Analyzing and Discussing Human Factors Affecting Surgical Patient Safety Using Innovative Technology: Creating a Safer Operating Culture

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Introduction: Surgical errors often occur because of human factor–related issues. A medical data recorder (MDR) may be used to analyze human factors in the operating room. The aims of this study were to assess intraoperative safety threats and resilience support events by using an MDR and to identify frequently discussed safety and quality improvement issues during structured postoperative multidisciplinary debriefings using the MDR outcome report.

Methods: In a cross-sectional study, 35 standard laparoscopic procedures were performed and recorded using the MDR. Outcome data were analyzed using the automated Systems Engineering Initiative for Patient Safety model. The video-assisted MDR outcome report reflects on safety threat and resilience support events (categories: person, tasks, tools and technology, psychical and external environment, and organization). Surgeries were debriefed by the entire team using this report. Qualitative data analysis was used to evaluate the debriefings.

Results: A mean (SD) of 52.5 (15.0) relevant events were identified per surgery. Both resilience support and safety threat events were most often related to the interaction between *persons* (272 of 360 versus 279 of 400). During the debriefings, communication failures (also category *person*) were the main topic of discussion.

Conclusions: Patient safety threats identified by the MDR and discussed by the operating room team were most frequently related to communication, teamwork, and situational awareness. To create an even safer operating culture, educational and quality improvement initiatives should aim at training the entire operating team, as it contributes to a shared mental model of relevant safety issues.

Key Words: surgical safety, team training, culture, human factors, technology, quality improvement

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Despite numerous improvement initiatives, such as the surgical safety checklists[1] and "safe surgery guidelines"[2] by the World Health Organization, the incidence of preventable surgical errors remains too high.[2–5] Studies have demonstrated that most surgical errors occurred not because of technical issues but rather to human factor–related issues.[6–9]

Human factors engineering studies the interaction among people, tools, and environments within complex systems, such as the operating room (OR).[10–12] It may help in identifying common safety threats, usually defined as "deviations from an ideal course that can increase risk of harm to patients."[13] In surgery, OR teams are often able to overcome safety threats, achieving good outcome. This is termed "resilience," referring to the phenomenon of a complex system such as an OR team being able to successfully adapt.[14,15] A knowledge gap in the literature on safety threats and resilience related to surgery exists.[5,16,17] Studies that comprehensively analyze interactions within the OR system impacting surgical quality and safety are sparse. A medical data recorder (MDR), similar to a system known in aviation as a "Black Box," may be used to collect and analyze multisource data. If it is well designed, it may facilitate the recognition of events and patterns influencing surgical safety by using validated rating scales and artificial intelligence (AI)–based technology.[7,18,19] The analysis of the system may be improved by machine learning software and consequently be of value when discussing patient safety threats.[20,21]

It is well known that debriefing is the cornerstone of any learning experience. Nevertheless, a true multidisciplinary debriefing culture in surgery is still lacking.[22–24] Multidisciplinary debriefing with the use of video and data recordings may give the team the opportunity to objectively discuss and learn from all the identified relevant factors affecting surgical patient safety.[25–27]

The aims of this study were (1) to use an MDR to identify common safety threat and resilience support events in surgery and (2) to identify frequently discussed safety and quality improvement issues during structured postoperative multidisciplinary debriefings using the MDR outcome report.

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METHODS

Subjects and Setting of the Intervention

In this cross-sectional study, a consecutive sample of 35 consented adult (>18 years old) patients who underwent general laparoscopic surgery between February 2017 and January 2018 was used.[28] Their surgeries were recorded using an MDR for the purpose of generating and researching the MDR outcome report to be used in team debriefing. Seven standard abdominal laparoscopic procedures were selected and performed by 4 staff surgeons and 1 surgical fellow, working at one tertiary academic medical center. The OR team was completed with anesthesiologists, surgical and anesthesiology residents, medical students, and OR nurses, in various constellations. Medical students assisted during the procedures by, for example, holding instruments. Cases were only recorded and included if every team member had given his/her formal written informed consent to use an MDR for the purpose of the study, before the start of the procedure.[28,29] The project was approved by the Works Council and Hospital Board of Directors. To address all ethical considerations, a Privacy Impact Assessment was conducted. This made sure the study was compliant with all applicable privacy, legal, and regulatory requirements.[29]

