A BLACK BOX IN THE OPERATING ROOM

TAKING THE NEXT STEP TO IMPROVE SURGICAL QUALITY AND SAFETY

Anne Sophie H.M. van Dalen

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PhD Thesis, University of Amsterdam, the Netherlands

ISBN: 978-94-6458-039-6
Lay-out and cover design: M.L.A.J.F. van Dalen and A.S.H.M. van Dalen
Printed by: Ridderprint I www.ridderprint.nl
Printed on recycled paper

Printing of this thesis was financially supported by the International Centre for Surgical Safety (St. Michael's Hospital), the Department of Surgery (Amsterdam UMC, location AMC), AMC Medical Research B.V., TMI and Chipsoft.

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ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad van doctor

aan de Universiteit van Amsterdam

op gezag van de Rector Magnificus

prof. dr. ir. K.I.J. Maex

ten overstaan van een door het College voor Promoties ingestelde commissie,

in het openbaar te verdedigen in de Aula der Universiteit

op vrijdag 18 februari 2022, te 14.00 uur

door Anne Sophie Helena Maria van Dalen

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Voor M.A. Talboom – van Giezen,
omdat alles altijd anders loopt dan je denkt

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GENERAL INTRODUCTION, AIM AND OUTLINE OF THIS THESIS

RATIONALE

In 1991, the Harvard Medical Practice study found that serious adverse events occurred in 3.7% of the hospitalizations (30121 patient records from 51 New York hospitals). Of these adverse events, 58% were attributable to error (i.e. preventable) and of this fraction, 13.6% resulted in death.[1] In 2000, the American Institute of Medicine's Committee on Quality of Healthcare published the To Err Is Human report with the main theme "How can we learn from our mistakes?" Only following this report, patient safety became a focal point for reduction of preventable errors in healthcare.[2,3] Since then, healthcare is increasingly focusing on improving safety and quality, resulting in an increased number of studies reporting on adverse events.[3-6] Nearly two decades after this notorious report, the World Health Organisation (WHO) showed data from European Union Member States, consistently suggesting that medical errors and healthcare related events occur in 8% to 12% of hospitalizations. Both a Dutch and Canadian study confirmed that a majority of the adverse events were related to surgical procedures.[7,8] Studies originating from different kinds of developed countries have showed that 14.4% of surgical patients experience adverse events, and more than one third (37.9%) of all surgical adverse events were regarded as potentially preventable.[9] On top of that, Makary et al. suggested that medical error is even the third leading cause of death in the United States.[10]

Despite insights resulting from before mentioned studies and efforts aimed at improving surgical patient safety, the incidence of preventable in-hospital medical errors is still too high. The delivery of safe surgical care is however extremely complex. The WHO has therefore made the reduction of surgical errors one of its primary goals.[6] By now, multiple factors have been identified that may influence patient safety and surgical outcome. These may include the surgical team, social interactions, technology, organizational and environmental factors, patient characteristics, and the complexity of the procedure itself.[11] Human factor failures, such as teamwork, communication, organization and distractions have been identified as major underlying causes for surgical adverse events.[12-14] Subsequently, the first steps towards preventing those adverse events should be about acknowledging, analysing, and understanding common error-event patterns.[15,16] For this, insights from actual situations within the environment are needed. The use of technology could support in preventing adverse events, but sustainable technical and innovative interventions to do so are still in their infancy. However, implementation of such quality and safety improvement innovations is challenging and bound by existing cultures, legislation and beliefs.[17] Indeed, safety behaviour may be influenced by several factors that need to be taken into account, such as believe in certain safety improvement outcomes, believe that engagement will actually lead to improved surgical safety, and the shared perception of the importance of safety improvement.[18,19]

LESSONS LEARNED FROM THE AVIATION INDUSTRY

History of aviation safety

The mythical Icarus died flying too close to the sun, which melted the wax that held the feathers on his wings together, the wings failed and he plummeted into the sea and drowned. He failed, due to his young man's arrogance or disobedience in not listening to his instructor father. His father Daedalus, avoided going close to the sun and flew all the way from Crete to Sicily, making this the first pilot error and accident investigation ever recorded.[20]

The first ever human flight was executed in 1903 by the now famous Wright brothers. It lasted just 12 seconds. Yet, by the end of 1905, they were flying figure-eight's over Huffman Prairie, staying aloft for over half an hour, or until their fuel ran out. It took the brothers a few crashes before the secret of building better flying machines was revealed to them, but only 2-years later, in 1905, the Wright Flyer was the world's first practical airplane.[20,21]

In 1910, Charles Rolls (Rolls-Royce Company), flew across the English Channel and back, his Wright Flyer's stabilizer broke off and he was the first man to die in a British air accident.[22] As a consequence, the British government enacted the Aerial Navigation Act that year, not for the safety of the aviator but for the purpose of protecting the public from danger.[23] In 1912, the Royal Aero Club of the United Kingdom (members were wealthy sportsmen wo raced cars, sailed the America's Cup and Skied the Cresta Run at St. Moritz) became interested in why accidents occurred and established a Public Safety and Accidents Investigation Committee. On May 13, 1912, the Aeroclub investigated the accident of a Flanders Monoplane that crashed at Brooklands Racetrack. This was the first accident to be published. Copies of the report went into widespread circulation and formed the basis of all British and Canadian accident reports in the future.[20] When the First World War began in the summer of 1914, governments considered aircraft pilots not to be circus performers anymore, but spies in the sky. Because of the war, aviation and consequently safety, matured almost overnight. First, the only instrument the pilot had was his wristwatch to measure flight times for navigation and fuel consumption. By 1915, other instruments started to appear in the cockpit, such as a compass, a tachometer, fuel and oil pressure gauges, and on experimental basis a radio. In 1915, the Royal Flying Corps (RFC) formed an Aircraft Inspection Department, dedicated solely to accident investigation. Post-war, the hearts and minds of the public, government and investors had to be convinced that flying was actually a safe, reliable and even a profitable mean of transport. Consequently, the war brought standard operating procedures and most importantly, pilot training.[20] To date, more than 100.000 flights a day, well and truly, are safely executed. If you consider non-commercial flights, that will be about 50 million flights per year. The chances of a plane being involved in a fatal accident is now one in 16 million. The year 2017 was the safest year for aviation ever, which reports only two fatal accidents, both involving small turbo-prop aircraft, with a total of 13 lives lost.[24,25] The safety levels that civil aviation has achieved over this short period is remarkable and almost impeccable.

History of the aviation black box

The aviation industry (flight and cockpit data recorder), offshore oil platforms and maritime transport (voyage data recorder) have been successfully using Black Boxes and mechanisms to proactively analyse suboptimal situations and 'errors' for quite some time.[26] Cockpit voice and data recorders, were originally developed between 1930 and 1950 to monitor the testing of experimental aircrafts. Today's solid-state data recorders store thousands of perimeters, few of which will ever be used in actual accident analysis. Most help schedule maintenance, anticipate technology failures, and optimize system performance. Voice recordings are now added and continue to provide a view into the

Figure 1. A flight and cockpit data recorder is actually orange (source: KLM)

human element of an event. Since 1995, recorders have also become the norm for rail and bus transport, and even private automobiles, as most new cars are now equipped with a downloadable Event Data Recorder linked to the car's airbag system.[27]

When the black boxes were first introduced in the airline industry, the idea was not well-received by the airlines. Pilots rejected the concept, fearing that these black boxes might be used to spy on crew. Pilots insisted that "no plane would take off with Big Brother listening." The Royal Australian Air Force further commented that "such a device is not required" and that "the recorder would yield more expletives than explanations."[28] Nevertheless, within a few years these "black boxes" were commercialised and by the late Sixties the device was a requirement in all civilian passenger-planes worldwide.[28] In these industries, black boxes have now been embedded in legal and operational frameworks where they function optimally and generate true value.[29]

Human factors in the operating room

The term "human factors" is used to describe the environmental, organizational, and job factors, in addition to the human and individual characteristics. Human performance can be affected by many factors such as circadian rhythms, state of mind, physical health, attitude, emotions, propensity for certain common mistakes, errors and cognitive biases.

Human errors in the operating room may influence the occurrence of errors that include medication errors, procedural errors and errors in execution.[30]

In the aviation industry, the role of human factors (situational awareness, decision making, communication, teamwork and leadership) in flight safety has been identified in the 1970s through analysis of data from cockpit voice recorders and flight data recorders after severe accidents. Analyses showed that human factors were the root cause in over 70% of accidents.[31] Human factors have become increasingly recognized as root causes in adverse outcome and patient injury or death related to surgical procedures. Fabri et al.[32] also demonstrated that human error is the leading cause of surgical error. In a recent report of sentinel event data between 2004 and 2014, the Joint Commission analysed 845 major peri- and postoperative complications and confirmed that human factors (63%), communication (53%) and leadership (41%) failures were the root cause of major loss of function or even death.[12]

Communication

Communication is "the exchange of information between a sender and a receiver." In the operating room, multiple individuals communicate simultaneously, hence it is one of the most studied and most critical human factors in medicine.[33] In the Safe Surgery Guidelines, the WHO has emphasised the need for effective, open and clear communication to improve the safe conduct of surgical procedures.[6] Regardless, miscommunication during surgical procedures still occurs frequently and has been implicated as one of the major causes of error and adverse outcomes in general surgery.[17,34] Moreover, communication skill has been measured as one of the worst aspects of team behaviour in the operating room.[17] Yet, miscommunication has multiple etiologies and therefore improvement initiatives need a multipronged approach.[33]

The aviation's well described cockpit resource management principles state that good communication principles are as follows; all team members should address one another directly by their name and the closed-loop communication technique should be used. Closed-loop communications means that the receiver repeats the message to ensure avoidance of miscommunication.[35]

Teamwork

Teamwork and safety culture, have been identified as key ingredients to the delivery of safer surgical care.[36 37] Teamwork is defined as the collaborative effort of a group to achieve a shared goal.[38] Culture is defined as the assumptions people hold about relationships with each other and the environment that are shared among an identifiable group of people (e.g. team, organization, nation) and manifest in individual's values, believes, social behaviour norms and artefacts.[39] The impact of cultural differences and safety attitudes on teamwork has been recognized.[37,40]

The operating room is a unique high-stress environment with different professionals roles and genders, whose goals and training differ widely but who are regardless required to work closely together.[41,42] For good teamwork, it is hence important to ensure a shared mental model, by creating an environment in which the entire team knows what is expected and what by each member of the team is found important.[43,44] Nevertheless, previous research has demonstrated that operating room staff may have discrepant attitudes concerning the teamwork they experience with each other, which may be the result of differences in status or authority, responsibilities and cultures.[43,45]

Situational Awareness

As explained by Graafland et al.[46], situational assessment results from a multitude of information sources in the modern operating theatre. The perception of reality of the team is not always accurate, which is caused by cognitive, communication, teamwork and environmental factors.[46] Situational awareness can be viewed as the product of an individual's perception and comprehension of the available information, and expectations towards the future course of the procedure.[47] It may occur at both individual and team level, both relying heavily on teamwork and communication.[48] In conclusion, the team's situational awareness emerges from coordination and communication between all members of the operating team.[41,48] This is best described by Endsley's model as shown in Figure 2.[46]

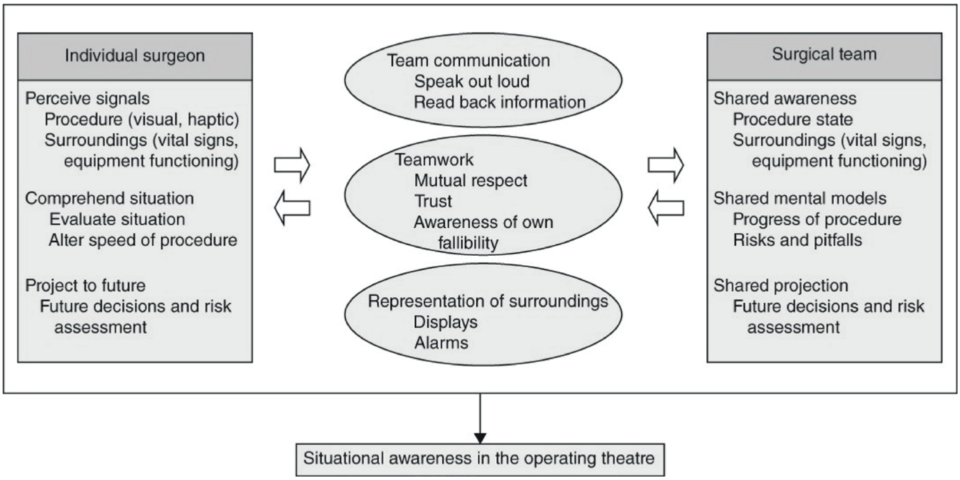

Figure 2. Individual and team factors influencing situational awareness in the OR.[46]

Cockpit resource management training

The foundation of crew resource management training are usually traced back to the Resource Management on the Flightdeck workshop, sponsored by the National Aeronautics and Space Administration (NASA) in 1979.[49] The research presented at this meeting identified that human error was the root-cause of the majority of air crashes and these where categorized as failures of interpersonal communications, decision making, and leadership. At this meeting, the Cockpit Resource Management label was applied to the process of team training to reduce “error” by making better use of human resources.[49] It considers human performance limitations (e.g. fatigue and stress) and the nature of human error, and defines behaviours that are countermeasures to error, such as leadership, briefings, monitoring and cross checking, decision making, and review and modification of plans.[50] This course evolved into what has become known as cockpit and then crew resource management (CRM). This training course is now required for flight crews worldwide, and data support its effectiveness in changing attitudes and behaviour and in enhancing safety.[50,51] Two important conclusions emerge from evaluations of CRM training: firstly, such training needs to be ongoing, because in the absence of recurrent training and reinforcement, attitudes and practices decay; and secondly, it needs to be tailored to conditions and experience within organisations.[50 52] It has now evolved from a focus on behaviour change to one dealing with more specific aviation concepts such as team building, briefing strategies, situation awareness, stress management, and decision making.[31] These training skills were adapted for acute medical care and the term crisis resource management was introduced.[31,53] Simulation-based CRM training has now become routine in anaesthesia, emergency medicine, critical care, as well as obstetrics and gynaecology.[54,55]

Surgical safety checklist

Substantial data exist regarding the impact of improving human factor skills, for example by using checklists, briefings and debriefings, coaching and simulation training.[46,56-58] Yet, the best way to go about improving the team's performance remains open for discussion.[59,60] Moreover, it appears that safety improvement initiatives are not easily sustained.[17,61] In 2007, WHO Patient Safety launched the Second Global Patient Safety Challenge, Safe Surgery Saves Lives, to improve surgical safety globally.[62] Anaesthesiologists, operating nurses, surgeons, safety experts, patients, and other professionals came together to develop a solution to the problem of unsafe surgery and introduced the WHO Surgical Safety Checklist.[63,64] As explained by the WHO, 'the WHO Surgical Safety Checklist (see Figure 3) is a simple tool to improve the safety of surgical procedures by bringing together the whole operating team (surgeons, anaesthesia providers and nurses) to perform key safety checks during vital phases of perioperative care: prior to the induction of anaesthesia, prior to skin incision and before the team leaves the operating room.'[62]

The first results concerning the use of this checklist in eight hospitals around the world was associated with a reduction in major complications from 11.0% before introduction of the checklist to 7.0% afterward.[65] This awareness has led to the development of the Surgical Patient Safety System (SURPASS) checklist, which was tested in six Dutch teaching and academic hospitals. Its use was associated with a reduction in the postoperative complication rate from 27.3 per 100 patients before implementation to 16.7 per 100 afterward and a reduction in in-hospital mortality from 1.5 to 0.8%.[66]

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1 / 2009 © WHO, 2009

Figure 3. The World Health Organization Surgical Safety Checklist

SURGICAL ADVERSE EVENTS IN THE OPERATING ROOM

Definitions

An adverse event is usually defined as "an unintended injury or complication resulting in harm that is caused by medical management error, the failure of a planned medical action to be completed, or any deviation from usual medical care that poses a risk of harm."[1,2,9] Adverse events are usually not the result of individual failure, but the consequence of an uninterrupted chain of events and decisions, spanning multiple phases of surgical care.[67] Active failures are the unsafe acts committed by people who are in direct contact with the patient or the system. Latent conditions are inevitable within the system. They arise from decisions made by designers, builders, procedure writers, and top level management. Such decisions may be mistaken, but they need not be.[67] Professor dr. Charles Vincent, one of the world's pioneers in patient safety, has identified the key patient safety terms

Table 1. Patient safety terms and their definitions by Vincent.[19]

Patient Safety Term	Definition
System	A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.
Safety	"The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare."
Hazard	Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.
Error	The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning).
Latent error	A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed.
Event	Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm.
Adverse Event	Unintended injury related to medical management, in contrast to complications of disease, that is serious enough to result in disability, death, or prolonged hospitalization.

and their definitions, as presented in Table 1.[19]

Type o f errors

There is consensus that both technical and non-technical errors should be recognized and prevented with appropriate educational interventions.[68] Non-technical errors are related to non-technical skills or human factors such as decision-making, communication, and leadership.[69]

Technical errors can be defined as manual errors of the surgeon (e.g. damage to adjacent structures) or anaesthesiologist (e.g. incorrect insertion of the nasogastric tube) and procedural errors due to lack of proficiency or experience.[13,70] Technical errors are distinct from technical events; a technical event is the damage or injury that can result from a technical error. While not all technical errors lead to technical events (e.g. a foggy laparoscope camera), the identification and root cause analysis of technical errors is critical for preventing the occurrence of technical events, for mitigating the likelihood of postoperative complications and adverse outcomes, and to improve surgical performance.

Operating environment

A human factors approach recognized that human error is often the result of a combination of both individual surgeon factors and work system factors, such as equipment used and for example communication between the team when this equipment malfunctions.[14] "Environment" is defined as "the circumstances, objects, or conditions by which one is surrounded". In the operating room, the environment comprises the physical space, the equipment, and the people (staff and patient). Ergonomics is defined as "an applied science concerned with designing and arranging things people use, so that the people and things interact most efficiently and safely". [17 71]

Even though most surgeons have become impervious to the complexity of the operating environment, there are numerous environmental factors that could potentially affect surgical performance and therefore patient outcome. These factors could include, layout, presence and flux of personnel and ambient factors such as noise, lighting and temperature.[14,17] Operating room layout and noise have received most of the attention in the literature; however other factors could be important as well. Dankelman et al.[72] showed that not only interaction between surgeon and staff, but also surgeon-instrument and staff-technology interaction need to be addressed in causal analysis of adverse events. Thereupon, to reduce human errors, not only the human but also the system should be approached.

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AIM AND OUTLINE OF THIS THESIS

The aim of this thesis was to implement the OR Black Box®, a video- and medical data recorder, in the operating room (OR). The OR Black Box (ORBB) was designed as a data-driven quality improvement initiative. It records a medical surgical procedure and generates an outcome report based on events regarding technical and non-technical skills. The outcome report was then used for multidisciplinary debriefing. This thesis will evaluate the implementation process, the outcomes of the debriefings, and factors that may contribute to improving surgical quality and patient safety in the operating room.

Part I: Implementation of the OR Black Box in the operating room

The first part addresses the important aspects, pre-requisites, and hurdles of the implementation of the ORBB. It investigates the important gaps in the current literature towards implementing postoperative team debriefing with the use of a ORBB and its outcome report. In **Chapter 1** the medicolegal and privacy perspectives on the use of video- and medical data recorders in the operating environment are evaluated. Lessons learned from the aviation safety system perspective are evaluated as well. The key dimensions and our practice recommendations concerning legal implications are presented. **Chapter 2** provides an overview of the current medical literature regarding debrief methods and models that could be of value to use for post-operative video-assisted team debriefing. A true debriefing culture in surgery is lacking to date. At the start of this project no debrief model fit for use with any video- and medical data recorder existed. We therefore developed a standardized debrief model to be used for the ORBB debriefings.

Part II: Increasing transparency in the operating room

The second part investigates the use of the ORBB, its performance report, and the standardized team debriefings to create more transparency in the OR and support the participating members in doing so. Overall, the results of the Transparency in the Operating Room (TOPPER) trial are presented. In **Chapter 3** the satisfaction of the participating operating team members regarding the use of the ORBB and its performance report for team debriefing is evaluated. **Chapter 4** assesses the outcomes of the performance reports and the debriefings. Common safety threats and resilience support events identified by the ORBB are described. Notes from the discussions around these events during the team debriefings are evaluated. Lessons learned by the team and what to improve regarding non-technical skills is highlighted.

