptimal Policies/ Procedures	No safety check	No protocol mandating clinicians to check with/communicate with team prior to execution of critical procedure step
	No cover when absent	Extra personnel are not called upon/are not available to cover/complete/support the required tasks of a team member when absent from the OR
	Failure to standardize	Failure to standardize safety/efficiency enhancing behaviour/procedure/protocol
Ineffective Staff Management	Staff change	Nursing/anaesthesia/surgery shift change/new clinician joining team while case is in progress
	Staffing communication failure	Staffing issues/changes are inadequately communicated to OR team
	Traffic	High traffic in the OR, personnel entering/exiting excessively
Inadequate Provision of Training	Inadequate training provided	Lack of organizational provision of training to clinical staff
EXTERNAL ENVIRONMENT		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
Latent External Threats	Budget constraint	Hospital budget constraints result in unavailability of preferred tools/resources
	Regulatory process	Regulatory process is delaying the procurement of required/desired equipment/instrumentation

## RESILIENCE SUPPORTS

PERSON		
Sub-category	Code	Description
Effective Guidance/ Instruction	Advising caution	Surgical team lead guides colleagues on when to proceed cautiously to ensure safe task execution
	Sharing knowledge	Care providers sharing relevant knowledge with one another to establish a better understanding of the procedure/task
	Skills coaching	Teaching/training/coaching on safe/effective surgical skill or technique
	Teaching tool safety	Guidance regarding the <b>safe</b> operation of tools that have the potential to cause harm if used incorrectly
Advantageous Clinician Condition	Experience	Clinicians have sufficient experience with required tasks to complete them correctly/efficiently + compensate for suboptimal conditions
	Adaptability	Clinician/team exhibit adaptability in the presence of dynamic/unpredictable/unideal system conditions
	Good situation awareness	Clinician perceives, comprehends, acknowledges and subsequently reacts to unusual circumstances/changes/deviations during procedure
	Calm control	Clinician demonstrates calm, controlled response to unexpected event (ex. Unexpected bleeding), maintains communication and task performance
Anticipatory Action	Contingency planning	Evidence of planning for unanticipated events + communicating plan to team
	Error margins	Surgeon executes surgical step while preserving margin for error

	Proactive team management	Leadership regarding the delegation of tasks to clinical team members in advance of their required completion (Ex. Surgeon tells nurse to get something in advance)
	Proactive task completion	Clinician proactively completes required task in advance of prepare tool/resource for use by surgical team before it is needed, without being asked
	Establishing next steps	Evidence of proactive planning for subsequent surgical tasks + communicating plan to team
Effective Teamwork	Collaborative decision-making	Discussion among surgeons/evaluating options prior to ultimate decision
	Interdisciplinary problem solving	Clinicians with different backgrounds collaborate to address a concern that has arisen
	Team harmony	Evidence of synergy/harmony among team members (Ex. Getting along well, enjoy working with each other)
	Debriefing	Team discussion at the end of case to evaluate surgical performance/explore concerns
	Shared mental model	Clinical team works to establish a shared mental model/shared understanding of the patient/procedure to enable smooth/safe workflow
High-Performance Behaviour	Evaluating circumstances	Clinician evaluates/examines the current surgical situation or state of the patient/procedure before continuing procedure/executing step
	Safety check	Clinician checks with team before executing critical step in procedure to ensure patient safety
	Paying attention	Supporting clinical team members diligently paying attention to progression of surgical case; listens attentively to teammates
	Effective technique	Clinicians favour safe/effective techniques
	Surgical quality control	Surgeon monitors and controls quality of surgical work performed, strives for excellence in task execution
Effective Communication	Direct address	Directly addressing colleagues so as to capture their attention when needed
	Communicating changes	Clinicians communicating changes in the state of the surgical system (Ex. Change of operative care plan, anaesthesia notifying when medication administered)
	Communicating progress	Surgery and anaesthesia communicating to ensure shared understanding of current system state
	Verbalize/narrate action	Clinical communicates/verbalizes/describes current action with team members during task execution
	Task verification	Clinician verifies the nature of the required task (ex. Surgical procedure) with another clinician/the patient record
	Detailed instructions	Clear, descriptive instructions from one clinician to another result in smooth, safe execution of task
	Voicing concerns	Clinicians are able to freely communicate case-related concerns to colleagues
Strong Leadership	Positive feedback	Positive feedback from experienced/leading clinician to subordinate colleague regarding performance
	No criticism	Non-criticizing approach to error response that promotes open communication/learning, eliminates fear of punishment
	Checking in with team	Lead surgeon checks to see how team is doing/feeling prior to proceeding with the case
	Encouraging open communication	Encouragement of open communication among team regarding safety concerns/discomfort/perceived issues by team lead
	Supervision	Supervision of team and surgical progress at critical points by individual with authority/experience
TASKS		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>