The MDR obtained diverse intraoperative data feeds, including audiovisual, environmental, and patient physiologic data.[30] Visual data feeds originated from capturing the surgical field, nursing station, laparoscopic camera, and anesthesia station, including the anesthesia patient-monitoring device. Recording began just after anesthesia induction, when the patient was put to sleep, and ended after skin closure, just before the drapes were removed. This was done to make sure that the patient's face was fully covered and thus not identifiable during the recordings of the MDR at our tertiary referral center. Patient-related data were stripped from personal identifiers immediately upon capture.

Then, all data were synchronized, encrypted, and sent via a secure digital channel to the MDR analysis center.[31] There, the data set was used for postprocessing, generating the MDR performance report. Postprocessing was partly automatic, using AI software and rating scales (i.e., nontechnical and technical skills, distractions),[30,32–34] identifying the events. The AI techniques that are used include machine learning and computer vision, which enable computers to learn from images and videos that are fed into them.[35] It was ensured that faces of staff and patients were blurred, and voices altered. Given the sensitivity of outcome, the report was double-checked for bias, error, and false positivity by qualified human experts in a multidisciplinary analysis team before it was finalized.

The performance report included video segments of all relevant identified safety threat and resilience support events. These events were coded using the automated Systems Engineering Initiative for Patient Safety (SEIPS) model. Our research group modified the SEIPS model to analyze the system factors that impact patient safety in minimally invasive surgery specifically.[12] This validated model helps to understand the healthcare system through the interactions of 6 categories: person, tasks, tools and technology, psychical and external environment, and organization.[7,14,15] The video segments selected by SEIPS included qualitative descriptions of the event. The finalized MDR outcome report was securely returned to the project coordinator to be used for the debriefing session.[28]

These debriefings were planned at least 48 hours (i.e., "cold debriefing"[36]) and thereafter, as soon as possible after the surgical case, to make it possible to conduct this in a neutral environment (outside the OR).[28,37] All team members were invited to participate by e-mail. The study coordinator scheduled the debriefing session on a moment during the week that suited as most team members as possible, taking into account the busy and irregular work shift schedules. An independent facilitator (professor of psychiatry) led the video-assisted debriefing using the standardized debrief model[37] to safeguard the debriefing process in a structured manner, securing safe, nonhierarchical and optimal debriefing for all team members.[37] The debriefing started by discussing what aspects of the case went well according to the opinion of the team members, by focusing on debriefing a resilience support event first. Hereafter, at least 2 other relevant events were chosen by alternating team members to discuss, labeled as either resilience or safety threat.[37]

Outcome and Data Collection Measures

The primary outcome focused on using the MDR to identify relevant safety threat and resilience support events in surgery, based on validated rating scales. Specifically for laparoscopic surgery, the modified and validated SEIPS model was used.[7,12] The modified SEIPS model uses more than 100 inductively developed codes, related to each of the 6 aforementioned categories: person, tasks, tools and technologies, organization, internal (physical) environment, and external environment.[12,15] A safety threat, in this study, is defined as any factor that could harm a patient, delay progress, or significantly disrupt the regular workflow. Delay in progress was identified when the surgical analysts saw that no meaningful progress was made during a case. A resilience support event reduces the risk of patient harm, and prevents a delay or disruption in workflow. The framework considers threats and resilience events from the entire OR workflow system. All events are then characterized in the MDR outcome report according to the categories, subcategories, and the individual SEIPS codes.[7] In Tables 2 and 3, all SEIPS categories and subcategories are presented. A full description of the framework can be found Appendix 1, http://links.lww.com/JPS/A465.

The secondary outcome relates to identifying the most frequently discussed safety and quality improvement issues during the postoperative multidisciplinary debriefing sessions. During the debriefings, the video-assisted performance report, including concise qualitative descriptions, was shown to and discussed with the OR team.[28] The study coordinator observed all the debriefing sessions. The study coordinator (A.S.H.M.v.D.) coded (descriptive) the discussed safety threat and resilience support events using the SEIPS category codes in the outcome report. Frequencies of the descriptive codes were reported. Take-home messages, feedback, conclusions, and general comments of the team members were noted as well, and examples were provided.