Part III: Improving surgical quality and safety in the operating room

The third part elaborates more on the intraoperative factors that either threaten patient safety or support system resilience during general laparoscopic surgery, as highlighted in Chapter 3 and 4. In **Chapter 5** the perceptions of the team members concerning human factors, such as communication and situational awareness in the operating room is assessed. Differences in those perceptions are evaluated.

In **Chapter 6** the importance of certain communication skills, like the closed-loop technique, in the operating environment are discussed. The implementation of the use of name stickers in the operating complex is evaluated. **Chapter 7** evaluates the attitudes of the various healthcare professionals working in the operating room towards our patient safety culture. And, the impact of participation in the Black Box team debriefings on their safety behaviour.

Part III: Future use of the OR Black Box in the operating room

Finally, perspectives on the future of the use of the ORBB are demonstrated. The ORBB collects complex big data sets to reveal patterns, trends, and associations, especially relating to human behaviour. Big data has the potential to become progressively useful in both guiding surgical care and optimizing workflow and clinical patient outcomes, if handled well. The ORBB system uses artificial intelligence (AI) and machine learning software to handle big data collection and analysis, as traditional data processing techniques are not able to handle these vast amounts of complex data. AI has just now made its introduction into medicine, and even more recently, into the OR. In **Chapter 8** the current applications of AI inside the OR are systematically reviewed and presented.

In **Chapter 9** the importance of focusing on improving the safety culture to reduce errors in the OR is highlighted. Therefore, the Six Sigma strategy is introduced and how to follow this with the use of the ORBB to create an even safer culture in the OR.

PART I

Implementation of the OR Black Box in the operating room

CHAPTER 1

Legal perspectives on black box recording devices in the operating environment

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British Journal of Surgery. 2019
doi:10.1002/bjs.11198

ABSTRACT

Background: A video and medical data recorder in the operating theatre is possible, but concerns over privacy, data use and litigation have limited widespread implementation. The literature on legal considerations and challenges to overcome, and guidelines related to use of data recording in the surgical environment, are presented in this narrative review.

Methods: A review of PubMed and Embase databases and Cochrane Library was undertaken. International jurisprudence on the topic was searched. Practice recommendations and legal perspectives were acquired based on experience with implementation and use of a video and medical data recorder in the operating theatre.

Results: After removing duplicates, 116 citations were retrieved and abstracts screened; 31 articles were assessed for eligibility and 20 papers were finally included. According to the European General Data Protection Regulation and US Health Insurance Portability and Accountability Act, researchers are required to make sure that personal data collected from patients and healthcare professionals are used fairly and lawfully, for limited and specifically stated purposes, in an adequate and relevant manner, kept safe and secure, and stored for no longer than is absolutely necessary. Data collected for the sole purpose of healthcare quality improvement are not required to be added to the patient's medical record.

Conclusion: Transparency on the use and purpose of recorded data should be ensured to both staff and patients. The recorded video data do not need to be used as evidence in court if patient medical records are well maintained. Clear legislation on data responsibility is needed to use the medical recorder optimally for quality improvement initiatives.

INTRODUCTION

The number of healthcare professionals using an audio, video or complete data recorder in the surgical environment, sometimes referred to as a medical data recorder (MDR) or 'black box', is increasing.[1–3] An MDR is able to record operational data (for example from overview cameras, laparoscopic cameras, anaesthetic and environmental equipment), enabling analysis of technical and non-technical elements.[4] It provides theatre staff the opportunity to learn from their performance or suboptimal situations to enhance team performance.[5–11] Surgical procedures may be recorded for purposes of education, research and quality improvement.[3,12] Although this has been associated with a reduction in errors, there are concerns about the adequacy of implementation related to privacy, ownership of data and medical negligence.[4,8,10,13,14] Understandably, medical practitioners fear that an MDR could be misused for punitive or controlling purposes, a situation that inevitably leads to scepticism, user resistance and loss of autonomy.[7,13,15] These very real medicolegal concerns are hindering the optimal use of the MDR.[3,5]

Other high-risk industries such as aviation (flight data recorder), offshore oil platforms and maritime transport (voyage data recorder) have used black boxes to analyse suboptimal situations and errors for quite some time16. In these industries, they have been embedded in legal and operational frameworks that are sorely lacking in the surgical environment.[7,17] This study reviewed the privacy law concerns, medicolegal considerations and universal legal requirements regarding MDR use.

METHODS

A comprehensive search for peer-reviewed literature published in the past 10 years (January 2007 to December 2018) was conducted using the PubMed and Embase databases and the Cochrane Library. The following search terms were included: video recording, operating room, theatre, endoscopic, medicolegal, legislation, ethics and law. Non-English and non-Dutch publications were excluded. The exact search algorithms can be found in Appendix S1 (supporting information). The articles reviewed comprised a broad range of methods, including mainly descriptive, opinion or narrative reviews. For this reason, no attempt was made to grade the levels of evidence systematically or to undertake a statistical analysis.[18]

In addition, jurisprudence on the topic from North American and European jurisdictions was searched for to find examples of medicolegal cases in which video recordings were used as evidence.[19,20] A professor of health law at the University of Amsterdam collaborated in this study, to ensure correct interpretation of the legal literature.

RESULTS

The literature search yielded 95 citations from the PubMed database, no review citations from the Cochrane Library and 26 from Embase. After removing duplicates, unrelated fields, abstracts without full text and non-relevant papers, 20 manuscripts were included in the review (Figure 1).

In 2016, one MDR was installed in an ENDOALPHA operating suite (Olympus Europa, Hamburg, Germany) in the Amsterdam University Medical Centre.[4,21] It has since been used to record selected laparoscopic abdominal procedures. This recorder is able to capture a multitude of data streams (overview cameras, laparoscopic camera, microphones, anaesthesia monitor). Procedures were recorded between the time-out and sign-out time stamp of the surgical procedure.[22,23] These recordings were analysed by a specialized trained team in Toronto, Canada.[4] The performance report generated was used as a tool for structured postoperative team debriefing.[24,25]

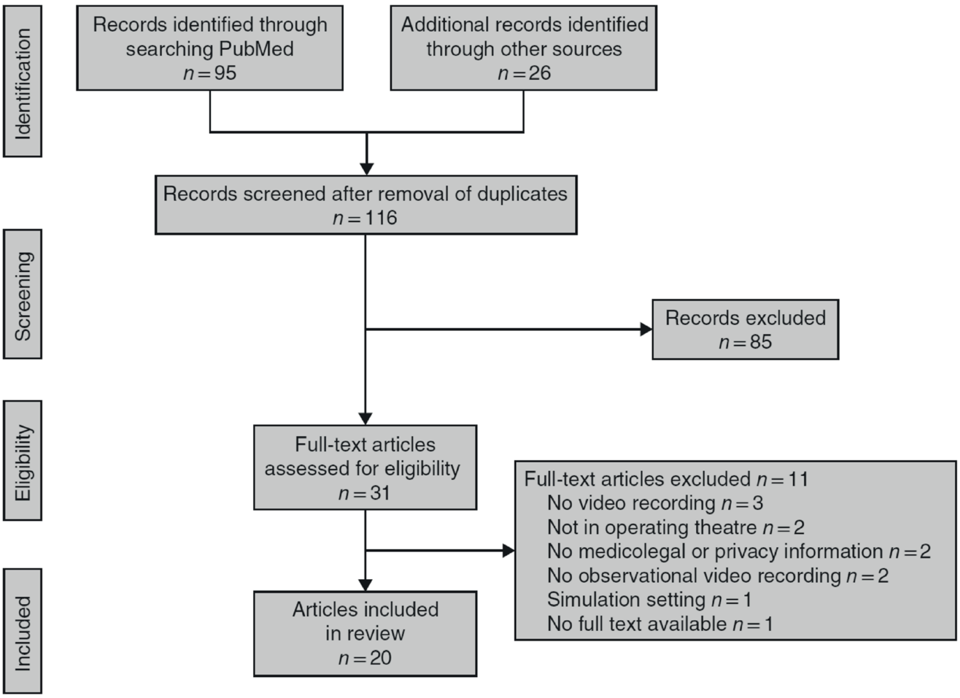

Figure 1. Flow chart showing selection of articles for review

Aviation safety system perspective

The safety initiatives of the aviation industry have been compared with those of healthcare.[15,26,27] Following a series of high-profile crashes that threatened the sustainability of the passenger jet industry, the National Aeronautics and Space Administration (NASA) research community and regulatory industries led investigations in the 1970s28. Since then, as part of joint NASA and Federal Aviation Administration (FAA) initiatives, behavioural science researchers have scrutinized tens of thousands of simulator and live flights. These recognized human performance as factors in aviation safety.[29–31] 'NASA now operates an Aviation Safety Reporting System (ASRS) that offers the incentives of anonymity and immunity to pilots who report an unsafe situation within 10 days of its occurrence.[26] All identifying information in the report is then removed before the incident is investigated and any lessons are publicized.' Later, if the FAA attempts to take punitive action against those involved, the ASRS reference number provides evidence of a constructive safety attitude, such that penalties are not imposed (provided that the mistakes were inadvertent and did not constitute a criminal offence).[26]

Safety management system requirements have also been introduced into European Union (EU) law. The European aviation safety system is based on a comprehensive set of common safety rules, which are overseen by the European Commission, the European Aviation Safety Agency and the National Aviation Authorities. These rules are directly applicable to all EU member states.[17] In addition, the EU has regulated the reporting, analysis and follow-up of aviation safety threats.[32] The current legislation sets out how relevant safety information relating to civil aviation is reported, collected, stored, protected, exchanged, disseminated, analysed and acted upon.[17,33]

The aviation industry holds Six Sigma (nearly perfect) safety records, because it uses the system approach, deals with errors non-punitively yet proactively, and reduces the consequences of error before escalation.[28,34–36] This way of reporting and managing error results in a 'just culture', where aviation professionals feel confident to report events (even their own mistakes), by promoting balanced accountability for individuals and organizations responsible.[17] This is a critical ingredient to the creation of a safety culture.[37] Other high-risk industries have adopted this philosophy, accepting that human error is both inevitable and ubiquitous.[36] The medical profession has incorporated some of these safety lessons.[30,31,38]

In the past few years, the number of patients harmed by medical error has gained public attention. Some of these mishaps have reached unsatisfactory conclusions for all involved parties.[31,39] The medical profession traditionally employs the personal approach, which acts as a disincentive to voluntary reporting, and inhibits the search for systemic conditions or triggers that lead to error.[40,41] These conclusions have resulted in several national and international guidelines and regulations, aimed at the broad implementation of safety systems that address human factors, such as teamwork and communication.[37,41,42]

Privacy perspective

The use of a MDR should conform to certain rules and requirements relating to the privacy of both the healthcare professional and the patient.[2,43] Throughout Western legislation, privacy laws relating to personal data, medical records and professional confidentiality apply to MDRs.[44–47] The new European General Data Protection Regulation (GDPR) took effect in May 2018. It was designed to harmonize all the data privacy laws across the EU.[48,49] It has a processing obligation that requires all individuals involved to be strictly and clearly informed about what happens to their personal data.[44,48,49] Researchers are respectively required to make sure that personal data collected from patients and healthcare professionals are used fairly and lawfully, for limited and specifically stated purposes, in an adequate, relevant and sober manner, and kept safe and secure and stored for no longer than is absolutely necessary.[47,50–52]

The privacy-by-design principle is of great importance, regardless of the country in which a project collecting medical data using an MDR is carried out.[48,53] According to this principle, the privacy of the users has to be taken into account from the very beginning of engineering the system, mainly by making optimal use of privacy-enhancing technical solutions.[54,55] Thus, video, audio and medical data related to healthcare staff should be anonymized as early as possible. This entails deidentifying the data (for example by voice alteration and image blurring), so that it cannot be linked back to the person.[56] The Health Insurance Portability and Accountability Act (HIPAA) in the USA, the Personal Information Protection and Electronic Documents Act in Canada and the GDPR in the EU require data protection with confidentiality and integrity.[57] Furthermore, they require that identifiable personal health information in any form, either electronic, written or oral, should be made available to patients.[3] As Henken and colleagues[43] state in their review, the distinction between information included in a patient record and information excluded from a patient record is therefore not as pronounced as in the EU. However, as in the GDPR, the HIPAA allows for the use of limited data sets (deidentified) for the purposes of research and quality improvement initiatives.[57]

In laparoscopic surgery, the patient's consent to the making of an intra-abdominal video could be included in the informed consent for the complete treatment, as it is used to perform the surgical procedure.[58–62] Consequently, only the laparoscopically generated video stream, but not the operating room overview video stream in which the theatre staff is visible, becomes part of the patient's medical record.[63] The GDPR data retention rule of thumb is 'as long as necessary, as short as possible'.[48] Data included in the patient's medical record must be accessible to the patient and stored for at least 5 years, depending on the country and state the patient is treated in.[64,65]

Medicolegal perspective

Data collected by MDR for the sole purpose of quality improvement and training of the operating team is not intended to be used for patient diagnosis, evaluation or treatment. The patient's medical record should only include information relevant to the patient's health and healthcare.[7,51,66] Thus, such data should not be added to patient's medical record nor handed over to the patient or their legal representatives.[3,7] This does not preclude the healthcare professional from reporting a calamity or a 'near miss' just as in an unrecorded surgical procedure. In the face of such an event, it is common for hospital protocols in North America and most European countries to require that the patient is informed of the situation as early as possible, and the incident clearly noted in the patient's medical record.[37,40,61,67]

In the case of a serious adverse event (a critical unexpected incident with the outcome severe injury or death) resulting in a lawsuit, a judge may decide to breach the legal protection of the healthcare professional by asking the institute for the video MDR data. However, reported cases indicate that in most jurisdictions judges are aware of the importance of protecting information that is collected for the sole purpose of quality improvement, and will breach this protection only if vital information is lacking in the medical record and cannot be retrieved in any other way.[7,44,68,69] However, even if video data have to be provided, various court cases have demonstrated that these recordings actually predominantly lend legal support specifically to the healthcare professional or surgeon.[43,70–76] An American medical malpractice claim showed that a surgeon could indeed prove, with the help of reviewing the videotape of the laparoscopic cholecystectomy in court, that the standard of care was not breached.[72] In a similar case, a Dutch urologist proved that he did not act negligently during the nephrectomy by showing the video recording of the procedure.[71]

Hoschtitzky and colleagues (London, UK)[70] demonstrated in their care report that the video recording provided supportive evidence of good practice and an open attitude to patient safety. With the help of the video recording, they were able to document all the surgical steps accurately and it allowed them to state confidently that no missing equipment was inadvertently left behind in the patient. On the other hand, in January 2016, a Dutch surgeon had a medical malpractice suit filed against him after a complicated cholecystectomy. He was unable to prove that he obtained the critical view of safety because he could not show the judge the video recordings. The surgeon was hence found guilty.[73] Besides that, when privileged information is used in court without justification, both American and European laws contain provisions that have consequences in favour of the unjustly accused.[37]

DISCUSSION

As is often the case with relatively new technology, legal guidelines on the use of MDRs are currently lacking. However, the general privacy principles are clear on how to design such a system and how to optimize conditions for use. Lessons are learned from the aviation industry, and the main issues that should be addressed are related to the privacy and legislation perspectives.

Patients may rely on professional ethics and best judgement in deciding which of the permissive uses of the MDR and disclosures the healthcare professional has to make.[57] Regardless of the national differences in legislation, the importance of the general privacy principles, to ensure clear consensus and openness between participants and researchers about the methods and purpose of the MDR, are to be highlighted.[2,56,77] Any possible information that might identify the patient or healthcare provider should either be blurred, scrambled or, whenever possible, removed as early as possible and not be reflected in the reporting output. Most importantly, as the patient is not the object of the study itself, patient identifiers should be removed. This means that written informed consent does not necessarily have to be obtained from the patients.[57,78,79] According to the general privacy rules, an opt-out option is sufficient and should be provided to the patient in a timely manner, with their decision clearly noted in the medical record.[3,5,80]
As far as the operating theatre staff is concerned, authors recommend that theatre staff, including medical students, are asked formally, upon embarking on such a quality initiative, to volunteer to work with the innovation.[62] An official informed consent stating the purpose of the data recordings, where the data recordings are analysed, what the expected benefits for the participants are, and how the data are stored securely may help in gaining support and momentum for the MDR initiative.[48,81,82] It should be emphasized that their safety and personal privacy is protected, ensuring full transparency of the methods used.[58,80,83–85] Based on this review and the authors' experience, an overview of the recommended practice and legal guidelines is presented in Table 1.

Informing patients about having a MDR that is used solely for the purposes of team debriefing may significantly contribute to the patient's trust, as most of them value this quality improvement measure. Regardless of this, healthcare professionals should not ignore the fact that, in time, society may shift towards favouring the idea that MDR-generated video and data recordings should be accessible to patients, next to the information that is already accessible via their medical record.[70,86–88]

Key dimension	Practice recommendations	Legal implications
What is the purpose?	Quality improvement, such as structured team debriefing or enhanced morbidity and mortality meetings. The purpose of data collection is for theatre staff to learn from what went well and what can be done better	It is important that the goal is clearly specified. When a MDR is used in the authors' centre, the patient is not the main focus of the initiative. The purpose is quality improvement of operating teams and workflow, or support of hospital quality safeguarding systems. Hence, the data are not required to be added to the patient's medical file. Only the laparoscopic camera footage is added and accessible to patient, in accordance with standard protocol
Who and what do the data cover?	The theatre staff is being recorded using audio and video during the surgical procedure; patient parameters on the anaesthesia monitor and the laparoscopic camera views are recorded. Other data sources considered to be of relevance may be added to the data set collected (door movements, room temperature, etc.)	Given that the purpose is quality improvement, patient consent may be assumed. The patient needs to be informed about planning of the operation by the surgeon and has the possibility to opt out without negative consequences (no delay in planning). The MDR is used as a quality improvement tool and so, if adequate safeguards are put in place, the hospital may state that the theatre staff is expected to participate
What about privacy and the privacy-by-design principle?	Recordings may initially collect, but not process, the patient's personal identifiers. The patient's personal identifiers need to be stripped from the file as soon as possible (deidentification). Faces of theatre staff need to be scrambled and voices altered. To protect the patient's privacy maximally, it is advised that their face and genitals are not recorded by cameras when this serves no purpose	General privacy principles must be respected Data are kept safe and secure, and stored for no longer than is absolutely necessary. The privacy of staff and patients needs to be taken into account from the very beginning by making use of privacy-enhancing technical solutions
Who is responsible for the data?	The hospital needs to assign a responsible person for the MDR. In trial settings, project coordinators and principal investigators are responsible for collecting the data and secure storage of the outcome report. In this case, the original data set (including video recordings) is sent immediately to the data analysis centre and, after it has been analysed, the pseudoanonymous outcome report is sent back. The original data are deleted, as the purpose of the original data has been fulfilled and the original data are no longer needed	An official agreement on confidentiality signed by the hospital directorate assures that the original and outcome data cannot be requested and used for any purpose other than that stated in the agreement Clear legislation is needed to make sure the inspectorate and other external parties cannot request the data
Which format should the data be in?	The original recordings are used for systematic analysis of the theatre team's performance. A performance report is created. Only the performance report, enhanced with video clips, is presented to the team. As soon as the performance report has been created (in this case within 48 h), the original data are deleted	The general privacy-by-design principles Data are used fairly, and for limited and specifically stated purposes in an adequate and relevant manner. The performance report is stripped of any identifiable information. To enhance privacy, the faces of theatre staff are blurred and voices altered

Table 1. Key dimensions, recommendations and legal guidelines on the use of a medical data recorder in the operating theatre.

In the future, society may decide to choose transparency over the medicolegal concerns of medical employees and demand full legal access for the patient to the information generated by MDRs.[4,85] In the USA, the state of Wisconsin[89] has already drafted legislation to allow patients to access video recordings of their surgical procedures. If future legislation were to support the position that the MDR should become part of standard care, and if the output should become part of the patient's medical record, healthcare professionals would be bound to work in a continuously monitored environment, where all results are accessible to patients. This may be an argument for organizations to start exploring optimal use of MDRs, which may secure optimal conditions for both patient and providers, as soon as possible.