Optimal Task Demands/ Workload	Good ergonomics	Safety/efficiency facilitated through optimizing ergonomics of task (Ex. Adjusting monitor to prevent neck strain, better port placement)
	Relaxed pace	No time pressure for task completion/ no unnecessary rushing
<b>TOOLS AND TECHNOLOGY</b>		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
Adequate Availability	Backups available	Alternative tool/tech/device is available to replace a malfunctioning one (i.e. Backups!)
	Options available	Multiple options of a given tool/resource are available for use (Ex. Multiple scopes available to choose from)
	Extras available	More surgical instrumentation/equipment/materials than originally are available in OR/available for retrieval from reserves outside of OR
	Preserved accessibility	Required surgical tools/equipment/materials remain accessible following completion of associated step/procedure and are available if revision required
Optimized Safety/Usability	Ergonomic tool	Device in use is notably ergonomic, appropriate weight, optimized for ease of use
	Intuitive	The expected use/function of surgical tool/instrumentation is made clear by its design
	Easily adjustable	Key equipment can be easily and quickly adjusted/re-configured for safety/ease of use (ex. Monitors can be adjusted quickly to achieve optimal viewing angle)
	Forced functions	Design-imposed constraints or forced functions (reducing risk of misuse)
Effective Functionality	Tool maintained	Maintenance of the tool throughout the case keeps it in optimal working condition
	Informative features	Surgical instrumentation/tool possesses feature that conveys important information to user (ex. Blinking lights when proper setup achieved, tactile feedback)
	Audible alarm	Critical surgical equipment produces an audible alarm to alert the clinical team when a related error/failure/complication occurs
<b>PHYSICAL ENVIRONMENT</b>		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
Optimal Workspace Design	Spacious	Configuration of OR equipment creates spacious pathways/ample space for clinician movement
	Workspace standardization	Design of the workspace area is standardized so as to facilitate efficiency/effective workflow (Ex. Standardized storage for intraoperative consumables)
Optimal Workspace Setup	Layout optimized	Layout of the OR is optimized as needed; ability to move equipment around in physical space; supports efficient workflow
	Efficient positioning	Positioning of people/patient supports efficient workflow
Optimal Ambient Conditions	Optimal lighting	Lighting in OR is appropriate for present surgical tasks
	Quiet	Peace and quiet in OR, no auditory distractions during procedural step
<b>ORGANIZATION</b>		
<b>Sub-category</b>	<b>Code</b>	<b>Description</b>
Effective Training Program	In situ training	Prioritization of practical, hands-on training/teaching (procedures, techniques, etc.) of staff within the OR that does not hinder case progression
	Trainee autonomy	Less experienced surgeon is given freedom to choose which step they feel comfortable with/want to practice
	Asking questions	Clinicians are free to ask questions/ask questions without penalty

Strong Safety Culture	Lessons learned	Clinical team discusses previous mistakes for the purpose of learning not to repeat them
	Communicating mistakes	Clinicians are able to openly communicate potential mistakes/errors to team (safety precaution) without penalty
	User feedback	Organization is receptive to user feedback concerning improving OR activities (Ex. Preference cart update)
Effective Policies/ Procedures	Double check	Evidence of double-check procedure for safe/effective execution of surgical/case-related tasks
	Timeout	Clear, organized, and timely execution of a standardized timeout procedure involving all necessary clinical specialties prior to surgery commencement
	Instrument count	Nursing instrument count at the end of the case
Effective Resource Management	Support services available	Ex. Technical support staff available to help surgical staff solve/troubleshoot equipment issues
	User-centered resource procurement	Decision regarding procurement of surgical instrumentation/tools/equipment are made with input from clinical user
Effective Scheduling/ Staffing	Staff continuity	Staff working on case do not switch/remain working for entirety of case (continuity of care/responsibility, shared understanding of case throughout)
	Backup staff available	Backup staff are available to assist/join OR team to ensure appropriate number of staff are present