Statistical Analyses

Descriptive statistics including mean (SD) for continuous data and frequency analysis (%) for categorical data was performed to describe the frequency and rates of safety threats and resilience support events present in the MDR outcome reports. Analyses were performed with SPSS statistics 24.0 for Windows (SPSS, Chicago, Illinois). For the secondary outcome, qualitative data analysis was used by observing and counting which specific SEIPS subcategory codes (i.e., safety threat versus resilience support; e.g., communication or teamwork) were discussed, per debriefing session. Narrative analysis was used to review the notes regarding the team's general comments, feedback, and take-home messages made during the debriefings.

RESULTS

In Table 1, the characteristics of the recorded and analyzed surgical procedures are presented. In total, 35 laparoscopic procedures were represented, performed by 4 surgeons, 2 surgical fellows, 12 surgical residents, 6 anesthesiologists, 5 anesthesiology residents, 9 anesthesiology nurses, 27 theater nurses, and 16 medical interns (n = 81).

TABLE 1. Procedure Characteristics

Total no. cases, n (%)	35 (100)
Fundoplication	8 (51.4)
Diaphragmatic hernia repair	6 (17.1)
Elective appendectomy	3 (8.6)
Subtotal colectomy	3 (8.6)
Unilateral adrenalectomy	2 (5.7)
Bilateral adrenalectomy	2 (5.7)
Sigmoid resection	2 (5.7)
No. cases performed by primary surgeon ID	
Surgeon 1	24
Surgeon 2	4
Surgeon 3	4
Surgeon 4	2
Surgeon 5 (fellow)	1

Identified Safety Threats and Resilience Support Events

In total, 400 relevant safety threat events and 360 relevant resilience support events were observed by the MDR. A mean (SD) of 52.5 (15.0) relevant events were identified per surgical case.

Both resilience support events and safety threats were mostly related to the SEIPS model[7,12] category *person* (n = 272 and n = 279, respectively). Most resilience support events were regarded as events categorized as *effective communication* (n = 77). Also, *high-performance behavior* (n = 56) was often observed, which was subcategorized as *surgical quality control*. Most safety threats identified from the MDR outcome reports were regarded as events caused by *unsafe acts* (n = 236). In Tables 2 and 3, an overview of the resilience support events and safety threats identified by MDR is presented.

Team Debriefing Observations

During the debriefings, events were also categorized as communication (person), situational awareness (person), organization, or environment, according to the SEIPS model.[7,12] The debriefings started with discussing a resilience support event (positive, "what went well?"), and these were most often related to effective communication (n = 26) or good situational awareness (n = 6). The second and third discussions usually concerned a safety threat, as the team was then asked "what can we do better?" and this was also most often related to communication failures (n = 10, n = 8) or lack of situational awareness (n = 10, n = 9). Because of time limitations, not all events included in the outcome report were discussed.

Team Debriefing Comment Notes

Suboptimal Communication

During the debriefings, the team realized that it is important to timely and regularly provide updates on the progress of the procedure or the patient's status. It became clear that often surgeons felt there was no reason to communicate progress, as it was assumed by them this would lead to irrelevant communication. Or it was assumed that an event, such as a minor bleeding or a longer period of hypotension, was irrelevant to know for others, as it was believed not to acquire their specific or immediate attention. During debate, it was realized that these assumptions often proved to be

TABLE 2. Overview of Relevant Resilience Support Events Based on the 35 MDR Outcome Reports