In the authors' opinion, the fear that a MDR bears an increased risk of medical negligence litigation, limited performance or loss of professional status is unjustified, as long as good professional standards of patient medical record keeping and reporting of adverse events are maintained.[31,39,40,70,75,90] To help dissipate any remaining fear, resistance or doubt, the principal investigator of the MDR project can instigate an official agreement on confidentiality signed and supported by the hospital directorate. The researchers and the institute are, in accordance with the official agreement, bound to refuse the disclosure of any output obtained by the MDR.[77]

It is important to emphasize that, if a severe adverse event occurs, video recordings usually help rather than harm the healthcare professionals involved. The chain of (re)actions and decisions resulting in the unwanted event are better understood with the objective help of the MDR. MDR data may help in augmenting the analysis of a calamity or near miss when constructing a public calamity report. The data source itself is protected by law. Besides, if he or she has provided reasonable quality standard of care, no punitive measures can be imposed.[91–93] Nevertheless, several hospitals in the USA ceased video recording after receiving legal advice to do so, as a result of their medicolegal concerns and the introduction of the HIPAA in 1996.[3] Hospital administrators, especially in the USA, are often extra cautious, owing to an increasingly hostile medicolegal environment.[12] Plenty of court cases have demonstrated that video recordings actually lend legal support to the healthcare professional or surgeon.[70–76]

Healthcare professionals who are not well informed may also respond reluctantly to the use of a MDR, because they are afraid they will have to behave differently: 'Can I still play music, make jokes or use bad language?'. It is important to take this viewpoint into account as well. Differences in staff perceptions of good behaviour may exist among team members working in a high-risk environment for behaviour that unsettles the team.[94–99] Disturbing behaviour or even bullying in the operating theatre, such as inappropriate joking or degrading comments, usually goes unreported and is considered part of the job.[99–101] Team members may feel powerless to address certain behaviour while it is occurring.[96,102] The ultimate impact of these issues is poor teamwork and an increased risk of adverse perioperative events.[94,99,103–105] Being able to look back on shared performance in a safe, neutral and moderated setting may help all team members get a clearer perspective on the situation. Indeed, it may help healthcare institutions in the further development of a framework for dealing with disruptive behaviour. This would ensure a productive, healthy and safe working environment, which is focused on education and rehabilitation rather than punishment.[106] Systematic postoperative team debriefing using a MDR, led by an independent facilitator, may help in objective assessment of issues that have traditionally been ignored, creating an unique opportunity to discuss appropriate solutions with the entire operating team safely and respectfully.

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CHAPTER 2

Development of a model for video-assisted postoperative team debriefing

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Journal of Surgical Research. 2020

ABSTRACT

Background: Video-assisted debriefing may be a powerful tool to improve surgical team performance. Nevertheless, a true operating team debriefing culture is lacking to date. This study aimed to find evidence on how to debrief the surgical team and develop a model suitable for debriefing using a video and medical data recorder (MDR) in the operating room (OR).

Methods: A review of the PubMed and Embase databases and Cochrane Library was performed. The identified literature was studied and combined with a conceptual framework to develop a model for postoperative video-assisted team debriefing. Thirty-five surgical cases were recorded with an MDR and debriefed with the operating team using the pro-posed debrief model and a standardized video-assisted performance report. A questionnaire was used to assess the participants' satisfaction with this debrief model.

Results: Debrief models and methods are extensively described in the current medical literature. An overview was provided. The OR team needs a structured debrief model, minimizing resource, effort, and motivational constraints. A structured six-step team debrief model suitable for video-assisted OR team debriefing was developed. The model was tested in 35 multidisciplinary MDR-assisted debriefing sessions and the debriefing sessions were overall rated with a mean of 7.8 (standard deviation 1.4, 10-point Likert scale) by participants.

Conclusions: Debriefing surgical teams using a video and MDR in the OR requires a model on how to use such recordings optimally. To date, no such model existed. The proposed debrief model was tested using a multisource MDR and may be used to facilitate OR debriefing across various settings.

INTRODUCTION

Postoperative team debriefing has shown to be powerful in improving both technical and nontechnical skills such as communication, teamwork, and situational awareness.[1,2,3,4] Nevertheless, a true operating team debriefing culture is lacking to date.[2,5] Various reasons, such as fear for punitive measurements, a lack of time, or logistics are often mentioned.

Historically, debriefing originated in the military. It was designed to retrieve all the information from a soldier or pilot after a mission and also to return to regular duties as soon as possible.[6,7] Debriefing, the concept of reflection on an event or activity and subsequent analysis, has proven to be valuable in assessing the individual for personal and team benefits.[8,9,10] The terms debriefing and feedback are often used interchangeably in the literature, but there are important distinctions to be made between the two.[11] Feedback may be defined as information about performance provided to participants with the intent to modify thinking and behavior to facilitate learning.[12] Feedback is thus viewed as a one-way conveyance of information to the learner. Debriefing may be identified as a facilitated reflective conversation between facilitator and learner, among learners themselves, or a combination thereof.[12]

Video and medical data recorders (MDRs), more popularly referred to as Black Box, in the operating room (OR) may act as a tool instrumental to team debriefing. Such systems may become a powerful element in quality improvement initiatives.[3,4]
The importance of operating team debriefing, augmented with or without video recordings or other data sources, has been emphasized in the current medical literature.[3,13,14] Yet, there is no consensus to date on how to optimally structure the process of team debriefing with the use of these systems.

This study aimed to (1) find evidence on how to structure debriefing for operating teams with the use of video recordings optimally, and (2) develop a standardized debrief model for multidisciplinary debriefing with multisource data from surgical cases recorded with video and MDR.

METHODS

This educational study aimed to develop a new model for postoperative video-assisted team debriefing. The problem with the currently available debrief models was identified by a literature search. The local needs were assessed.[15,16,17] The constructed debrief model is consequently based on evidence-based best practices derived from the literature review, combined with local needs, experiences, and observations.[15] This is outlined in a flowchart (Figure 1).

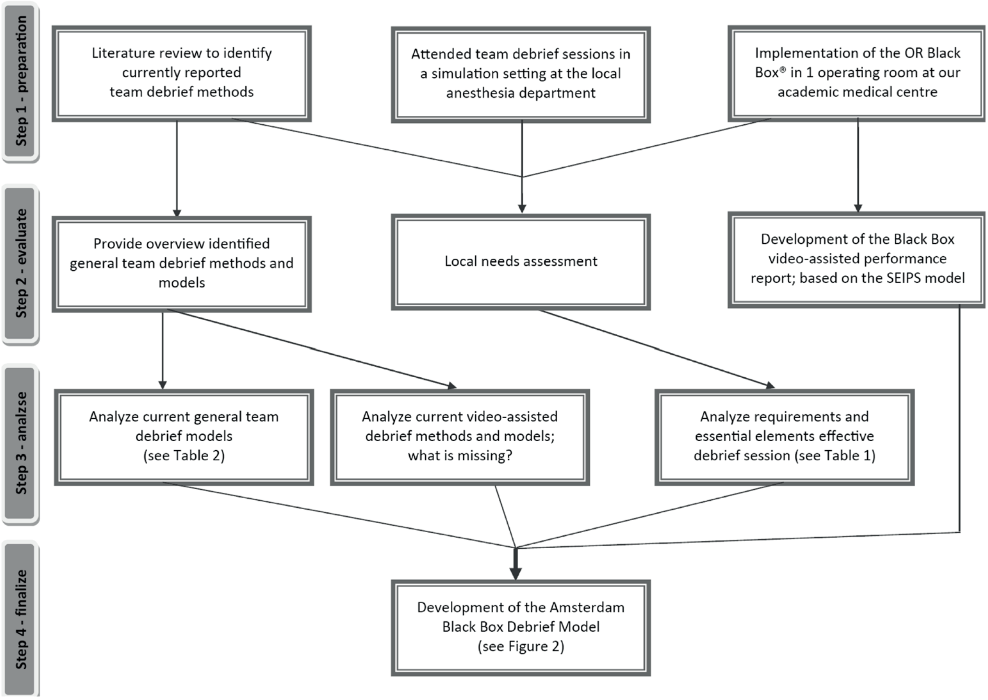

Figure 1. Flowchart illustrating the development process of the Amsterdam Black Box debrief model. SEIPS; Systems Engineering Initiative for Patient Safety.

Setting

The OR Black Box, a video and MDR, was implemented in one OR at our tertiary referral university medical center to use it as a data-driven quality improvement initiative for multidisciplinary debriefing.[18,19]

In this pilot study, 35 laparoscopic abdominal cases were recorded, analyzed, and debriefed with the entire OR team. As the patient was not the main subject of this quality improvement study, institutional review board approval was not required. However, this study was formally approved by the Hospital Directorate and Works Council (staff representation). To ensure the privacy of all participants, the research protocol was checked to be compliant with applicable privacy, legal, and regulatory requirements by conducting an official Privacy Impact Assessment.[20] The study subjects were voluntarily asked to give their formal written informed consent before participation.[19,21] The OR Black Box obtained all intraoperative data feeds, including audiovisual recordings in the OR, and depersonified patient physiological data.[22] The data feed combined views of the surgical field, nursing station, laparoscopic camera, and anesthesia station, including the anesthesia patient-monitoring device. Recording began just after the patient was being put to sleep and ended after skin closure, just before the drapes were removed. The multisource data recorded by the OR Black Box are automatically analyzed with the help of artificial intelligence (AI) and machine learning software.[23] The data, multisource and synchronized on capture, were used to generate the standardized OR Black Box performance report that included video segments of all identified safety threats and resilience support events, coded according to the validated Systems Engineering Initiative for Patient Safety model.[24] The video segments included qualitative descriptions of the event. An example of the original standardized performance report is demonstrated elsewhere.[19] The developed debrief model was used to help lead the video-assisted Black Box team debriefings. The results of the pilot study concerning the satisfaction of the team with the use of the OR Black Box for team debriefing and what was actually discussed during the team debriefings are presented in another study.[19,24]

Literature search and outcomes

First, problems with the currently reported debrief methods were identified by a literature review. A comprehensive search for the peer-reviewed medical literature regarding debriefing for medical teams and in other industries with and without the use of video and medical data recording in a clinical setting was performed and updated on July 17, 2019.

2

The PubMed and Embase database and Cochrane Library were used with the following search terms: debrief, operating room, team, surgical, nurse, trauma, aviation, military, feedback, and training. The exact details of the literature search can be found in the online Appendix (https://bjssjournals.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.1002%2Fbjs.11198&file=bjs11198-sup-0001-SupInfo.doc).

Articles reviewed revealed a broad range of methods, including descriptive or narrative reviews, systematic reviews, and qualitative and quantitative studies using both experimental and semi-experimental methods. Therefore, no attempt was made to validly grade the levels of evidence or perform a statistical analysis.[25]

Instead, we hand searched the references of the articles reaching full text review. This was done to identify any articles possibly missed in the initial search and to transparently assess all possible relevant materials to provide a comprehensive overview of debriefing elements, tools, and models in the current medical literature. Second, the theories of Thomas et al.[16] and Ericsson[17] were combined to build a conceptual framework, which was used to define what a debrief model should include.[15] The authors combined relevant findings from literature, experience with team debriefing in simulation settings, and implementation of the OR Black Box and its performance report to develop a novel model to be used for video-assisted team debriefing. Finally, the proposed Amsterdam Black Box debrief model was tested in 35 multidisciplinary debriefing sessions with the use of the OR Black Box performance report. After every debriefing, the participating team members were asked to fill out a questionnaire to evaluate their satisfaction with the use of the OR Black Box, the performance report, and the debriefing session in general. The results regarding the team's satisfaction with the OR Black Box are presented in another study.[19] Descriptive data, including means (standard deviation [SD]), of the questionnaire answers related to the debriefing sessions itself, are presented in this study to provide more information on the validation of the debrief model.

RESULTS

Evaluation of the debrief methods described in the current literature

The literature search yielded 176 citations from the PubMed database, 173 from the Cochrane Library, and seven from the Embase database. After removing the duplicates (n = 12), 354 citations remained. A total of 106 abstracts were excluded with the main reason being irrelevant to the search. Full text screening of 248 articles was performed and of those 134 were excluded with the main reason of not describing the specific debriefing method (n = 129). After screening the full text of the remaining articles, 114 were included in this study, of which 30 studies described the Critical Incident Stress Debriefing method, mainly used for patients with a posttraumatic stress disorder. Furthermore, about 15 studies described the advocacy-inquiry and good-judgment method, six studies used experiential learning cycle of Kolb, and four studies described the GAS (Gather-Analyze-Summarize) model. For the complete flowchart of the literature search see the Appendix.

The identified debriefing methods were described across different health care settings, such as after resuscitation or other critical incidents (e.g., posttraumatic stress), on site ("hot debriefing"; e.g., during the operative sign out), or later after the event or actions ("cold debriefing"). Additional methods such as video-assisted debriefings (VADs), guidance of an instructor, an individual leader or within-team leader, and use of a checklist (e.g., crew resource management checklist or objective structured assessment of debriefing) were described as well.[1,26,27,28,29,30,31,32,33,34] Yet, most studies (129 of 134 excluded full text articles) neither described nor followed a structured debriefing approach.

Evaluation of the requirements for postoperative video-assisted team debriefing

The OR team needs a structured debrief model, minimizing resource, effort, and motivational constraints.[15,16,17] Lederman[35] has identified structural elements of effective debriefing, which include the facilitator, or referred to as "debriefer" and the participants, the experience, the impact of the experience, recollection of the experience, mechanisms for reporting on the experience, and time to process. The essential elements of an effective debriefing session were described as follows: creating the correct conditions, timing, the appropriate environment, the amount of involvement of the debriefer, and the debriefing tools. He has stated that creating the correct conditions is, in fact, the key to a successful team debriefing.

Health care teams are often characterized by powerful status- and role-based hierarchies. Leadership coming from hierarchy and role might be fact of life, sometimes even considered to be a requirement for teams to function value in practicing health care optimally. However, it is important to realize that hierarchy and status may also affect group dynamics negatively in subsequent debriefing.[2,36]

When reflecting on actions, it may be important that participants share the feeling of being safe and respected in their individual roles and privacy. This may help participants to open up and speak their mind freely.[21,37] An independent moderator to lead team debriefing may be key, safeguarding aforementioned conditions.

When it comes to providing effective feedback, it has been emphasized in the literature that it ought to be purposeful, solution-oriented, and specific.[10,39,40,41] Cooperrider and Whitney[41] and Benammar[42] describe this as the appreciative inquiry method, in which they highlighted the importance of "focusing on the good, not on the bad." The advocacy-inquiry method emphasizes the importance of "debriefing with good judgment." Accordingly, the debriefer provides the feedback as neutral as possible to maintain a trusting relationship with the team.[43] Subsequently, ineffective feedback has been marked by evocative questions, giving hints, judgment, finishing other people's sentences, and giving examples of your own experiences.[38]

The Harvard Center for Medical Simulation developed a tool to assist in evaluating the debriefing: Debriefing Assessment for Simulation in Healthcare. Accordingly, the debriefer creates a positive and safe learning environment, establishes structured and organized debriefings, provokes engaging discussions and encourages reflective practice by all the team members. He or she motivates the team to close the gap between the goals and what to do to attain them in the future.[44,45] The summarized identified essential elements to be used for structured team debriefing are presented in Table 1.

	References
Engaging learning environment	
Quiet room on "neutral ground" (outside the operating room)	Carlier *et al.*,[32] Dieckmann *et al.*,[46] Akaike *et al.*,[47] Moerkamp[48]
Everybody sitting in a circle and on eye level	Fanning and Gaba,[11] Anderson[8]
Clear learning objectives	Jaye *et al.*,[49] Friedman *et al.*[50]
Correct conditions	
Safety regarding privacy (confidentiality agreement)	Dieckmann *et al.*,[46] Moerkamp[48]
Everybody is treated equally	Dieckmann *et al.*,[46] Moerkamp,[48] Ahmed *et al.*[51]
Structured and organized debriefing sessions	Adler *et al.*,[7] Bredmose *et al.*,[52] Ahmed *et al.*,[53] Amin *et al.*,[54] Bonrath *et al.*,[55] Dedy *et al.* [56]
Effective feedback	
Focus on the good, not the bad	Cooperrider and Whitney,[41] Benammar,[42] Moerkamp,[48] Buxton *et al.*,[57] Dedy *et al.*[56]
Purposeful and specific content	Alexander *et al.*,[58] Hattie and Timperley,[38] van Bommel and Stegen,[39] de Moor Centrum,[59] Abella,[60] Kessler *et al.*,[10] Ahmed *et al.*,[51] Abdool *et al.*[61]
Low level of involvement by an independent "debriefer"	Fanning and Gaba,[11] Boet *et al.*,[14,62] Butteris *et al.*,[41]

Table 1. Overview of the essential elements of team debriefing.

Evaluation of described structured models for team debriefing in the current literature

Several debrief models have been identified from the literature search. It has been emphasized that adults learn best when they are actively engaged in the process. Also, when they participate, play a role, and experience not only concrete events in a cognitive fashion but also transactional events in an emotional fashion.[11] This type of learning was best described by Kolb as "experiential learning": learning by doing, thinking about it, and assimilation of lessons learned into everyday behavior.[63] Consequently, most of the reported debrief models are adapted from the experiential learning cycle of Kolb, which describes four phases on how to use an experience as a source of learning and development.[63] In this model, it is stated that you first have the concrete experience that results in a reaction and feelings. Second, reflective observation follows, which means objectively describing and discussing what really happened. Third, all the team members analyze and discuss what they believe happened during the event. This is to clarify possible differences in perceptions and to gain insights into why their perceptions might differ. Finally, the team discusses what can be done to improve and how to do it better in the future.[64]

Mitchell and Everly[28] have summarized their view on critical incident stress management and debriefing in a seven-phase model. This model was described in many instances (30 of 114 included studies). It is to be used after a critical incident and accentuates on the psychological aspects of experiencing the particular traumatic event. Hence this model was considered not to be fit to use for (video-assisted) debriefing of operating teams.

The American Heart Association developed the quite similar Structured and Supported Debriefing GAS model, which stands for gather, analyze, and summarize.[65] The gather phase focuses on the perspectives of the team members, in the analyze phase the team examines the actions ("what went well, what did not?"), and in the summarize phase the team focuses on what should be done differently in the future. Table 2 presents a complete overview of the identified debrief models.

Phases	Debriefing models		
3 Steps	Plus delta model 1. What went well? 2. What would we like to change? 3. How to change?	GAS model 1. Gather 2 Analyze 3. Summarize	DIAMOND model 1. Description 2. Analysis 3. Application
4 Steps	Experiential learning cycle of Kolb 1. Concrete experience 2. Reflective observation 3. Abstract conceptualizing 4. Active experimentation	Advocacy-inquiry model 1. Observe 2. Comment (advocate) 3. Explore (inquiry) 1. Discover (mutual learning)	Patrenek's 4 Es 1. Event 2. Emotion 3. Empathy 4. Explanation
5 Steps	Hewson's feedback model 1. Orientation and climate 2. Elicitation 3. Diagnosis and feedback 4. Application 5. Review	SHARP model 1. Set objective 2. How did it go? 3. Address concerns 4. Review learning points 5. Plan ahead	Team STEPPs 1. Team and leader assembly 2. Discussion of postoperative plan 3. What went well? 4. What needs improvement? 5. Communicate check-back
6 Steps	EE-CHATS 1. Emotion 2. Experience counts 3. Higher order thinking 4. Accentuate the positive 5. Time 6. Structure	Thiagarajan's six phases 1. How do you feel? 2. What happened? 3. What did you learn? 4. How does this relate to the real world? 5. What if? 6 What next?	

TeamSTEPPS = team strategies and tools to enhance performance and patient safety; SHARP = 5-step feedback tool for surgery.

Table 2. Overview of the most often described debrief models.

Evaluation of the described methods for video-assisted team debriefing in the current literature

Studies describing methods to debrief with the use of video recording were sparse. The use of a video or MDR in the OR facilitates in audiovisual and data capture that may be used for VAD.[3,18] An MDR in the OR is, however, still quite a new technological innovation, especially when used for video-assisted structured team debriefing of actual surgical procedures.[19,66] Yet, VAD is an increasingly used component of debriefing in simulation and resuscitation settings and might be a solution for providing objective perceptions of

time, space, and use of equipment.[5,67,68,69] Previous research has shown that there was a sense that VAD also had benefits of removing the debriefer from the position of the critic who told the learners how to improve. By showing the team a video ("a picture paints thousand words"), the debriefer may present the team an objective view of the situation. This may help the moderator in taking the role of facilitator instead of feedback provider.[5] Furthermore, participants may feel that video presents a more unbiased way of conveying feedback than from the participant's memory.[5] The value of video to debrief important skills such as communication, teamwork, and situational awareness has been highlighted as well.[5,70] However, the problem is that the team may first need a method to analyze the complete video recordings objectively. Otherwise, valuable time is lost "searching" for relevant feedback moments to discuss during debriefing.[55,71,72]
Several models have been developed to objectively assess the nontechnical skills of the team. The Nontechnical Skills for Surgeons (NOTSS), Scrub Practitioners' List of Intraoperative Nontechnical Skills (SPLINTS), and Anesthesia Nontechnical Skills rating systems have been proven to be effective tools that may be used to rate the nontechnical skills of the operating team when assessing the video recordings.[73,74,75]

The Systems Engineering Initiative for Patient Safety model provides a framework for understanding the structures, processes, and outcomes of the work system in health care and patient safety. It combines the human factor with the system aspects, such as environment (e.g., distraction in the OR) and organization (e.g., schedules, safety culture, or coordination), all influencing team performance.[76]

It is also important to realize that it may neither be realistic nor useful to look back on entire video recording of the surgical case. Both the team and debriefer could be overloaded with a multitude of not very informative data. Debriefing may not be one-way conveyance of information, but rather an active multiway discussion. The benefit of using a video or MDR is that aggregated and condensed information may be obtained, resulting from actual use. Hence, an output report containing summarized video clips of positive and negative events deemed relevant, rated with the use of validated and objective nontechnical rating scales such as the NOTSS, SPLINTS, and Anesthesia Nontechnical Skills, may be of much help structuring the team debriefing.[77,78]

Development of the Amsterdam Black Box debrief model

According to the flowchart in Figure 1, a structured debrief model that may be used for postoperative video-assisted team debriefing was developed. In Figure 2, this proposed debrief model, named the Amsterdam Black Box debrief model is presented.

The debrief model consists of six steps: (1) introduction, (2) experience, (3) observation, (4) analyze, (5) application, and (6) summarize. This model is presented in Figure 2. An independent debriefer facilitates the debriefing session using the model (i.e., neither the surgeon nor the anesthesiologist). During the short introduction (welcome address and thanking the team members), the purpose of the debriefing is stated, the expectations of the participants are set, and it is emphasized that the debriefing session takes place in a safe environment. This means that everything that will be discussed remains confidential, according to the general privacy regulations.[21,79] If possible, first let the team watch the summarized video clip, as part of the experience step. The debriefer may then ask them to write down any notes or comments. The debriefer may let the team pick an event demonstrated in the video clip (if possible, with the performance report feedback), according to the predefined important debriefing human factor topics: communication, situational awareness, organization, or environment. If needed, the observation step may provide the team the opportunity to add any objective details on the shown event in the video clip (e.g., “what happened exactly?” “what did you do as a respond to the event?”). Next, the debriefer makes start with something positive by asking the team “what went well?” The analyze step is furthermore used to ask the team members questions such as “what could have done better?” “What made you act or react like this?” “What would you have done in this situation?” The debriefer is encouraged to not ask any questions starting with “why,” because the team members may then feel criticized.[80] During the application step, the team may focus on how to apply or perform the discussed issue in the future. After this, the team returns to the experience step, in which the team chooses another event shown in the performance report video clip. This circle of steps may be completed about 2-3 times, depending on the time. Last but not least, the debriefer may ask team members to shortly name the “take home message.” After this, there may be time for the team to say things that have not been on the table yet, things they wish to add to the discussion. The team is again thanked for their participation and an evaluation questionnaire may be handed out.

Experience with the Amsterdam Black Box debrief model

In total, 35 surgical cases were recorded and analyzed with the OR Black Box and debriefed with the use of the Amsterdam Black Box debrief model. The baseline characteristics of the participating team members were presented by our study group.[19] Some 151 questionnaires were completed. Ideal length of a team debriefing session was stated as 30 min (median, interquartile range 52.5). Overall, the debriefings were rated with a mean of 7.8 (SD 1.4, 10-point Likert scale). The question “How well was this debriefing organized?” was answered with a mean of 8.1 (SD 1.4). The debriefings were considered to be useful (mean 8.1, SD 1.5, 10-point Likert scale) and educational (mean 8.2, SD 1.4, 10-point Likert scale). Finally, the team members felt that their time on attending the debriefings was well spent (mean 8.2, SD 1.3, 10-point Likert scale).

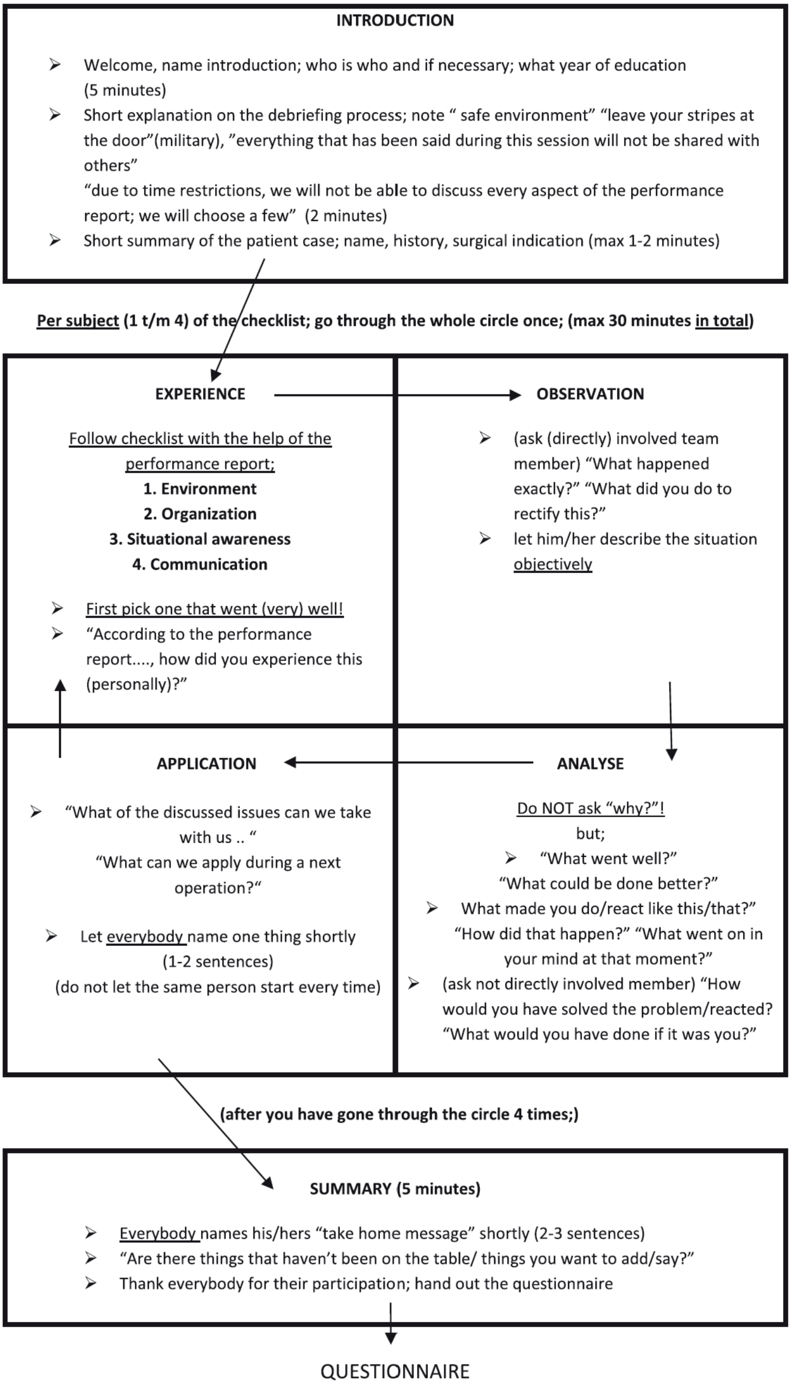

Figure 2. The Amsterdam Black Box debrief model.

DISCUSSION

A wide range of approaches to team debriefing is available in the current medical literature. Health care professionals of all kinds may arrive to the OR with various sets of experiences, ingrained personality traits, and established relationship patterns. All of them may benefit from team debriefing considerably, but most of them do not yet have sufficient of any experience in structured debriefing.[9,11,43,81] Although the term simulation was excluded from the search, debriefing techniques were most often reported in the context of simulation training only, not reflecting true clinical workflow. Yet, debriefing may be considered an even more powerful learning experience for the OR team when it takes place following the real clinical setting, such as after surgical procedures.[82,83] The use of a standardized debrief model for multidisciplinary debriefing has been recommended.[69,84]

Using video recordings during the debriefings were also recommended, as they can provide objective feedback and may help teams develop a shared mental model about the situation.[3,85] However, peer-reviewed articles on how to actually debrief with the use of a video and MDR and especially on how to optimally translate it into surgical and clinical practice appear to be lacking. No debrief model suitable for postoperative video-assisted team debriefing was found in the current medical literature. Therefore, the identified approaches, elements, and methods on how to debrief the OR team with the use of a video or MDR were summarized in the structured Amsterdam Black Box debrief model. The participants who experienced the use of this debrief model believed the Black Box debrief sessions were useful and educational, and believed that their time was well spent.

Recommendations

A good team debriefing session is characterized by the establishment of a safe environment, facilitating an open, honest, and positive discussion focusing on an objective view of the situation.[86] Honest participation means that the participants can safely ask themselves and each other “what went well, what could be better, and what should we do differently next time?” The debriefer is only present to guide if needed, by asking open questions, summarizing, and by letting the team members do most of the talking.[87] In that way, all participants may develop a high level of reflection by creating their own conclusions and motivation for change.[11,88] It may be advised to schedule debriefings outside the immediate OR environment on a round table setup, so the team can sit comfortably, on eye level, and be on neutral ground with one another.[8,9,11,46] Beepers and telephones might be muted or tucked away. Having a coffee or a snack when debriefing with the team may help to relax and facilitate the atmosphere.

When using an MDR, a summarized performance report based on validated rating scales is recommended for both logistic and informational seasons. Such output may include specific and condensed feedback on all identified relevant positive and negative events.[24,89] It may be recommended to focus on the nontechnical aspects, such as communication rather than individual technical events, as this might be more educational than debriefing individual technical skills.[90,91,92,93] The NOTSS and SPLINTS rating scales may be used for this purpose. By integrating AI and machine learning software, the video and medical data output can be largely automatically analyzed, sparing the involved health care professionals' hours of looking back at video footage.[23,94] An example of the new OR Black Box performance report that uses these ratings scales and AI to analyze the video and medical data recordings is demonstrated in Figure 3. The surgical procedure is summarized in one overview slide. By clicking on the purple or blue diamonds or red circles, the video-augmented feedback regarding intraoperative event is shown (see black arrow and popped-up screen).

Hospital directorates who support participation of debriefings can facilitate in allocating time, making it possible to attend the debriefings preferably in normal working hours. It may also be advised to plan the debriefing not immediately after the surgical procedure, but within a time-span of some days, as direct "hot" debriefing is often not practical in the workplace.[2,44] This time span gives the operating team some time to process and "wind down" and in case of video recording, to optimize the supporting performance report.[31,87,95]

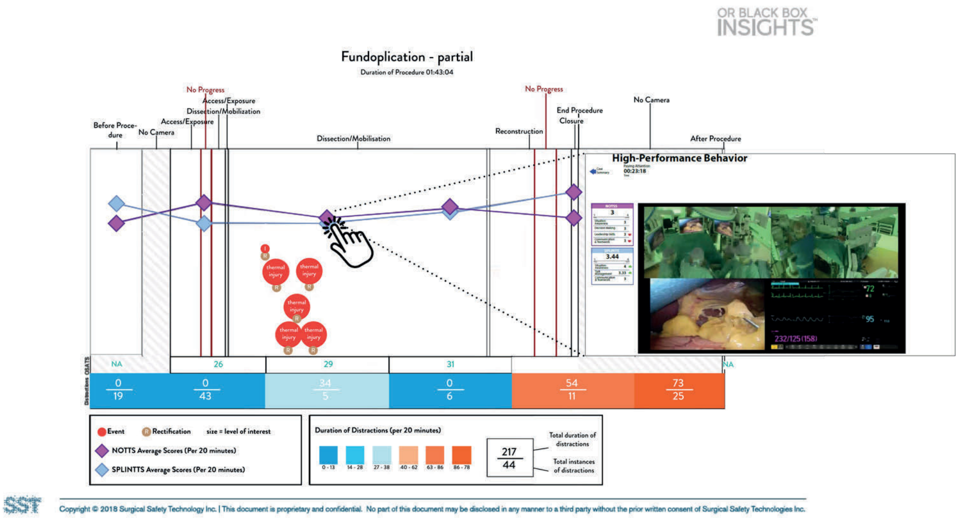

Figure 3. New OR Black Box performance report example.

Limitations

This study has some limitations to take into account. This literature review was based mostly on narrative review articles. Therefore, a systematic review and corresponding critical appraisal of the identified articles was not performed. The debrief model was developed based on a summary of the identified debrief methods and experience with debriefing in simulation settings by the authors. Also, this model was only tested in one tertiary referral university medical center and with the use of one version of an MDR. Therefore, no strong conclusions can be made regarding the validation of the debrief model. More empirical evidence across user settings is recommended to better validate the model and to find more evidence on how to implement VAD models for clinical surgical settings. Another limitation is the lack of concrete results regarding actual performance improvement. The survey of the pilot study was only able to evaluate self-reported satisfaction.[19]

Future studies should evaluate whether the use of the debrief model in video-assisted team debriefing may actually change the behavior of the participating team members when they face the debriefed events in a similar case. Finally, the use of an

MDR may be more expensive than the use of debrief methods without such detailed feedback. However, external or hospital funding may help support the educational project as the use of an MDR for postoperative team debriefing is a data-driven quality improvement initiative.[21,37]

Conclusions

Although the power of multidisciplinary debriefing has long been highlighted, structured team debriefing of actual surgical cases—with or without the use of an MDR in the OR—is not a common practice to date. Debriefing augmented with information coming from a video and MDR in the OR is believed to be even more objective, effective, and educational. No debrief model fitting the use of a video and MDR in the OR existed to date. The standardized Amsterdam Black Box model was proposed by the authors. The model was tested and may be used in structured operating team debriefings using a video and MDR in the OR. Future studies are needed for adequate validation of the debrief model and to evaluate its impact on the improvement of team behavior and performance.

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PART II

Increasing transparency in the operating room

CHAPTER 3

Implementing structured team debriefing using a Black Box in the operating room: surveying team satisfaction

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Surgical Endoscopy. 2020
doi.org/10.1007/s00464-020-07526-3

ABSTRACT

Background: Surgical safety may be improved using a medical data recorder (MDR) for the purpose of postoperative team debriefing. It provides the team in the operating room (OR) with the opportunity to look back upon their joint performance objectively to discuss and learn from suboptimal situations or possible adverse events. The aim of this study was to investigate the satisfaction of the OR team using an MDR, the OR Black Box®, in the OR as a tool providing output for structured team debriefing.

Methods: In this longitudinal survey study, 35 gastro-intestinal laparoscopic operations were recorded using the OR Black Box® and the output was subsequently debriefed with the operating team. Prior to study, a privacy impact assessment was conducted to ensure alignment with applicable legal and regulatory requirements. A structured debrief model and an OR Back Box® performance report was developed. A standardized survey was used to measure participant's satisfaction with the team debriefing, the debrief model used and the performance report. Factor analysis was performed to assess the questionnaire's quality and identified contributing satisfaction factors. Multivariable analysis was performed to identify variables associated with participants' opinions.

Results: In total, 81 team members of various disciplines in the OR participated, comprising 35 laparoscopic procedures. Mean satisfaction with the OR Black Box® performance report and team debriefing was high for all 3 identified independent satisfaction factors. Of all participants, 98% recommend using the OR Black Box® and the outcome report in team debriefing.

Conclusion: The use of an MDR in the OR for the purpose of team debriefing is considered to be both beneficial and important. Team debriefing using the OR Black Box® outcome report is highly recommended by 98% of team members participating.

INTRODUCTION

Despite various efforts aiming to improve surgical safety, the incidence of surgical adverse events remains high to date.[1–3] Studies have estimated one-third of surgical adverse events to be potentially preventable.[1, 2, 4, 5] Adverse events are usually not the result of individual failure, but the consequence of an uninterrupted chain of events and decisions, spanning multiple phases of surgical care. An important number of these adverse events occur within the operating room (OR) and are most often unnoticed by the team.[2, 6, 7] Therefore, a suggested approach towards error reduction could focus on finding and implementing mechanisms to facilitate the awareness of such unnoticed events.[8] Subsequently, steps should be undertaken to acknowledge, analyse and understand common error-event patterns.[7, 8] Several studies have highlighted the importance of non-technical skills in the OR to avoid error. Skills associated with error reduction or prevention are teamwork, situational awareness and communication.[9–11] Therefore, interventions to improve surgical quality and safety should involve all members of the operating team.[11–13]

A Medical Data Recorder (MDR) is similar to a system better known in aviation as a 'Black Box' or a 'Flight Data Recorder'. It may have the potential to look back upon joint performance jointly to improve quality and safety in the OR. The outcome of using an MDR may be used for purposes of multidisciplinary debriefing in a privacy-protected environment if it is well constructed for this purpose. This may provide surgical teams with the opportunity to assess unnoticed events and look back upon their actual performance to learn and improve. Hence, it may avoid future adverse events that possibly compromise surgical safety.

Despite aforementioned insights and currently available technology, reported surgical safety improvement initiatives using an MDR are still limited. Moreover, an actual multidisciplinary debriefing culture for teams performing surgery is lacking.[14–17] The aim of this study was to investigate the participants' satisfaction with an MDR, the OR Black Box® and its subsequent performance report used as a tool for structured postoperative multidisciplinary debriefing.[18]

METHODS

Participants, privacy and surgical case selection

To ensure the privacy of all participants, the research protocol was checked to be compliant with applicable privacy, legal and regulatory requirements by conducting an official Privacy Impact Assessment (PIA).[19] Legal guidelines were explored before set-up of study.[19] This study was approved by the Hospital Directorate and Works Council (staff representation). An institutional review board (IRB) approval did hence not have to be obtained.[19]

The research coordinators (AvD and MS) gave several oral presentations at the different clinical departments involved in the OR to inform all participants about the Transparency in the Operating Room (TOPPER) trial. The objectives and methods were explained, questions were answered and they were asked to give their written informed consent prior to participation.

From February 2017 until January 2018, consecutive elective gastro-intestinal laparoscopy cases were recorded using the OR Black Box® (Surgical Safety Technologies Inc., Toronto, Canada). The standardized questionnaire was tested for its adequacy and measured the operating team's satisfaction, using factor analysis for optimal assessment of underlying constructs. Patients were pre-operatively informed about the study and asked whether they would have any objections to be operated in an OR where an MDR was being used ("opt-out" option).[19]

Operating room set-up

The OR Black Box® is an MDR that was installed in the 'ENDOALPHA' operating suite (Olympus Europa SE & Co. KG, Hamburg) in the Amsterdam University Medical Centres, location AMC.[18, 20] This recorder is able to capture a multitude of data streams in perfect synchronization. Figure 1 depicts the OR theatre set-up, including the position of the cameras, microphones and OR Black Box® touchscreen.

Cases were recorded between the time-out and sign-out time stamp of the surgical procedure, according to most recent SURPASS (Surgical Safety Checklist) guidelines, with the consented patient fully draped to optimally ensure the consented patient's privacy.[19, 21, 22] Patient parameters were recorded and retrieved in real time via the anaesthesia monitor. All captured data were collected upon generation by the OR Black Box® encoder, stripped from personal identifiers and subsequently synchronized. Immediately following, the dataset was securely encrypted by the OR Black Box® system before it was transmitted to the Canadian contractor. This was done with secure Virtual Private Network technology (VPN) using a system push command upon action of the study investigator, immediately after procedural sign-out.