Category (Total n = 360)	Subcategories	No. Observations	Examples
Person (n = 272)	Effective guidance/instruction	46	Skills coaching, sharing knowledge, advising caution, teaching tool safety
	Advantageous clinician condition	27	Good situation awareness, experience, adaptability
	Anticipatory action	15	Proactive task completion, establishing next steps, proactive team management
	Effective teamwork	34	Debriefing, shared mental model, collaborative decision making, interdisciplinary problem solving
	High-performance behavior	56	Surgical quality control, safety check, evaluating circumstances
	Effective communication	77	Direct address, communicating changes or progress, verbalize action, voicing concerns, task verification
	Strong Leadership	16	No criticism, positive feedback, checking in with team, supervision
Tasks (n = 3)	Optimal task demands/workload	3	Good ergonomics, Relaxed pace
Tools and technology (n = 2)	Adequate availability	0	Backups/extras/options available, preserved accessibility
	Optimized safety/usability	2	Ergonomic tool, intuitive, easily adjustable, forced functions
	effective Functionality	0	Tool maintained, informative features, audible alarm
Physical environment (n = 30)	Optimal workspace design	0	Spacious, workspace standardization
	Optimal workspace setup	28	Layout optimized, efficient positioning
	Optimal ambient conditions	2	Optimal lighting
Organization (n = 53)	Effective training program	18	In situ training, trainee autonomy, asking questions
	Strong safety culture	1	Lessons learned, communicating mistakes
	Effective policies/procedures	33	Timeout, instrument count, double check
	Effective resource management	1	Support services available
	Effective scheduling/staffing	0	Staff continuity, backup staff available

TABLE 3. Overview of Relevant Safety Threat Events Based on the 35 MDR Outcome Reports

Category (Total No. Threats, n = 400)	Subcategories	Number of Observations	Examples
Person (n = 279)	Unsafe act	236	Active attention failure, substandard skill/technique error, protocol violation
	Suboptimal clinician condition	4	Lack of situation awareness, suboptimal mental state
	Inadequate experience/knowledge	5	Insufficient task or tool experience/knowledge
	Leadership failures	4	Failure to explore concerns, failure to guide/supervise
	Team effectiveness issues	5	Personnel late, suboptimal team dynamics, unnecessary conversation
	Communication failures	24	Unclear, absent, or delay
Tasks (n = 23)	Suboptimal task demands/workload	4	Bad ergonomics, time pressure
Tools and technology (n = 23)	Preventable secondary tasks	8	Diversion; personnel or tool/technology or workspace issue
	Patient-related challenges	6	Patient complexity, challenging patient management, challenging anatomy
	Disruptions	5	Unnecessary verbal interruption, other case interruption
	Lack of familiarity	1	Unfamiliar configuration/setup/tool
	Substandard functionality/utility	14	Malfunction, assembly failure
	Safety/reliability issues	8	Unintended effects, inconsistent functionality, tool/task mismatch
	Usability issues	0	Suboptimal ergonomics, inefficient, technology instructions unclear
	Inadequate availability	0	Item unavailable or missing
Physical environment (n = 29)	Suboptimal workspace setup	29	Unergonomic configuration, inefficient configuration/positioning
	Suboptimal workspace design	0	Insufficient space, valuable elements missing
	Suboptimal ambient conditions	1	Bad lighting, distracting workflow/electronic/human sounds
Organization (n = 46)	OR resource mismanagement	0	Inadequate resource allocation, support services unavailable
	Safety culture deficiencies	10	Inadequate risk resolution, unsafe staffing
	Perioperative process failures	1	Inaccurate documentation, incomplete information
	Suboptimal policies/procedures	35	No safety check, failure to standardize, no cover when absent
	Ineffective staff management	0	Staff change, traffic
	Inadequate provision of training	0	Inadequate training provided
External environment (n = 0)	Latent external threats	0	Budget constraint, regulatory process

false. Surgeons also often assumed that other team members, and the anesthesiologists in particular, could clearly hear the surgeon asking questions or giving directions. During the debriefings, surgeons came to realize this was usually not the case. Directions got lost in the chatter, and noises generated by equipment in the OR. Team members realized that the closed-loop communication technique—which was often not followed—deserves to be respected to avoid miscommunication.

Safety and Reliability Issues

Risks to the sterile field were discussed, such as the surgeon holding the instrument under the armpit during a quick instrument change, instead of handing it over to the scrub nurse. As a result of the debriefing, this particular surgeon became aware of this and changed her operative setup. They decided that, in the future, the scrub nurse should actually stand on the right instead of the left side. This was believed to result in a more efficient workflow and better teamwork, subsequently reducing chances of severing sterility.