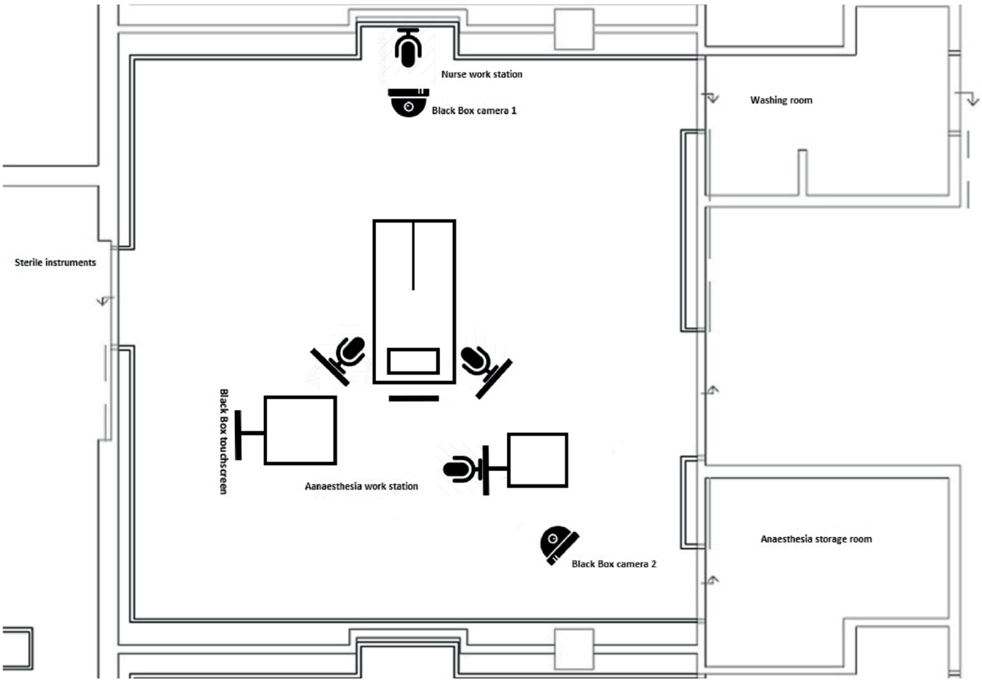

Figure 1. Overview of the operating theatre including position of the ceiling-mounted cameras and OR Black Box® microphones, attached to the operating theatre monitors.

Construction of the Black Box performance report

The OR Black Box® dataset was decrypted and analysed partly using software algorithms by the contractor, the Surgical Safety Centre (Canada, Toronto). Subsequently, deep-learning algorithms flagged 'near miss' events in the dataset, and events were 'tagged' when they were considered to be relevant. Following, the dataset was analysed by the OR Black Box® analysis team (a specialized trained team of surgeons and human factors specialists) in full to double-check for fault-positive, negative and inappropriate placed flags of the learning algorithms in order to avoid faulty analysis. Since the software and analysing team uses English as primary language, the team was asked to speak English during the recording of the surgical cases. Study participants were told that they could always revert back to Dutch, if necessary. Yet, the debriefings were done in Dutch. As the contractor of the MDR resides in Canada, the Canadian analysis team was briefed about local standard operating procedures before start of study, by all the participating surgeons. The analysis was based on well-known, scientifically validated rating scales that can be found in literature, such as the System Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety, the Non-Technical Skills for Surgeons (NOTSS), The Scrub Practitioners' List of Intraoperative Non-Technical Skills (SPLINTS) system and the Disruptions in Surgery Index (DISI).[23–26] This original 'tagged performance report' was considered to be too lengthy and granular for feasible debriefing the operating team, hence it was further translated into a graphical summarized performance report.

This graphical performance report model compromised a summarized 'video clip' of about 10 min. Figure 2 shows an example of the OR Black Box® performance report. The video clip included the 2 overview camera's, the anaesthesia monitor and laparoscopic camera as depicted in Figure 1 and 2. The structured feedback from the OR Black Box® analysis team (Toronto, Canada) was added to the summarized 'video clip' in annotations, including all relevant positive (green line) and negative events (red line) of the particular case. As shown in Figure 2, the timeline of the procedure and video clip is visualized in the lower part of the report. The green and red lines represent the positive and negative rated human factor events. The green or red squares within these lines represent a specific safety threat or resilience support event for which written feedback is provided in the right upper part of the report. These events were discussed during the team debriefing. All personally identifiable information was stripped from the performance report (faces are blurred, voices were altered and patient data were removed). The original OR Black Box® data were analysed within 48h and the resulting outcome report was securely sent back to the project coordinators (AvD and MS), to be used for the debriefings only.

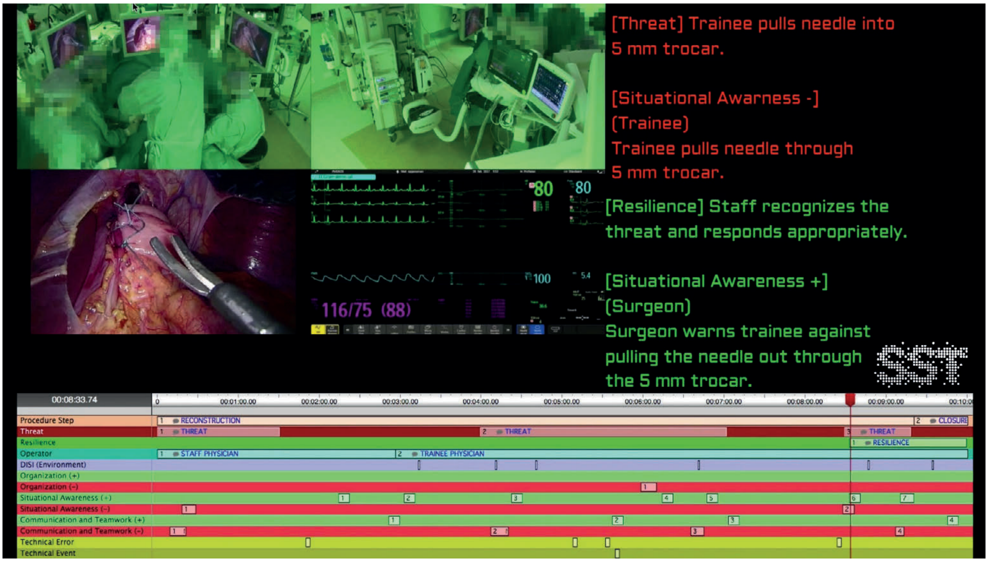

Figure 2. Example of the OR Black Box® performance report, including video clip, used in the postoperative team debriefngs

Team debriefing

The procedures were debriefed in a standardized way with the help of a, by the authors (AvD and MvH), developed debrief model to be used with the OR Black Box® output. The debriefing methods are presented in another study and were based on insights derived from literature review.[27–29] Represented in the model are the following categories: environment, organization, situational awareness and communication & teamwork. The debriefing sessions were done in Dutch. The debriefings were led by an “independent moderator” (a professor of psychiatry) to structure the debriefing process optimally, by guiding the process and providing feedback as neutral as possible whilst maintain a trustful relationship within the team.[28, 29]

Questionnaire and statistical analyses

All survey data collection and statistical analyses were executed by the authors at our academic medical centre (AvD, and SvD) to adjudicate possible conflicts of interest. The founder and equity holder (TG) of Surgical Safety Technologies (SST) Inc., Toronto, Canada was involved in the co-development and delivery of the structured performance outcome reports, but not in set-up nor outcome analysis of study.

Following the TOPPER-trial team debriefing sessions, participants completed a standardized questionnaire surveying user satisfaction regarding the performance report and OR Black Box® as a tool for team debriefing. The original questionnaire is written in Dutch and can be found in the Appendix. As the debriefing was also done in Dutch and the questionnaire was analysed by the Dutch study coordinator (AvD, SvD), it was not translated to English.

Exploratory factor analysis of the questionnaire was used to measure the satisfaction of the users. This included a principal-axis factor analysis which was conducted on the 23 items (10-point Likert scale questions) with oblique rotation. The Kaiser–Meyer–Olkin (KMO) and Bartlett's test was used to verify the sample size adequacy of the completed satisfaction questionnaires. The correlation matrix and anti-image matrix (values < 0.5) were used to decide which questions had to be removed, because these questions correlated too highly (> 0.9) or poorly (< 0.2). The questions clustered in the satisfaction factors were tested for reliability by the Cronbach's alpha test (> 0.7).[30]

Linear regression analysis was used to determine whether independent covariates were significantly correlated with the, in the factor analysis identified, different satisfaction factors. Covariates with a threshold *p* value of 0.20 were entered in the multivariable linear regression model. Multivariable regression analysis was performed to estimate differences in variables associated with the selected satisfaction factors. The multivariable regression model was created using a backward stepwise fashion. Covariates in the multivariable regression model with a threshold *p* value of 0.05 were considered to be significantly associated with the outcome variable. The *B* values with 95% confidence intervals (CI) were presented. All statistical analyses were conducted using SPSS statistics 24.0 for Windows.

RESULTS

In total, 35 surgical procedures were recorded of which 18 were laparoscopic fundoplications, 6 laparoscopic diaphragmatic hernia repairs, 3 elective laparoscopic appendectomies, 3 laparoscopic subtotal colectomies, 2 laparoscopic unilateral adrenalectomies, 2 laparoscopic bilateral adrenalectomies and 1 laparoscopic sigmoid resection. In these cases, 4 surgeons, 2 surgical fellows, 12 surgical residents, 6 anaesthesiologists, 5 anaesthesiology residents, 9 anaesthesiology nurses, 27 theatre nurses and 16 medical interns participated (N = 81). The baseline characteristics of participants are presented in Table 1.

The debriefings took place approximately 14 working days (median, IQR 41) after the recorded procedure. On average, 4 (out of 7–8) team members (median, IQR 3) attended their team debriefing. In total, 151 questionnaires were completed. The mean score on the question: "How important do you feel it is to be able to structurally debrief surgical procedures with the entire team" was 8.44 (SD 1.2, 10-point Likert scale).

TABLE 1. Baseline characteristics

Role in the operating theatre	**Age** (median)	**Gender** (N per total cases)	**Years working at this hospital** (median)	**Times participated in Black Box debriefing** (N per total cases)	**Optimal length of debriefing** (minutes, mean)	**Would you recommend participating in a Black Box team debriefing to your colleagues?** (N, yes vs no)
Primary surgeon	47.0 (IQR 1.0)	31 female 2 male	8.0 (IQR 1.0)	5 (first time) 8 (1-5 times) 5 (6- 10 times) 14 (>10 times)	27.1 (SD 5.7)	33 yes 0 no
Assisting surgeon	33.0 (IQR 6.0)	13 female 6 male	1.0 (IQR 4.5)	8 (first time) 11 (1-5 times) 0 (>5 times)	20.7 (SD 8.3)	18 yes 1 no
Anaesthesiologist	41.0 (IQR 13)	8 female 12 male	7.0 (IQR 6.0)	9 (first time) 11 (1-5 times) 1 (6-10 times) 0 (>10 times)	32.6 (SD 10.7)	18 yes 2 no
Anaesthesiology nurse	31.0 (IQR 26)	7 female 14 male	6.0 (IQR 3.5)	10 (first time) 11 (1-5 times) 0 (>5 times)	33.9 (SD 14.9)	21 yes 0 no
Scrub nurse	29.0 (IQR 32)	18 female 1 male	3.8 (IQR 4.3)	5 (first time) 13 (1-5 times) 0 (>5 times)	32.2 (SD 9.9)	18 yes 0 no
Circulating nurse	42.5 (IQR 18)	22 female 0 male	5.0 (IQR 17.0)	8 (first time) 13 (1-5 times) 0 (6-10 times) 1 (>10 times)	40.5 (SD 11.5)	22 yes 0 no
Medical intern	25.0 (IQR 1.0)	11 female 7 male	-	10 (first time) 8 (1-5 times) 0 (>5 times)	27.5 (SD 13.2)	18 yes 0 no

Factor analysis of the satisfaction questionnaire

The twenty-three questions, answered on a 10-point Likert scale, were evaluated in the factor analysis. The mean scores of each question are presented in Table 2. Mean scores of the questions demonstrated that the team members considered structured team debriefing to be important, useful, and educational.

The team members had a mean score of 8.2 (SD 1.1, 10-point Likert scale) regarding satisfaction with the use of the performance report (including video clip) as instrument for a structured operating team debriefing. Question 4 had a very low inter-correlation with question 14b and 20 (< 0.2) hence had to be excluded from the analysis (see Online Appendix). An increase in Cronbach's alpha to 0.851 was achieved by eliminating question 19b (factor 2). After exclusion of question 4 and 19b, a high KMO value of 0.937 and a significant Bartlett's test (p value < 0.0001) confirmed that the questionnaire sample was indeed of adequate size for the analysis.[31]

Resulting from the factor analysis, some questions clustered on three separate factors. These factors met the Kaiser's criterion of 1 and in combination these 3 factors explained 64.9% of the variance (see Online Appendix).

Factor 1 represents the team member's attitude towards the "value of team debriefing with the OR Black Box® performance report", i.e. whether it was useful and educational. Factor 2 represents the team member's satisfaction with the use of the OR Black Box® performance report as instrument for a structured team debriefing. Factor 3 represents team member's attitude towards the "benefits of team debriefing" with the OR Black Box®, i.e. the ability of the debriefings to improve the team's communication, situational awareness and teamwork skills, and patient safety. Table 2 shows the factor loadings, per question (pattern matrix is attached in the appendix). The factor loadings demonstrate which questions clustered to factor 1, 2 or 3, respectively, and how much value they added to their factor. Figures 3, 4 and 5 show the overall mean scores, per role in the OR, of the questions included in factor 1, 2 or 3, respectively.

TABLE 2. Overall mean scores per question of the standardized post-debriefing questionnaire and their corresponding factor(s)

Question	Overall mean score (10-point Likert scale, N=151)	Factor loadings after rotation for Factor 1	Factor loadings after rotation for Factor 2	Factor loadings after rotation for Factor 3*
0. How important do you find it to be able to structurally debrief surgical procedures with the entire team?	8.4 (SD 1.2)	0.511	-	-0.332
1. How would you rate today's debriefing?	7.8 (SD 1.4)	0.803	-	-
2. How well met the covered topics with the preset goals of this team debriefing?	7.8 (SD 1.4)	0.339	0.611	-
3. How well-suited were the room and facilities for this debriefing?	8.5 (SD 1.1)	-	-	-
4. How well was this debriefing organized?	8.1 (SD 1.4)	-	-	-
5. Was content of the performance report useful for you?	7.8 (SD 1.6)	0.699	-	-
6. Do you think the content of the performance report was useful for your team members?	8.2 (SD 1.3)	0.538	-	-
7. Do you estimate this debriefing to be of value to increase your own *situational awareness?*	8.4 (SD 1.2)	0.389	-	-0.396
8. Do you estimate this debriefing to be of value to increase the *situational awareness* of operating teams, in general?	8.5 (SD 1.1)	-	-	-0.698
9. Do you think participating in the Black Box debriefings will help you to communicate (even) better with your colleagues in the operating room?	8.6 (SD 1.1)	-	-	-0.819
10. Do you think that participating in Black Box debriefings is of value for operating teams to better communicate with each other in the operating room?	8.5 (SD1.1)	-	-	-0.887
11. Do you think that participating in Black Box debriefings is of value to be able to improve future teamwork in the operating theatre?	8.5 (SD 1.1)	-	-	-0.801
12. Do you think that the OR Black Box® is a valuable instrument to enhance patient safety?	8.8 (SD 6.4)	-	-	-0.555

13. Was this debriefing educational?	8.2 (SD 1.4)	0.846	-	-
14A. In case you learned something from this debriefing, to what extent do you expect it to be applicable in future surgical procedures?	8.7 (SD 5.7)	0.573	-	-
14B. In case you learned something from this debriefing, how motivated are you to practice in future surgical procedures?	9.96 (SD 9.7)	-	0.383	-
15. Did you find this debriefing to be useful?	8.1 (SD 1.5)	0.791	-	-
16. How well did this debriefing meet your expectations?	8.0 (SD 1.3)	0.743	-	-
17. Did you find the time you spent on attending this debriefing well spent?	8.2 (SD 1.3)	0.706	-	-
18. What is the ideal length of a team debriefing according to you? (minutes)	30.6 (SD 11.9)	-	-	-
19A. Of how much value would it be for you, to be able to choose which moments are being debriefed with the help of the anonymous video clips yourself?	7.5 (SD 1.9)	-	-	-
19B. Of how much value would it be for you to be able to get access to the performance report and/or anonymous video clips personally, after the Black Box procedure?	7.8 (SD 1.5)	-	0.655	-
20. How valuable did you find the anonymous video clips as part of the performance report?	8.4 (SD 1.1)	-	0.661	-0.318
21. Do you find that, if available, it should be possible to use the OR Black Box® when the operating team wants to debrief a particular surgical procedure? (yes, no)	148 (98.7%, N=150)	-	-	-
22. Would you recommend participating in a OR Black Box® team debriefing to your colleagues? (yes, n)	148 (98.0%, N=151)	-	-	-
23. Did you miss something in the performance report? (yes, no)	25 (16.6%, N=151)	-	-	-
24. Did you miss something in de briefing/method of debriefing with the performance report (including video clip)? (yes, no)	27 (17.9%, N=151)	-	-	-

The multivariable linear regression, correcting for all potential confounders (simple linear regression table in the Online Appendix), showed that the primary surgeon was significantly more satisfied concerning all 3 satisfaction factors, compared to the other team members. Number of previously attended Black Box team debriefings was significantly associated with a higher satisfaction score for all 3 satisfaction factors (Beta coefficient = 0.29, 95%CI 0.09–0.49, Beta coefficient = 0.414, 95%CI 0.25–0.57, Beta coefficient = 0.422, 95%CI 0.59–0.26). Number of team members attending the team debriefing and number of work days between the procedure and debriefing were not significantly associated with the satisfaction scores. Total number of events reported in the performance report feedback was negatively associated with satisfaction factor 1 (Beta coefficient = − 0.013, 95%CI − 0.02 to − 0.002). Results of the multivariable linear regression analyses are presented in Table 3.

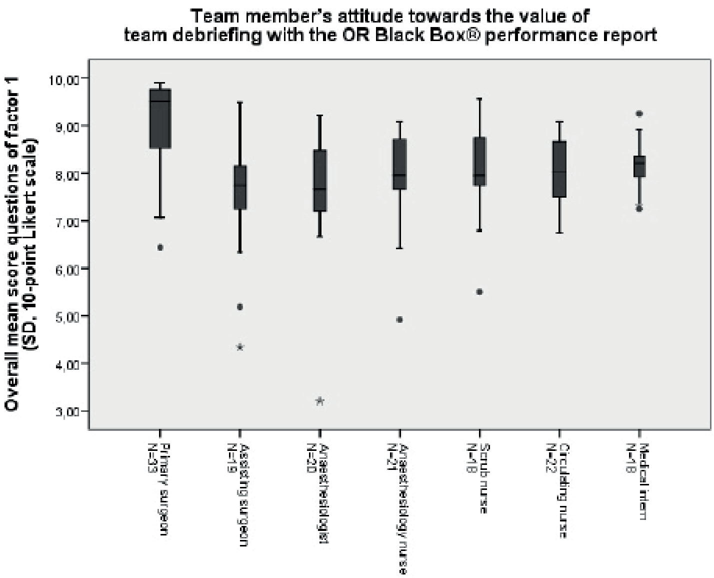

Figure 3. Total mean scores of the questions (Q0, Q1, Q2, Q5, Q6, Q7, Q13, Q14a, Q14b, Q15, Q16, Q17) included in factor 1 representing the team member's attitude towards the value of team debriefing with the OR Black Box®, per role in the operating theatre.

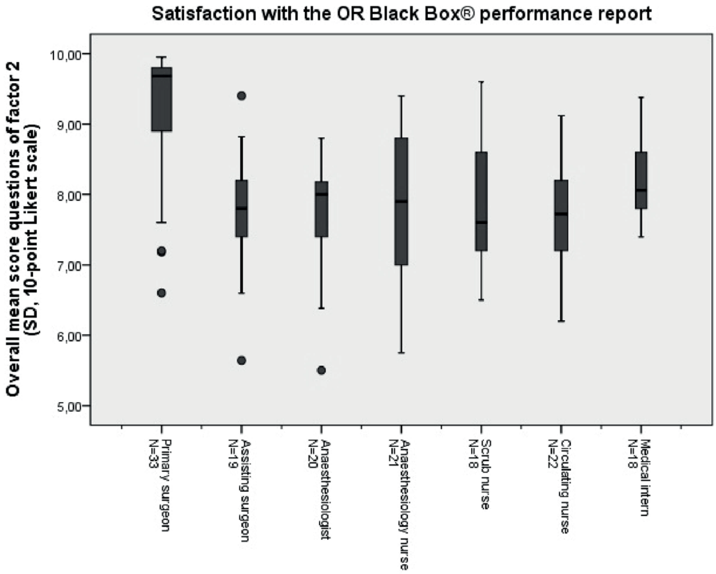

Figure 4. Total mean scores of the questions (Q2, A14b, Q19b, Q20, Q25) included in factor 2 representing satisfaction with the OR Black Box® performance report, per role in the operating theatre.

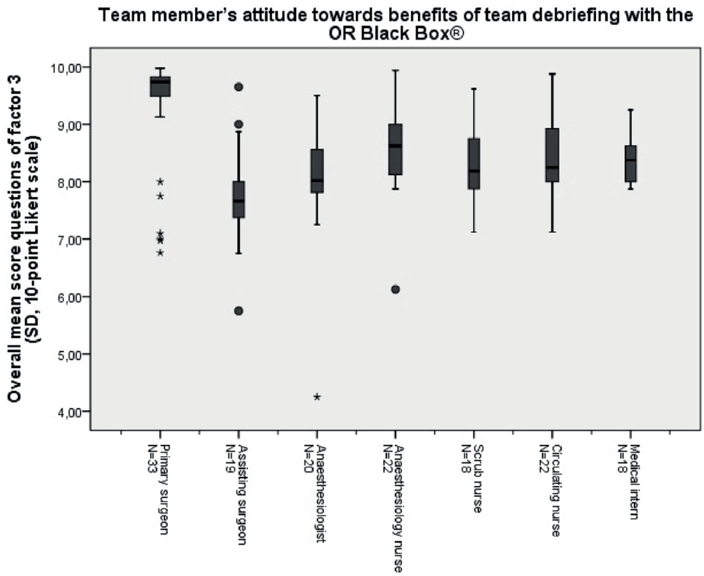

Figure 5. Total mean scores of the questions (Q0, Q7, Q8, Q9, Q10, Q11, Q12, Q20) included in factor 3 representing the team member's attitude towards benefits of team debriefing with the OR Black Box®, per role in the operating theatre.

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TABLE 3. Multivariable linear regression models for the 3 factors

Variables	Factor 1 Attitude towards value of team debriefing with the OR Black Box®		Factor 2 Satisfaction with the OR Black Box® performance report		Factor 3* Attitude towards benefits of team debriefing with the OR Black Box®	
Surgical procedure (upper-GI vs adrenal, vs colorectal)	-	-	-	-	-	-
Role in the OR (ref = main surgeon)						
assisting surgeon	*B* = -0.652	95%CI -1.13 to -0.18	*B* = -0.659	95%CI -1.09 to -0.23	*B* = -0.842	95%CI -0.43 to -1.26
anaesthesiology (including anaesthesia-nurse)	*B* = -0.329	95%CI -0.71 to 0.05	*B* = -0.524	95%CI -1.0 to -0.30	-	
OR nurses (SN & CN)			*B* = -0.653	95%CI -1.0 to -0.30	-	
Age	*B* = 0.016	95%CI -0.001 to 0.034	-	-	-	
Sex	-	-	-	-	-	
Years working at the AMC	-	-	-	-	-	
Number of previously attended Black Box debriefings (first time, 1-5 times, 6-10 times, >10 times)	*B* = 0.29	95%CI 0.09-0.49	*B* = 0.414	95%CI 0.25-0.57	*B* = 0.422	95%CI 0.59-0.26
Number of team members attending the debriefing	-	-	-	-	-	-
Number of work days between procedure and debriefing	-	-	-	-	-	-
Performance report feedback						
Total number of all (positive and negative) events in performance report	*B* = --0.013	95%CI -0.02 to -0.002	-	-	-	-

*all values in this factor pattern matrix were negative, therefore negative values in the model may be considered positive and positive values may be considered negative

B = the beta coefficient, which is the degree of change in the factor for every 1-unit of change in the predictor variable.

DISCUSSION

This study focuses on the satisfaction of the OR team with the use of a new monitoring system, the OR Black Box®, and its subsequent output used in team debriefing. This outcome was chosen because for people working in the OR it is vital to feel comfortable and secure, in order to be able to adopt such an innovative system. The team has to be satisfied with a system that 'watches' and 'judges' them. Only then, a quest to learn from unnoticed or differently perceived errors may take place.[32] Overall, satisfaction of the surgical team with the use of the OR Black Box® and corresponding outcome performance report for postoperative structured team debriefing was very high. Ninety-eight percent of participants would recommend postoperative multidisciplinary debriefing with the use of the OR Black Box® derived output to their colleagues. Although team debriefing is not yet common practice in most hospitals, participating surgical team members have considered structured team debriefing to be important, useful, and educational.[17, 33–37] These results show that number of previously attended team debriefings is positively associated with user satisfaction. This implicates that there is no 'wear out' of participating to debriefing, in contrast. One may even argue that new users over time become bigger advocates for the debriefing, using the system for this purpose. The type of procedure, years working at the hospital and age did not seem to influence satisfaction, suggesting that there is no extinguish of participation interest and that bias due to the 'novelty effect' is minimal.[38] This is an encouraging finding, when implementing innovations in the operating theatre.[39, 40]

As to be expected, the primary surgeons, drivers of the initiative, were significantly more satisfied than the participating assisting surgeon, anaesthesiologist and OR nurses in the surgical team. The phenomenon of perceived difference of perception about the same situation between the surgeon and other team members is acknowledged in literature.[41–43] It may also be contributed to the so-called 'Rashomon' effect, which occurs when the same events is described in significantly different ways by different people who were involved.[44] Indeed, based on the respective roles, disagreements exist regarding the evidence of events in the OR. Also, subjectivity versus objectivity in perception, memory and reporting is in play, when looking back upon situations. Surgeons,

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in comparison with the other team members, experience and therefore describe or remember certain events differently. The need for a more multidisciplinary approach to quality improvement initiatives may hence be recommended.[37, 45, 46] Moreover, it is known that communication and the performance of the team is usually graded higher by the surgeon.[47–49] This may further be explained by the fact that this project was an initiative led and strongly supported by the participating surgeons. As participants were asked to voluntarily participate in the TOPPER-trial, it was to be expected that they would be satisfied with the outcomes of project, introducing a positive selection bias in our study. Yet, at the start of the project, only a few anaesthesiologists and nurses felt comfortable enough to decide to participate and sign the informed consent. Interestingly, over time, their participation numbers kept on growing steadily in the study. An effect that can presumably be contributed to the 'grapevine', e.g. the positive responses of the already participating team members. Indeed, several healthcare professionals who were initially unsure or even quite sceptical towards the initiative decided to participate in the team debriefing during the trial based on positive experiences shared by their peers. When these second group of adopters overcame their initial scepticism, they reverted their opinion due to actual user experience. They came to better understand how their privacy was protected and experienced the benefits first-hand. As a result, initial laggards became the most important drivers and advocates for the initiative.

In this study, only 3 participants indicated not to recommend participation to peers, of which 1 surgical resident and 2 anaesthesiologists. The surgical resident commented that the answer was 'no', because during that particular debriefing, the staff surgeon had to cancel his or her attendance to the team debriefing last minute. Without the staff surgeon, in combination with a relatively 'uneventful case', the surgical resident considered the team debriefing to be not so useful. Two anaesthesiologists answered 'no' on the question if they would recommend use of the system for team debriefing to peers. Anaesthesiology data were indeed captured in real time by OR Black Box® (e.g. blood pressure, heart rate, oxygenation, etcetera) and reflected in Black Box® output, but the assessment algorithms at that time were not well enough developed to provide the same granularity of assessment as for the surgeons and OR nurses. Also, to protect the privacy of the patient, the OR Black Box® capture of data started when the team started draping, when the patient was hence already under anaesthesia. Recordings were stopped before extubation. Thus, the assumed-to-be more critical moments in anaesthesiology care were not part of the performance report and could not be debriefed using the outcome report. Nevertheless, technical aspects were not the main learning points according to user insights from both surgeons and anaesthesiologists. Take-home-messages, noted during the team debriefing sessions from the anaesthesiologists, were mainly about communication patterns, such as "clear and closed-loop communication is important" and "I should be more specific when asking the surgeon". In fact, miscommunication has been implicated as one of the major causes of error and adverse outcomes in general surgery.[10, 11] Indeed, these learning aspects need to be taking into account when training surgical teams, which is usually not the case in the separate specialist curricula to date. Authors feel there is an opportunity here for improvement. Apart from training teams in simulative settings jointly, use of the OR Black Box® in team debriefing to look back upon joint performance may help strengthening the surgical safety culture. This, because the OR Black Box® performance report has been built focusing on those aspects regarded to be especially important for joint performance; being human factor skills, like communication and teamwork, next to technical error.[50] Postoperative multidisciplinary debriefing, with the use of the performance report, may hence contribute to prevention of unintentional miscommunication in the OR, especially between the surgeons and anaesthesiologists.[51]

Taking into account the different busy work schedules and irregular shifts, planning the team debriefing sessions was difficult sometimes. However, the number of working days between procedure and debriefing session, and number of attending team members did not seem to affect the participant's satisfaction. Nevertheless, it was decided to reschedule the session, when not enough team members could attend (4 out of 7) to persevere the benefits of multiple viewpoints in the discussion.

Several team members quoted; "because of the Black Box, I was more aware of my communication and this actually improved my way of communicating". Yet, the performance report showed that there was still some "irrelevant chatting" or "loud

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music". This indicates that procedures were performed in the familiar and natural way.[26, 52, 53] Quotes during the debriefings confirmed that there was often a very relaxed and good atmosphere in the OR. This may suggest that surveillance awareness and language did not seem to affect the surgical team's performance and satisfaction.[54]

This is not the first study describing the use of a video and MDR in the operating theatre.[55–57] However, the TOPPER- trial is, to the author's knowledge, the first study that used a structured and automatically analysed video-assisted performance report as a tool for structured multidisciplinary debriefing, including all members of the operating team. In contrary to others, this study comprehensively explored the participant's satisfaction with the use of an MDR in the OR, its performance report, and debrief methods. As stated in the literature review by Jue et al., the OR Black Box® is currently the most widespread surgical data recording technology in use in operative settings.[57]

This pilot study has some limitations. As mentioned, the participants were asked to voluntarily participate and therefore the results may represent the opinion of beforehand enthusiastic, positively minded participants. One out of the six participating surgeons (MS) was beside a participant, also the project leader. This is an important bias to take into account whilst interpreting the results. To avoid bias, the 6 surgeons did not participate in the data analysis. On the other hand, leading by example is not necessarily wrong in starting disruptive initiatives. One may even argue that such an initiative simply needs a strong driver from within the community and leadership in order to succeed and result in successful implementation. Overall, the level of satisfaction among various users is very high, one may argue that the system lives up to different expectations indeed and certainly did not disappoint.

Another barrier to interpretation of the study may be the fact that participants were asked to speak English during the OR Black Box® recordings. As mentioned above, the data analysis centre is situated in Toronto, Canada, and neither the software nor the 'raters' were able to understand and analyse Dutch. To facilitate interpretation of this learning system and maximize the information in the newly designed outcome report, authors chose upfront to revert away from bias that may have been caused by language issues. Indeed, it was believed to be not so much of a problem as the Dutch, especially when highly educated, are fluent in speaking and understanding English.[58,59] Although it was agreed that during the procedure the team members could always revert back to Dutch if considered necessary, having to speak English was mentioned to be a limitation to the natural workflow in the evaluation of the study, especially by the OR nurses. Another limitation of the study is that its results may have been influenced by the Hawthorne effect, a well-described phenomenon of an unintentional change of behaviour or productivity in response to the presence of an 'observer'.[60, 61] It is known that this effect typically fades with time, as the team members are getting used to the observation, especially if the presence of an observer is not directly visible.[62] Our video recordings were made with surveillance cameras that were already mounted into the ceiling in most of our operating rooms. This non-obstructive set-up for observation is likely not to attribute much to a possible Hawthorne effect, as one is likely to forget a camera that is not disturbing one's activities when focusing at tasks.

The patient itself was not the main subject of this study. Therefore, no correlations could be made with the operative patient outcomes or clinical endpoints. Future studies may prove the direct or indirect benefits for the patients.

Scheduling the multidisciplinary debriefings for such an amount of consecutive surgical cases with so many different team members proved to be a challenge during this study. Authors would have preferred scheduling the debriefings sooner to the surgery, but this proved not feasible in all cases. Nevertheless, having the objective information including the video footage in the outcome report sparked the memory satisfactory, according to participants. Results of this study show that neither the number of team members attending the team debriefing, nor number of workdays between the procedure and debriefing was significantly associated with the satisfaction scores. As a recommendation, authors believe that inviting OR personnel to participate in about 2 multidisciplinary debriefings per year may already be a great facilitator in better understanding each other's need. Whether or not it is widely generalizable to have an independent person, such as a professor of psychiatry, moderate the sessions and the cost-effectiveness remains open to discussion.

As a result of the positive outcomes of this study, the OR Black Box® system is about to be implemented in full operational modus on multiple clinical operating theatres in our academic medical centre. The performance report is currently, with the help of machine learning software, continuously improving and can now be used for multiple purposes including open surgery in multiple medical centres.[63] Future studies have to determine the effect of including the recording of the entire procedure (start when patient enters the OR and stop when patient leaves the OR) and subsequent anaesthesiology data analysis feedback embedded in the performance report. Further building and incorporating deep-learning artificial intelligence software algorithms capable to process OR Black Box® data are going to provide more accurate assessment of false/true negative/positive events.[64] This may result in scalability of the model, feasibility of team debriefing and an even higher level of user satisfaction. A multicentre study is to be advocated to assess if the OR Black Box® performance report in combination with the Black Box Debrief Model is culturally robust and able to guide discussion during postoperative multidisciplinary debriefings in other medical centres as well.

Acknowledgements

The authors would like to thank all the surgical residents, anaesthesiologists, anaesthesiology residents, operating nurses and anaesthesiology nurses for their participation in this project and the supervising assistants for scheduling the participating team members for the selected procedures. We would like to thank the OR Black Box® analysis centre for analysing the cases and providing the performance reports for the team debriefing sessions. We would also like to thank our technical team for making the installation of the OR Black Box® in our medical centre possible.

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APPENDIX

TOPPER trial OR Black Box® Europe

Feedback Tevredenheidsvragenlijst

ACHTERGROND

1. Uw rol in de operatiekamer:
   a. 1^e Operateur
   b. 2^e Operateur
   c. 1^e Anesthesioloog
   d. 2^e Anesthesioloog
   e. Anesthesiemedewerker
   f. Instrumenterende OK-assistent
   g. Omloop OK-assistent
   h. Coassistent

2. Leeftijd:_______________

3. Geslacht:______________

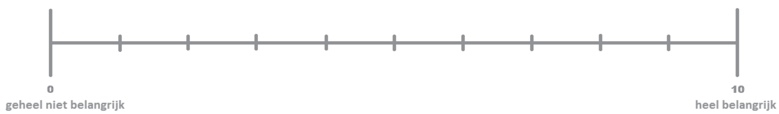
4. Opleidingsjaar (*indien van toepassing)*: ____________ of

   jaartal van registratie voor uw huidige functie:__________________________

5. Aantal jaren werkzaam in het AMC:_____________

6. Heeft u eerder met een OR Black Box® performance report nabespreking meegedaan?
   a) Nee, dit is de eerste keer
   b) 1 – 5 keer eerder meegedaan
   c) 5 – 10 keer eerder meegedaan
   d) >10 keer eerder meegedaan

7. Hoe belangrijk vindt u het in teamverband en gestructureerd kunnen nabespreken van operaties?



TOPPER trial OR Black Box® Europe

NABESPREKING (plaats een kruisje op de lijn)

1. Hoe zou u de nabespreking van vandaag scoren?

0 heel slecht — 10 heel goed

2. Hoe goed voldeden de behandelde onderwerpen aan het vooraf gestelde doel van de nabespreking? *("Het meten van de tevredenheid van het operatieteam ten aanzien van het gebruik van het performance report (incl. video 'clips') voor een gestructureerde nabespreking in teamverband")*

0 heel slecht — 10 heel goed

3. Hoe geschikt waren de ruimte en voorzieningen voor deze nabespreking?

0 heel ONgeschikt — 10 heel Geschikt

4. Hoe goed was deze OR Black Box® nabespreking georganiseerd?

0 heel slecht — 10 heel goed

5. Was de inhoud van het OR Black Box® performance report voor u nuttig?

0 helemaal NIET nuttig — 10 heel nuttig

VERTROUWELIJK

Studie ID Kleur O

TOPPER trial OR Black Box® Europe

6. Denkt u dat de inhoud van het OR Black Box® performance report voor uw teamleden nuttig was?

0 helemaal NIET nuttig — 10 heel nuttig

7. Schat u in dat deze nabespreking van waarde is om de *situational awareness* (“*het bewust zijn van de volledige situatie om u heen”*) van uzelf te verhogen?

0 helemaal NIET waardevol — 10 heel waardevol

8. Schat u in dat deze nabespreking van waarde is om de *situational awareness* van operatieteams als geheel te verhogen?

0 helemaal NIET waardevol — 10 heel waardevol

9. Denkt u dat deelnemen aan de OR Black Box® nabesprekingen u helpt om (nog) beter te communiceren met uw collega’s op de operatiekamer?

0 heel slecht — 10 heel goed

10. Denkt u dat het deelnemen aan de OR Black Box® nabesprekingen waardevol is voor operatieteams om beter met elkaar te kunnen communiceren op de operatiekamer?

0 helemaal NIET waardevol — 10 heel waardevol

TOPPER trial OR Black Box® Europe

11. Denkt u dat het deelnemen aan de OR Black Box® nabesprekingen waardevol is om in de toekomst beter samen te kunnen werken op de operatiekamer?

0 helemaal NIET waardevol — 10 heel waardevol

12. Denkt u dat de OR Black Box® een waardevol instrument is om de patiëntveiligheid te vergroten?

0 helemaal NIET waardevol — 10 heel waardevol

13. Vond u deze OR Black Box® nabespreking leerzaam?

0 helemaal niet leerzaam — 10 heel leerzaam

14a. Indien u iets geleerd heeft van deze OR Black Box® nabespreking, in welke mate verwacht u dan dat het geleerde ook toepasbaar is bij volgende operaties?

0 heel slecht — 10 heel goed

O niet van toepassing

14b. Indien u iets geleerd heeft van deze OR Black Box® nabespreking, hoe gemotiveerd bent u dan om het geleerde daadwerkelijk toe te passen bij volgende operaties?

0 heel ONgemotiveerd — 10 heel gemotiveerd

O niet van toepassing

VERTROUWELIJK

Studie ID Kleur O

15. Vond u deze OR Black Box® nabespreking nuttig?

0 helemaal NIET nuttig — 10 heel nuttig

16. Hoe goed voldeed deze OR Black Box® nabespreking aan uw verwachtingen?

0 heel slecht — 10 heel goed

17. Vond u het deelnemen aan deze OR Black Box® nabespreking een goede besteding van uw tijd?

0 heel slecht — 10 heel goed

18. Wat is voor u de ideale lengte van een team nabespreking?

___________minuten.

19a. Hoe waardevol zou u het vinden als u de mogelijkheid had om zelf te kiezen welke momenten tijdens de nabespreking teruggekeken worden d.m.v. de toegevoegde anonieme video 'clips'?

0 helemaal NIET waardevol — 10 heel waardevol

19b. Hoe waardevol zou u het vinden als u de mogelijkheid had om na de Black Box operatie zelf inzage te krijgen in het performance report en/of de video 'clips'?

0 helemaal NIET waardevol — 10 heel waardevol

TOPPER trial OR Black Box® Europe

20. Hoe waardevol vond u de video ‘clips’ als onderdeel van het performance report?

21. Vind u dat, indien beschikbaar, het mogelijk moet kunnen zijn de OR Black Box® in te zetten als het operatieteam een operatie wil nabespreken?

JA / NEE

Toelichting:

22. Zou u deelname aan de OR Black Box® nabespreking aanraden aan uw collega’s?

JA / NEE

Toelichting:

23. Heeft u iets gemist in het performance rapport?

VERTROUWELIJK

Studie ID Kleur O

24. Wat hebt u wellicht gemist in de nabespreking / wijze van nabespreking met het performance rapport (incl. video ‘clips)?

25. Hoe tevreden bent u over het gebruik van het performance report (incl. video ‘clips’) als instrument voor een gestructureerde operatieteam nabespreking?