During the debriefings, it was repeatedly noticed that the team did not report a monitor malfunction to the technical staff. This resulted in a recurring sterile field breach every time the monitor "ran away," thereby accidently touching the sterile drape. No one felt responsible enough to report the malfunction, because there was no protocol indicating who is actually responsible for reporting faulty equipment.

Team Effectiveness

Irrelevant chatting by the surgical team was discussed. The anesthesia team members felt that, in general, this was a positive thing because it was interpreted as a sign that the surgeons are "relaxed, not stressed, and that the procedure is going according to plan." However, sometimes the anesthesiologist was actually rather bothered by the noise. It became clear that when there was irrelevant relaxed chatter, it was more difficult to filter out and hear the surgeon's questions amid such chatter. This was not always expressed. Nevertheless, surgeons noted that there was sometimes "tension on the line," without understanding the reason for it.

Another discussed event was the fact that surgeons proceeded with surgery while, upon their request, the anesthesiologist was

tilting the operating table. Anesthesiologists commented that he or she would always say out loud; "I am moving the table up/left/right/down," but was unable to view the monitor showing the laparoscopic field while doing so. Anesthesiologists realized that it was simply assumed by them that if the surgeon does not respond, it is safe to move the table. However, this was not always the case.

The final count of the gauzes, before the sign-out procedure, was also repeatedly discussed.[1] The scrub nurses commented that this is often a "chaotic phase" because the surgeons are closing up the abdomen often asking for assistance of the nurse, who is then in the middle of completing the count. During the debriefings, the team realized this was an unrecognized issue. The nurses commented they appreciated this recognition and would prefer to have a short "pause" during the count. Nurses also realized they need to ask for such a "time out" actively, as, otherwise, it is likely not to happen.

DISCUSSION

This structured analysis of 35 laparoscopic cases using audiovisual data from the MDR outcome report revealed that both resilience support events and safety threats most frequently originate from interactions between persons and are not so much related to organization or environment. During the multidisciplinary debriefing sessions, the team most often discussed events related to communication and situational awareness, also both factors associated with persons according to the SEIPS model.[15]

Effective communication is a strong predictor of good teamwork.[9,38] The results of this study may once again highlight the importance of clear communication in the OR.[5,9,39] These results are in line with the other studies that used video recording in the OR, also demonstrating that, in most cases, communication was the root cause of adverse events.[26,40,41] Debriefing in surgery seems to be vital, as it was only during the postoperative debriefings that the team members realized the important impact of miscommunication. The debriefing discussions showed that safety threats regarding miscommunication were often caused by incorrect assumptions between the OR team members. Indeed, it has been demonstrated that team debriefing can drive the quality improvement process by identifying and, most importantly, addressing recurring, new, or unrecognized safety issues.[42,43] Moreover, especially those who work in a hectic environment might be the ones who benefit from regular feedback on their work, because without feedback, improvement will not occur.[42,44]

Traditionally, OR teams are hierarchical and divided by role, which often discourages team members to speak up to or confront a surgeon.[45,46] However, participants in this study indicated that debriefing provided them with the opportunity to "speak up" more easily. Other factors perceived to prevent a person from speaking up have been examined in many fields outside of health care, including psychology, business, and aviation.[47] Cultural, professional, and organizational factors predispose people to avoid speaking up and are often the final barrier to an adverse event in the making.[47–49] Speaking up to raise concerns about a perceived safety threat or behavior may therefore have a direct and preventive effect on adverse outcomes.[48,50]

Team members also indicated that participating in the debriefings made them feel "more valuable" and "part of the team." This may have a positive impact on the personal well-being of the team members, job satisfaction, and organizational commitment.[51–53] Promoting these human factors is key when it comes to improving team performance and hence safety culture.[51–54]