0 heel ONtevreden — 10 heel tevreden

-Dank voor uw medewerking-

CHAPTER 4

Analyzing and discussing human factors affecting surgical patient safety using innovative technology: creating a safer operating culture

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Journal of Patient Safety. 2022

ABSTRACT

Introduction: Surgical errors often occur due to human factors related issues. A medical data recorder (MDR) may be used to analyze human factors in the operating room (OR). 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 was analyzed using the automated Systems Engineering Initiative for Patient Safety (SEIPS) 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 of 52.5 (SD 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 out of 360 versus 279 out 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 OR 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.

INTRODUCTION

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

Human factors engineering studies the interaction amongst people, tools, and environments within complex systems, such as the operating room (OR).[10-12] It may help 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 literature exists on safety threats and resilience related to surgery.[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 aim of this study was 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.

METHODS

Subjects and Setting of the Intervention

In this cross-sectional study, a consecutive sample of 35 consented adults (>18 years) 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 their formal written informed consent to use an MDR for the purpose of the study, prior to 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 (PIA) was conducted. This made sure the study was compliant with all applicable privacy, legal and regulatory requirements.[29]

The MDR obtained diverse intra-operative data feeds, including audio-visual, 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, in order 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 following, all data were synchronized, encrypted, and sent via a secure digital channel to the MDR analysis centre.[31] There, the dataset was used for post-processing, generating the MDR performance report. Post-processing was partly automatic, using AI software and rating scales (i.e non- 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 six categories: person, tasks, tools and technology, psychical and external environment, and organization.[14 15 7] 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, non-hierarchical 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 two other relevant events were chosen by alternating team members to discuss; either labelled as 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. The specifically for laparoscopic surgery modified and validated SEIPS model was used.[7,12] The modified SEIPS model utilizes over 100 inductively developed codes, related to each of the 6 above mentioned categories; person, tasks, tools and technologies, organization, internal (physical) environment, and external environment.[12,15] A safety threat is in this study 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 reduces the risk of patient harm, 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 Table 2 and 3 all SEIPS categories and subcategories are presented. A full description of the framework can be found Appendix 1.

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, were shown to and discussed with the OR team.[28] The study coordinator observed all the debriefing sessions. The study coordinator (AvD) 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 are provided.

Statistical analyses

Descriptive statistics including mean (standard deviation (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. 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, and 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 are represented, performed by 4 surgeons, 2 surgical fellows, 12 surgical residents, 6 anesthesiologists, 5 anesthesiology residents, 9 anesthesiology nurses, 27 theatre nurses and 16 medical interns (N=81).

TABLE 1. Procedure characteristics.

Total number of cases, n %	35 (100%)
Fundoplication	18 (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%)
Number of 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 of 52.5 (SD 15.0) relevant events were identified per surgical case.

Both resilience support events and safety threats were mostly related to the Systems Engineering Initiative for Patient Safety (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 Table 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 discussion 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). Due to time limitations, not all events included in the outcome report were discussed.

TABLE 2. Overview of relevant resilience support events based on the 35 MDR outcome reports.

Category (Total N = 360)	Subcategories	Number of 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 & 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 number of 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
	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
Tools & Technology (N = 23)	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

	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

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 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 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 in order 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 set-up. 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 as 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 amidst such chatter. This was not always expressed. Nevertheless, surgeons noted there was sometimes ‘tension on the line’, without understanding the reason for it.

Another discussed event was the fact that surgeons proceeded with surgery whilst, 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 whilst 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. Yet, this was not always the case.

The final count of the gauzes, before the sign-out procedure [1], was also repeatedly discussed.The scrub nurses commented that this is often a ‘chaotic phase’ as 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 audio-visual 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 appears 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 discourage team members to speak up to or confront a surgeon.[45 46] Yet, 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 healthcare, including psychology, business, and aviation.[47] Cultural, professional, and organizational factors predispose people to avoid speaking up, and is 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 does not appropriately capture the complex, independent factors surrounding intra-operative 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, which impact on workflow is not yet understood nor investigated before requires a strict implementation plan; usually starting with qualitative research. For that, this was a pilot study with 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.

Secondly, the operating team members were the focus of this quality improvement pilot study.[28] The patient data and post-operative outcomes were therefore not included as outcome parameter of this study. This, 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 endpoints were made. Now that a baseline has been set, future studies are needed to assess (in)direct positive impact of a possible reduction of safety threats on patient outcomes.

Thirdly, even though the events were labelled according to a validated framework, it may still be biased by subjectivity. As example, 'substandard technique', may have been labelled incorrectly, as surgical techniques may differ amongst 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 centre.[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] Yet, the video recordings were made with surveillance cameras that were already mounted into the OR ceilings. This non-obstructive set-up for observation is likely not to attribute much to a possible Hawthorne effect, as one usually forgets a camera not 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 world-wide.[72] Our center intends to install the new OR Black Box system -updated with improved AI and machine learning software- in multiple operating rooms to continuously record and analyze surgeries.[35] New research lines will be started and 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.

Conclusion

Relevant surgical safety threats identified using the human factors model, were most often originating 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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APPENDIX

SEIPS SYSTEMS-BASED CLASSIFICATION SCHEME FOR SAFETY THREATS AND RESILIENCE SUPPORTS IN LAPAROSCOPIC SURGERY FRAMEWORK AND THEIR OBSERVED FREQUENCY

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
	Protocol violation	Clinician knowingly violates standard protocol/safe operating procedure or failstotake necessaryprecautions/steps(Ex. Participationofobserverin 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 (*potential* to contribute to error)
	Insufficient tool experience/knowledge	Individual lacks experience to correctly/safely/efficiently operate or handle surgical tool (*potential* 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
TOOLS AND TECHNOLOGY		
Sub-category	**Code**	**Description**
Lack of Familiarity	Unfamiliar configuration/setup	Tool/instrument/techconfigured inawaythatisunusual/unfamiliar to user
	Unfamiliar tool	Cliniciansareusingatool/ instrument/equipmentthatis differentfrom their usual tool/is new/isunfamiliar
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 instrumentsforce userstochange/adapttheirsurgical approachwitheach change in instrument

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	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.
PHYSICAL ENVIRONMENT		
Sub-category	**Code**	**Description**
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

ORGANIZATION		
Sub-category	**Code**	**Description**
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/supporttherequired tasksofateammemberwhen 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		
Sub-category	**Code**	**Description**
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 SUPPORT

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 theprocedure/task
	Skills coaching	Teaching/training/coaching on safe/effective surgical skill or technique
	Teaching tool safety	Guidance regarding the safe 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. Unexpectedbleeding), maintainscommunicationand taskperformance

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 eachother)
	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		
Sub-category	**Code**	**Description**
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
TOOLS AND TECHNOLOGY		
Sub-category	**Code**	**Description**
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
PHYSICAL ENVIRONMENT		
Sub-category	**Code**	**Description**
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

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	Quiet	Peace and quiet in OR, no auditory distractions during procedural step
ORGANIZATION		
Sub-category	**Code**	**Description**
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

PART III

Improving surgical quality and safety in the operating room

CHAPTER 5

Assessing the team's perception on human factors in the operating room environment

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American Journal of Surgery. 2020
doi.org/10.1016/j.amjsurg.2020.11.008

Human factor failures have been identified as major underlying causes for surgical adverse events. However, the impact of such adverse events might not always be evident nor apparent.[1]

The operating room (OR) is a unique and high-stress environment. Professionals from various specialties, disciplines and level of seniority are required to work closely together as a team. For effective teamwork, it is hence important to ensure that a shared mental model is perceived by all members of the team. This requires the creation of a supportive and safe environment in which the entire team is able to speak up, and team members know what is expected.[2] A high level of individual 'human factor skills' is required as well. Prior research has demonstrated that OR staff may have discrepant attitudes about the level of human factor skills exhibited from one another, which may be caused by differences in status or authority, responsibilities, and culture.[3]

The Human Factors Analysis and Classification System (HFACS) was developed in response to a trend showing that human error was a primary causal factor in 80% of all flight accidents in the Navy and Marine Corps.[4] HFACS is based on the "Swiss Cheese" model of human error which looks at Reason's four levels of human failure, including organizational influences, unsafe supervision, preconditions for unsafe acts, and unsafe acts.[5] The HFACS model, as shown in Figure 1, may offer tools for human factor analysis to plan solutions to prevent human factor failures.[4]

In order to get more insights in relevant human factors in the OR, we carried out an international multi-center survey study in St. Michael's Hospital (Toronto, Canada) and the Amsterdam UMC, location AMC (The Netherlands). In both locations, a medical data recorder, the OR Black Box® (ORBB) is in use. Between September 2016 and July 2018, 117 elective laparoscopic procedures were recorded using ORBB. The Surgical Team Assessment Record (STAR) questionnaire was administered in both centers. This questionnaire investigates the HFACS's organizational, environmental and personal factors.[6] The questionnaire, previously used and validated across different surgical settings, was adjusted to better reflect and fit these HFACS factors possibly leading to unsafe acts in laparoscopic surgery.

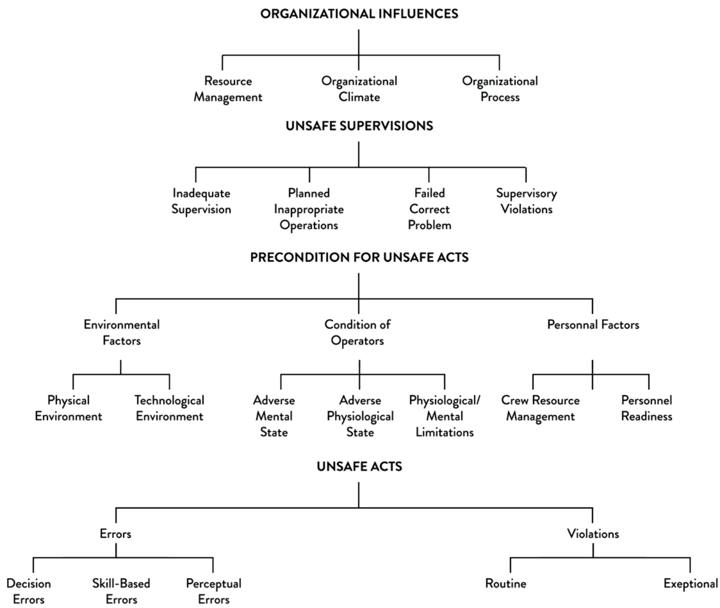

Figure 1. The HAFCS model framework.

All 507 questionnaires were completed by the asked team members after each surgical case, of which 230 (91 cases) at St. Michael's Hospital (SMH) and 277 (35 cases) at the Amsterdam UMC. The laparoscopic cases included 40 Roux-Y gastric bypasses, 24 Toupet fundoplications, 14 diaphragmatic hernia repairs, 4 colorectal resections and 4 uni- or bilateral adrenalectomies. In total for both sites, 119 questionnaires were completed by staff surgeons, 96 by surgical residents, 76 by surgical fellows, 78 by the anesthesiology team members (including anesthesia nurses), 41 by scrub nurses, 44 by circulating nurses, and 53 by medical students.

According to the HFACS model, there are several important factors that may lead to peri-operative unsafe acts and consequently 'human factor failures' by the OR team. Personal readiness, was rated significantly lower by the surgical fellows compared to the rest of the team (median 3/5, IQR 0.0, versus 4/5, F-test p-value <0.0001). The same applied to the fellow's assessment of the team's ability to deal with unexpected events (median of 3/5, IQR 0.0, versus 4/5, F-test P-value <0.0001), and the communication between their team members (median of 3/5, IQR 0.0 versus of 4/5

IQR 0.0, F-test P-value <0.0001). These are both important aspect of the team's crew resource management skills.

Why did the surgical fellows rate their own well-being significantly lower than their resident counterparts? This may be in part caused by stress surrounding career choices and stability. Other factors known to influence staff well-being include workload, climate, or perceptions of teamwork. These human factor elements have been found to have significant associations with burnout symptoms, job satisfaction and organizational commitment. Burnout symptoms, such as emotional exhaustion, fatigue and an inability to concentrate, may hinder one's capacity to ensure surgical safety.[7] Teamwork and well-being have been linked in a similar manner to mental stress and surgical performance.[8] Hence, promoting staff well-being may serve to improve crew resource management skills, organizational outcomes and consequently surgical safety.

Concerning the environmental factors, the staff surgeons more often identified distractions (51.3%, n = 61) and aberrations (60.5%, n = 72) during surgery, compared to all the other team members. These were usually related to technological issues, such as inadequate anastomosis closure (n = 20), bleeding (n = 16), small bowel injury (n = 10), malfunction equipment (n = 9), or poor trocar placement (n = 6).

Although distractions or aberrations during surgery are inevitable and almost 'come with the job', they can be detrimental to overall team performance. Each team member may have a different sense of what is a distraction or aberration, and thus act differently in identifying threats to surgical safety. Indeed, individuals vary in feeling the urge or responsibility to alert the team on a perceived distraction or aberration. They may act differently taking responsibility attempting to resolve the possible safety threat. Yet, the delivery of safe, high-quality care depends on the sound judgement and decision-making capacity of all members of the operating team. Highly cohesive teams with strongly connected members may support the expression of individual opinions, which may promote identification of an active or latent unsafe acts.[9] If unsafe acts are identified pro-actively, this may mitigate peri-operative errors, as these are usually the result of a cumulation of minor active or latent aberrations resulting from different factors in the OR.[5]

Participants in this survey study were under video and audio monitoring, which may have biased their answers and influenced their work condition. The non-obstructive set-up for observation with ORBB may however not attribute much to this possible Hawthorne effect, as one usually forgets a camera not disturbing one's acts, when focusing at their tasks. The team hence reverted back to normal behavior very quickly.

A deeper understanding of the etiology and effect of environment and personal factors on performance may lead to more targeted and sustainable quality improvement initiatives. A supportive team-based approach is recommended, to limit the amount of unnecessary safety threats during a surgical procedure.[2] Further work is needed to elucidate the impact of human factors on team performance and surgical safety. Further studies should focus on using objective date, such as derived by ORBB, to evaluate human factor behavior in the OR, and to define what type of human factors are most relevant and valuable to surgical safety, and to incorporate in team-based training.

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CHAPTER 6

Improving teamwork and communication in the operating room by introducing the theatre cap challenge

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Journal of Perioperative Practice. 2021

ABSTRACT

Objective: One of the steps of the Surgical Safety Checklist is for the team members to introduce themselves. The objective of this study was to implement a tool to help remember and use each other's names and roles in the operating theatre.

Methods: This study was part of a pilot study in which a video- and medical data recorder was implemented in one operating theatre and used as a tool for postoperative multidisciplinary debriefings. During these debriefings, name recall was evaluated. Following the implementation of the medical data recorder, this study was started by introducing the theatre cap challenge, meaning the use of name (including role) stickers on the surgical cap in the operating theatre.

Findings: In total, 41% (n=40 out of 98) of the operating theatre members were able to recall all the names of their team, at the debriefings. On average 44.8% (n=103) was wearing the name sticker.

Conclusions: The time-out stage of the Surgical Safety Checklist might be inadequate for correctly remembering and using your operating theatre team members' names. For this, the theatre cap challenge may help.

INTRODUCTION

The importance of clear communication in the operating theatre (OT) has been widely recognised (Espin et al 2020). Yet, ineffective communication is a major root cause of surgical adverse outcomes (Leonard et al 2004, Wahr et al 2013). The crew resource management principles, adapted from the aviation industry, emphasise the importance of using the closedloop communication (CLC) technique in preventing adverse events (El-Shafy et al 2018). CLC includes three components: (1) an initial message that starts with stating the name of the recipient, known as directed call out, (2) verification by the named recipient, including repeating the critical aspect of the message, known as check back and (3) verification by the message sender that the recipient has interpreted the sent message correctly, known as closing the loop (Davis et al 2017, El-Shafy et al 2018). Accordingly, the World Health Organization (WHO) Surgical Safety Checklist (SSC) briefing includes an introduction stating name and role of all team members before start of a procedure. However, there is little data to support how name and role introductions improve name recall amongst staff (Birnbach et al 2017, Burton et al 2018). Simple strategies to remember and use each other's names and roles, besides the SSC introduction round, writing down the names on a whiteboard, and briefing exist. In addition, the Patient Safety Network's 'Theatre Cap Challenge' emphasises the importance of visible staff identification, by putting your name and role on your surgical cap when working in highly stressful environments such as the OT (Burton et al 2018). Some departments, such as the trauma room, already used name stickers to identify the staff, so this method may be easily rolled out in the OT (El-Shafy et al 2018). During the roll out of the use of the theatre cap challenge, the aims of this study were to (1) evaluate if name and role instructions as part of the WHO's SSC were actually completed, (2) how well team members were able to remember and recall each other's name and (3) evaluate the introduction of the theatre cap challenge at our medical centre.

METHODS

This study was part of a pilot study aiming to implement a video- and medical data recorder (MDR) in an OT, used as a tool for structured postoperative multidisciplinary debriefings to improve surgical safety (van Dalen et al 2020b). Thirty-four laparoscopic (gastro-intestinal) procedures were recorded with the MDR and debriefed with the entire OT team outside the OT (in a neutral environment), using the MDR outcome report (van Dalen et al 2020a). The Works Council (staff representation) and Hospital Directorate approved the study. All subjects gave their written informed consent for participation in the MDR procedures and the MDR debriefings.

During the multidisciplinary debriefings of the MDR pilot study, the study coordinators hypothesised that the OT team members were often not able to remember the names of their peers and that miscommunication was one of the main topics during these debriefings (van Dalen et al 2020b).

Name recall was therefore evaluated by asking the participants (i.e. the entire OT team) before start of each postoperative multidisciplinary MDR debriefing, to write down the names of all the participating team members with whom they had worked during the particular case. Sitting at a table, they noted their team members' names and pairing role on a paper sheet. The completed sheets were returned to the study coordinator. Subsequently, their own name was written on a triangular name plate, so that all names were visible throughout the debriefing (see Figure 1). Moreover, the study coordinator was present in the OT during all 34 recorded procedures and noted whether or not an official introduction round was carried out with the entire team in the OT, according to the SSC (SURPASS = Surgical Patient Safety System) (de Vries et al 2008, WHO 2009).

Following the results of the name recall evaluation, the theatre cap challenge was introduced by placing name and role sticker stations in the dressing rooms of the operating complex (November 2018), as shown in Figure 2. The OT staff was notified accordingly via email and asked to wear the name stickers on their surgical caps. Use of the name stickers was voluntary. Board members and team leaders acted as role models in wearing the name stickers.

Figure 1. Name plates during the postoperative team debriefing sessions.

Figure 2. Name sticker station on the operating room complex, with a sign (on the right) kindly asking to put the stickers on the surgical cap.

RESULTS

The study coordinator observed that one out of four staff surgeons carried out an official introduction round, during which all team members present, publicly said their full names including role. The SUPRASS item 'confirm all team members have introduced themselves by name and role' was in all 34 cases checked off as completed. All names and roles were noted on the whiteboard in the OT before start of procedure, usually by the circulating nurse although surgeons also did write down their name with their phone number themselves.

In total, 238 postoperative questionnaires were completed directly after the 34 recorded surgical procedures. According to the specific OT team member filling out the questionnaire, in 82.4% (n=196) of the cases it was stated that the entire OT team was indeed introduced.

In total, 41% (n=40, out of 98) of the OT team members were able to recall all the names of their team members attending the postoperative MDR team debriefing. As shown in Table 1, the name of the primary surgeon was remembered most often (93%, n=68) and the name of the medical intern least often (32%, n=18). The primary surgeon could remember the name of the anaesthesiologist only on 50% of occasions (n=14) and the scrub nurse's name in 58% of times (n=12). The anaesthesiologist could remember the name of the primary surgeon in 75% of the time (n=9) and the scrub nurse's name in 38% of the time (n=8).

As shown in Table 2, there was no significant difference between the times the OT team was introduced prior to the start of the surgical procedure, according to the questionnaire, versus times the names of the specific OT team members were remembered at the postoperative MDR team debriefing. There was no significant correlation between name and role introduction actually being performed and the percentage of correct name recall (P-value<0.310, 96%CI −0.83 to 4.06).

About one year after implementation (September 2019), the theatre cap challenge was evaluated by asking a medical student, unfamiliar to OT staff, to count (on two randomly chosen mornings at the start of the working day and one time during lunchtime break, for 1.5h) how many individuals, and who were actually wearing the name

TABLE 1. Number of times the team member remembered the name of their fellow team member.