The evidence on the impact of the team's skills on patient outcomes is still limited, as it is difficult to analyze these factors with traditional research methods.[26,55–57] Objective multisource data is needed.[26,55] Video recording surgical procedures using an MDR is therefore believed to have multiple benefits.[58–60] The complex interactions between the clinicians and their environment can be captured at a level of detail that exceeds the capability of human observers and surpasses their level of objectivity.[61–63] Ongoing research is recommended to improve the AI algorithms for this purpose.[19] Consequently, other healthcare professionals are also taking advantage of the use of video recording in and outside the OR.[60,62,64,65] These innovative systems are likely to significantly enhance our understanding of the complex web of factors at play and their effects on patient outcomes and safety.[26,52] Future studies are needed to evaluate the feasibility, deployment, and generalizability of such AI-based systems across different operating environment settings.[20,21]

By evaluating qualitative observational data through debriefing and discussion, rather than by independently rating performance using the Likert-type scales of typical existing global rating tools, a more nuanced understanding of events may be gained.[66] Simply describing "errors" committed in surgery and reporting their frequency do not appropriately capture the complex, independent factors surrounding intraoperative events.[48,53] Explicit clarification is necessary. To this end, team debriefing may be applied as an approach to improve patient safety.[26,42,67]

This study has some limitations. It is important to stress that implementation of such a novel system, whose impact on workflow is not yet understood or investigated before, requires a strict implementation plan, usually starting with qualitative research. For that, this was a pilot study with a limited sample size. It was not possible to identify a trend or reduction in safety threats. Nevertheless, capturing and discussing these safety threats in debriefing in itself may be considered of value to patient safety, if done in a structured manner.

Second, the operating team members were the focus of this quality improvement pilot study.[28] The patient data and postoperative outcomes were therefore not included as an outcome parameter of this study. The reason for this was also to protect the privacy and safety of all study participants, according to the latest data and privacy protection regulations.[29] As such, no correlations between number of safety threats or resilience support events and patient outcomes or clinical end points were made. Now that a baseline has been set, future studies are needed to assess the (in)direct positive impact of a possible reduction of safety threats on patient outcomes.

Third, even though the events were labeled according to a validated framework, it may still be biased by subjectivity. As example, "substandard technique" may have been labeled incorrectly, as surgical techniques may differ among surgeons and centers. Hence, the term "substandard" may be disputable. Nevertheless, machine learning and AI software is currently being used to continuously improve and optimize the analysis of the MDR, customized per center.[31,68]

Lastly, results may have been influenced by the Hawthorne effect, meaning unintentional change of behavior or productivity in response to the presence of an "observer."[69,70] However, the video recordings were made with surveillance cameras that were already mounted into the OR ceilings. This nonobstructive setup for observation is likely not to attribute much to a possible Hawthorne effect, as one usually forgets a camera when it is not disturbing one's activities.[28,71]

To date, the OR Black Box user network has grown to various other medical centers worldwide.[72] Our center intends to install the new OR Black Box system—updated with improved AI and machine learning software—in multiple ORs to continuously record and analyze surgeries.[35] New research lines will be started and will focus on change of safety behavior (i.e., team debriefing

and training), how to build stronger teams based on the identified safety threats (e.g., human factors, distractions, equipment failure), and its impact on patient outcomes. Indeed, scheduling the multidisciplinary debriefings, with an independent facilitator, for such an amount of consecutive surgical cases, and with so many different team members proved to be a challenge.[28] In the future, it may be recommended to invite staff working in the OR to participate in about 1 to 3 team debriefings per year to continue evaluating safety behavior and culture. In the successor project, this issue ought to be evaluated and how to sustainably implement this quality and safety improvement initiative.

CONCLUSIONS

Relevant surgical safety threats identified using the human factors model were most often originated from the interaction between team members. Postoperative structured multidisciplinary debriefings using innovative technology, such as an MDR, may help facilitate better teamwork, situational awareness, and communication. To create an even safer operating culture, educational and quality improvement initiatives should aim at training the entire operating team and consequently creating a shared mental model regarding preventing patient safety threats.

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Statement of ethics: Every team member had given his/her formal written informed consent before the start of the procedure.[28,29] The project was approved by the Works Council and Hospital Board of Directors. To address all ethical considerations, a Privacy Impact Assessment was conducted. This made sure the study was compliant with all applicable privacy, legal, and regulatory requirements.

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