	Did remember/know the name of;							
	Primary Surgeon (N=73)	Assisting Surgeon (N=55)	Anaesthesiologist (N=49)	Anaesthesiology nurse (N=49)	Scrub nurse (N=53)	Circulating nurse (N=44)	Medical intern (N=57)	
Total times their name was remembered	93% (n=68)	80% (n=44)	59% (n=29)	76% (n=37)	64% (n=34)	66% (n=29)	32% (n=18)	
Role in the OR								*P*-value*
Primary Surgeon		14 (N=14, 100%)	6 (N=12, 50%)	11 (N=13, 85%)	7 (N=12, 58%)	8 (N=12, 67%)	3 (N=11, 27%)	*P*<0.0001
Assisting Surgeon	14 (N=14, 100%)		6 (N=7, 86%)	6 (N=10, 60%)	6 (N=9, 67%)	3 (N=6, 50%)	4 (N=8, 50%)	*P*<0.0001
Anaesthesiologist	9 (N=11, 75%)	6 (N=8, 75%)		7 (N=8, 88%)	3 (N=8, 38%)	3 (N=6, 50%)	0 (N=6, 0%)	*P*<0.0001
Anaesthesiology nurse	12 (N=14, 86%)	9 (N=10, 90%)	6 (N=8, 75%)		6 (N=8, 75%)	6 (N=6, 100%)	3 (N=6, 50%)	*P*<0.0001
Scrub nurse	11 (N=12, 92%)	5 (N=9, 56%)	7 (N=9, 29%)	5 (N=7, 71%)		8 (N=8, 100%)	3 (N=9, 33%)	*P*<0.0001
Circulating nurse	12 (N=12, 100%)	3 (N=6, 50%)	2 (N=7, 29%)	5 (N=5, 100%)	8 (N=100%)		4 (N=7, 57%)	*P*<0.0001
Medical intern	10 (N=10, 100%)	7 (N=8, 88%)	2 (N=6, 33%)	3 (N=6, 50%)	4 (N=50%)	1 (N=6, 17%)		*P*<0.0001

* Chi-square test

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stickers. On average 44.8% (N=230) was wearing the stickers whilst working in the OT. In 40.8% (n=42), they had put them on the surgical cap and in 59.2% (n=61) on the chest or name badge. Out of the 103 identified subjects in the theatre complex, 17 (16.5%) were surgeons, 29 (28.2%) were OT theatre nurses, 31 (30.1%) were anaesthesia nurses and 15 (14.6%) were medical interns.

We found that on average almost half of the OT staff (44.8%, n=103 out of 230 observations) was now wearing the stickers on their surgical cap whilst working in the OT complex. Of this randomly observed sample (n=103), 17 (16.5%) were surgeons, 29 (28.2%) were OT nurses, 31 (30.1%) were anaesthesia nurses and 15 (14.6%) were medical interns. Those who did not want to wear the name stickers commented 'I am not new', 'we do not wear them in an OT where everybody already knows each other' or 'it feels like kindergarten'. However, those who did wear them commented 'it looks silly, but it works', 'I feel more part of the team when I am certain that everybody is able to use my name', 'I have been working here for 30 years and still do not know everybody's name' and 'it is useful, because especially during stressful situations names are forgotten'.

TABLE 2. Number of times the team was introduced preoperatively versus times the names were remembered at the team debriefing.

Yes, name was remembered of;	"yes, names were introduced preoperatively"	"no, names were not introduced preoperatively"	*P*-value*
Primary Surgeon (N=73)	59 (94%)	9 (90%)	*P* = 0.67
Assisting Surgeon (N=55)	37 (80%)	8 (80%)	*P* = 1.0
Anaesthesiologist (N=49)	25 (56%)	4 (100%)	*P* = 0.08
Anaesthesiology nurse (N=49)	31 (76%)	6 (75%)	*P* = 0.97
Scrub nurse (N=53)	30 (65%)	4 (57%)	*P* = 0.68
Circulating nurse (N=44)	23 (61%)	6 (100%)	*P* = 0.58
Medical intern (N=48)	16 (38%)	2 (33%)	*P* = 0.82

*Chi-square test

DISCUSSION

During the pilot study MDR debriefings, participants realised how difficult it apparently is to remember each other's names. Moreover, participants indicated they felt ashamed or awkward for not knowing the names of their colleagues, with whom they had worked multiple times before. The importance of awareness and education in communication skills in a high-risk environment such as the OT may hence not be underestimated (Catchpole and Russ 2015, Rydenfalt et al 2013). Davis et al (2017) demonstrated directed communication was associated with an increased likelihood of receiving a proper answer and confirmation that the message was received. Increased incidence of check backs (ie as part of the CLC technique) reduced the number of ineffective communication events, provided opportunities for clarification of safety-critical information, and enhanced the OT team's shared mental model. They also emphasised that addressing each other by name before sending the message may avoid unnecessary miscommunication.

Perhaps not surprisingly in daily practice with many checklists to complete, the name introduction item was usually 'checked off' by the team, without actually officially have taken place. Team members may say that they had worked with the same team members before; 'We know each other already'. Yet, 59% of the time, the staff could not recall all the names of the team members whom they had performed the surgical procedure with. Non-compliance with this step of the SSC has been demonstrated in other studies (Levy et al 2012, Rydenfalt et al 2013) and once again highlights the problem with checklists. Just 'checking the box', by having it secured in the patient file does not mean the check has actually been performed, questioning its true value (Catchpole and Russ 2015, Rydenfalt et al 2013).

Usually, OT staff uses the team brief and the time-out as part of the five steps to safer surgery, before the start of the surgical procedure to introduce their name and role (Russ et al 2015). This may be helpful, but not suffice to adequately remember all the names. In certain situations or phases of a procedure, with staff fully focusing on important tasks, it is notably difficult to recall names, because faces are behind surgical caps and masks. Especially now during the COVID-19 pandemic, protective clothing and respiratory masks make it even more difficult to recognise each other in the hospital.

In addition to that, team members may not always be able to make eye contact whilst concentrating behind the surgical drape or looking at the laparoscopic monitor. All these factors may complicate interaction and communication. The team has to respond to stressful situations, such as performing surgery during the COVID-19 pandemic, by promoting trust and coherency among colleagues. In these situations, it is particularly important to use the directed call out and CLC techniques.

Other studies have shown that the name of the primary surgeon is often the easiest to remember (Birnbach et al 2017, Burton et al 2018). Moreover, surgeons may be more often annoyed by the official introduction by names and nurses are usually more grateful (Haynes et al 2009). This may explain why nurses wear the name stickers more often. Studies have demonstrated that good leaders are often characterised by remembering and using the names of the people they work with (Lussier and Achua 2015). Although some may not see or understand the power of something as simple as knowing and using one another's name, it is generally known that people feel more appreciated and are happier to help if you call them by their name, enhancing coherency of the team.

Limitations of this study are the small sample size and the single-centre study design. It was not possible to correlate the use of the name stickers to the number of communication events during the surgical procedures. We did not take into account the number of times a new OT member (name) was introduced per team and per case, which may have caused a bias. Future studies are needed to evaluate the actual impact of putting your name on your surgical cap on the use of the CLC technique, name recall, and subsequently the incidence of ineffective communication in the OT. This is the aim of the follow-up project of this pilot study, by using the improved version of the MDR (Saver 2019, Surgical Safety Technologies). Regardless, it may be considered important that every professional working in the OT realises the importance of the CLC technique, for which all team members need to be able to know and use each other's name.

There are many reasons why people find it difficult to remember the names of their team members during surgery. Regardless, it remains difficult to remember and use names, even when the names are introduced prior to start of the procedure, are written on a whiteboard and when team members have worked with one another multiple times before. Therefore, implementation of name stickers in the OT is recommended as it may facilitate the CLC technique in a simple manner. For this, a culture change in the OT environment is needed, which takes time and commitment (Burton et al 2018, Vaughn et al 2018). Patience and role modelling by leaders showing the way with using the name stickers to improve communication is important, and may promote positive safety behaviour, such as work satisfaction, providing feedback or error reporting (Catchpole et al 2021, Wakefield et al 2010). The results from this study recommend all team members to participate and embrace the theatre cap challenge, to create an even more positive safety culture by improving communication in the OT.

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CHAPTER 7

The influence of working in a Black Box monitored operating room on safety behaviour: surveying attitudes towards patient safety culture

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Submitted

ABSTRACT

Background Despite numerous initiatives to improve quality and safety in the operating room (OR), the incidence of preventable surgical errors remains too high. An operating room Black Box® (ORBB), a medical data recorder, was therefore implemented in one OR of our tertiary referral centre. Its output was used as template underpinning structured postoperative team debriefings. In order to sustainably implement a quality and safety improvement initiative such as the ORBB, it is considered important to understand the attitudes, beliefs and perceptions concerning safety of all healthcare professionals involved. The aim of this study was 1) to assess OR staff's attitudes towards patient safety culture in the OR specifically, and 2) to evaluate if working with an ORBB influences their perception of patient safety.

Methods The Dutch version of the validated Hospital Survey on Patient Safety Culture was administered to all professionals working in the OR complex. Ten questions regarding the use of the ORBB were added. The mean and the positive response rates (PRR) of the 11 patient safety culture dimensions in the questionnaire were calculated.

Results In total, 126 professionals completed the survey (response rate 24.18%). Overall perception on patient safety was scored with a mean of 3.06 (SD 0.46) on a 5-point Likert Scale). Safety dimensions achieved lower scores from the OR nurses compared to the other professionals in the OR. Overall, the attitude of OR professionals participating in team debriefings using ORBB is positively correlated with their perception on patient safety (P-value<0.024, 95%, CI 0.034-0.474, Bèta-coefficient 0.196).

Conclusions There is a variety in perception of the safety culture in the OR between the different OR professionals. Professional participation in ORBB assisted debriefings may impact safety behaviour, as it provides the opportunity to discuss differences in perceptions concerning beliefs, opinions, needs and attitudes on improving surgical safety. The results of this study may help centres to implement this quality and safety improvement system more broadly and in a sustainable manner.

INTRODUCTION

Studies have demonstrated that human factor failures are most often the root-cause of surgical adverse events, rather than technical skills.[1, 2] Consequently, video- and medical data recording in the OR is increasingly used as an intervention to improve surgical quality and safety.[3, 4] Such a medical data recorder, the OR Black Box (ORBB), is implemented at our tertiary referral centre.[5] It was assumed that use of the ORBB output as discussion template for structured team debriefings may help foster a shared mental model on peri-operative situations.[3,4] Implementation of such a quality improvement intervention is however challenging. It is bound by existing cultures, beliefs, ethics, medicolegal- and privacy issues, logistics, time and finances.[6]

In the OR, professionals from various specialties, disciplines and level of seniority work closely together in a high-stress environment. Their safety behaviour (e.g. reporting incidents, speak up when an error occurs) may be improved by use of the ORBB. Important factors influencing the intention to engage in safety behaviour are; behavioural beliefs (whether the individual believes that the behaviour will improve safety), behavioural outcomes (whether the individual has experienced improved safety resulting from the behaviour), and an individual's perception about their colleagues' safety behaviour.[7] In order to sustainably implement a safety improvement initiative such as the ORBB, it is hence important to understand the attitudes, beliefs and perceptions concerning safety culture of all professionals working in the OR.[8]

The aim of this study was 1) to assess OR staff's attitudes towards patient safety culture in the OR specifically, and 2) to evaluate if working with an ORBB influences their perception of patient safety.

METHODS

This cross-sectional single-centre survey study explored the attitudes towards safety culture among OR staff specifically, using the Agency for Health and Research Quality's (AHRQ) Hospital Survey on Patient Safety Culture (HSOPSC). The questions of the original (English) questionnaire can be found on the official AHQR website (https://www.ahrq.gov/sites/default/files/wysiwyg/sops/quality-patient-safety/patientsafetyculture/hospitalscanform.pdf). The validated Dutch version of the HSOPSC was chosen.[9] Questions were provided using a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree) or from 1 (never) to 5 (always). The survey contained 42 items, across 11 patient safety culture dimensions. These safety dimension have been previously assessed and validated for clustering into categories using factor analysis.[9,10]

Participants and setting

This survey was administered to all healthcare professionals working in the OR complex at one tertiary referral centre, including individuals who previously participated in a pilot initiative concerning the use of an ORBB. A privacy impact assessment was performed prior to start of this survey study, according to the new European General Data Protection Regulation (GDPR). The survey was stated in Dutch, voluntary and anonymous to team member's name, but not to role in the OR, work department, and work experience (Appendix 1).

The original survey was supplemented with 10 questions regarding the use of the ORBB. The questions we used for this study were; "have you participated in the Black Box debriefings?" and "do you believe use of the OR Black Box® can improve surgical safety?". Responses were provided using a 5-point Likert scale. Because this was the first centre to have implemented ORBB for multidisciplinary debriefing, it was not possible to send out the survey to other centres using the ORBB for this purpose.

The ORBB

Highly performing teams working in the OR need to have a proactive attitude towards error reporting, management and prevention to improve surgical safety, but need to be provided the tools to do so.[11] The ORBB was therefore introduced in one OR and used as a tool to support structured postoperative team debriefing with the aim to improve safety behaviour.[5,12]

Details on implementation of the ORBB, legal considerations and the results of the pilot study itself are presented in previous articles.[1,5,6,13] An explanatory summary on the use of ORBB was created after completion of the ORBB trial is visually presented in an online publicly available video named "A Black Box in the operating theatre. Good idea?" (https://www.youtube.com/watch?v=_Vu2AQa10NY). Participation in this video was voluntary and it was created for a congress about the ORBB at our centre.

Whilst implementing the ORBB, there was a lot of resistance from the OR staff, as they presumably did not believe in the outcomes of the ORBB and were afraid their privacy could not be protected. Yet, those who did decide to participate, based on positive experiences shared by their peers, reverted their opinion when they came to better understand how their privacy was protected and consequently experienced the benefits first-hand.[5] The positive compliance of the OR team members who chose to participate was previously demonstrated in another study.[5]

Outcomes and data collection

In order to improve the surgical safety culture, it may be considered important to start with understanding the current safety behaviour of those working in the OR (i.e. why do they do things or why do they think about problems this way?).[11,14,15] The primary aim of this study was therefore to evaluate the attitudes of all healthcare professionals working at the OR complex of one tertiary referral centre. The secondary outcome was to evaluate if implementing ORBB for team debriefing purposes is of influence on staff's perception towards patient safety.

The survey was digitally administered (by e-mail) to all the healthcare professionals, by the OR manager, with approval of the heads of all the departments. The online tool LimeSurvey® was used, according to the recommendations of the hospital's privacy officer. After about 4 weeks, one reminder was digitally sent. Because of the GDPR and guidelines of the privacy officer, it was not possible to use a direct approach as a reminder strategy. Data was anonymously collected and stored by the study coordinator (AvD).

Statistical Analysis

The questions of the validated Dutch survey were transformed into the 11 predefined patient safety dimensions.[10,16] Each safety dimension is composed by the sum of the means of the questions belonging to that particular safety dimension.[10]

Descriptive analysis was used to provide an overview of the baseline characteristics, such as years working at the hospital, role in the OR and amount of hours working per week. The overall means, including the standard deviation (SD), of the 11 safety dimensions were presented. These were compared between the professions with the one-way analysis of variance test to identify whether there was a difference between the different OR team members.

The positive response rate (PRR) was determined for each safety dimension, according to the recommendations of the Agency for Healthcare Research and Quality (AHRQ) user guide.[17] The PRR represents the number of persons (i.e. percentage) who answered the question with a mean of 3.5 or higher, on the 5-point Likert scale. The PRR thus indicates the percentage of respondents who have a positive attitude towards patient safety. The PRR for each dimension is the mean value of the PRRs for all dimension items. If the PRR is over 75%, the dimension is considered "highly positive."[18]

Descriptive analysis was used to provide an overview of the answers related to the use of the ORBB. Linear regression was used for selecting relevant variables, with a threshold P-value of 0.20, to build the multiple linear regression model. The multiple linear regression model was built with backward elimination to evaluate possible factors associated with the overall perception of patient safety.

RESULTS

On March 26th 2019 the survey was sent to 24 surgical staff members, 4 surgical fellows, 23 surgical residents, 71 staff anaesthesiologist, 74 anaesthesiology residents, 86 anaesthesiology technicians, 139 operating theatre nurses, 14 urology professionals, 9 paediatric surgeons, 9 cardiothoracic surgeons, 19 orthopaedic surgeons, 6 plastic surgeons, 13 neurosurgeons, 28 gynaecologists, and 2 Ear, Nose and Throat (ENT) staff members. In total, 521 healthcare professionals working in the OR (across all different surgical specialties) received the survey. Before sending out the general reminder, 82 professionals completed the survey (initial response rate of 14.56%). A general reminder was sent on April 25th 2019. The survey was closed on May 29th 2019. In total, 126 professionals completed the entire survey. This resulted in a final response rate of 24.18%. Most responses were received from the operating nurses (23.02% of total) and staff surgeons (24.6% of total). The complete details and baseline characteristics of the respondents are presented in Table 1.

Patient Safety Dimensions

The overall means of the 11 validated patient safety dimension and PRR's are presented in Table 2. The operating nurses rated the overall perception of safety the lowest (mean 2.89 (SD 0.45)) while the anaesthesiology residents rated it to be the highest (mean 3.39 (SD 0.32)). Teamwork within the department was rated the most positive with an overall mean of 3.69 (SD 0.64), PRR 73.02%), followed by communication openness (mean 3.60 (SD 0.76), PRR 63.49%). Overall, changing shifts was rated the lowest (mean 2.90 (SD 0.48), PRR 21.43%). As presented in Table 2, there were significant differences concerning several safety dimensions between the different roles in the OR (Teamwork within department (P 0.001), Non-punitive response to error (P 0.016), Communication openness (P 0.001), Feedback and learning from errors (P 0.045), Supervisor expectations and actions promoting safety ($P < 0.0001$), Adequate staffing ($P < 0.003$). The overall means of the 11 validated dimensions per department are presented in Figure 1.

Table 1. Baseline Characteristics (N = 126)			
	N completed survey	% of total	N received survey (response rate per department)
Department			
Anaesthesiology	49	38.89	231 (21.21%)
General Surgery	17	13.49	51 (33.33%)
Operating Room Complex	35	27.78	139 (25.18%)
Urology	4	3.17	14 (28.57%)
Neurosurgery	5	3.97	13 (38.46%)
Orthopaedic surgery	3	2.38	19 (15.79%)
Paediatric surgery	2	1.59	9 (22.22%)
Cardiothoracic surgery	2	1.59	9 (22.22%)
Plastic surgery	1	0.79	6 (16.67%)
Gynaecology	6	4.76	28 (21.43%)
Ear, Nose and Throat (ENT)	2	1.59	2 (100%)
Years working at hospital?			
<1 years	4	3.17	-
1-5 years	29	23.02	-
6-10 years	31	24.6	-
11-15 years	23	18.25	-
16-20 years	11	8.73	-
>20 years	28	22.22	-
Years working at current department?			-
<1 years	6	4.76	-
1-5 years	32	23.1	-
6-10 years	30	25.4	-
11-15 years	22	17.46	-
16-20 years	10	7.94	-
>20 years	26	20.63	-

How many hours per week?			-
<20 hours/week	6	4.76	-
20-39 hours/week	61	4.3	-
40-59 hours/week	44	48.41	-
60-79 hours/week	14	11.11	-
>79 hours/week	1	0.79	-
Role at department?			
Staff surgeon (including orthopaedic-, plastic-, paediatric-, cardiothoracic-, neuro-)	31	24.6	80 (38.75%)
Staff anaesthesiologist	22	17.46	71 (30.99%)
Surgical fellow	1	0.79	4 (25%)
Surgeon in training	4	3.17	23 (17.39%)
Anaesthesiologist in training	7	5.56	74 (9.46%)
Anaesthesia nurse	20	15.87	86 (23.26%)
Operating nurse	29	23.02	139 (20.86%)
Other	10	7.94	44 (22.73%)
How long working within this role?			
<1 year	5	3.97	-
1-5 years	28	22.22	-
6-10 years	23	18.25	
11-15 years	22	17.46	-
16-20 years	14	11.11	-
>20 years	34	26.98	-
In contact with patients?			
Yes	120	95.23	-
no	6	4.76	-
Participated in the OR Black Box trial?			
Yes	18	14.3	-
No	108	85.7	-

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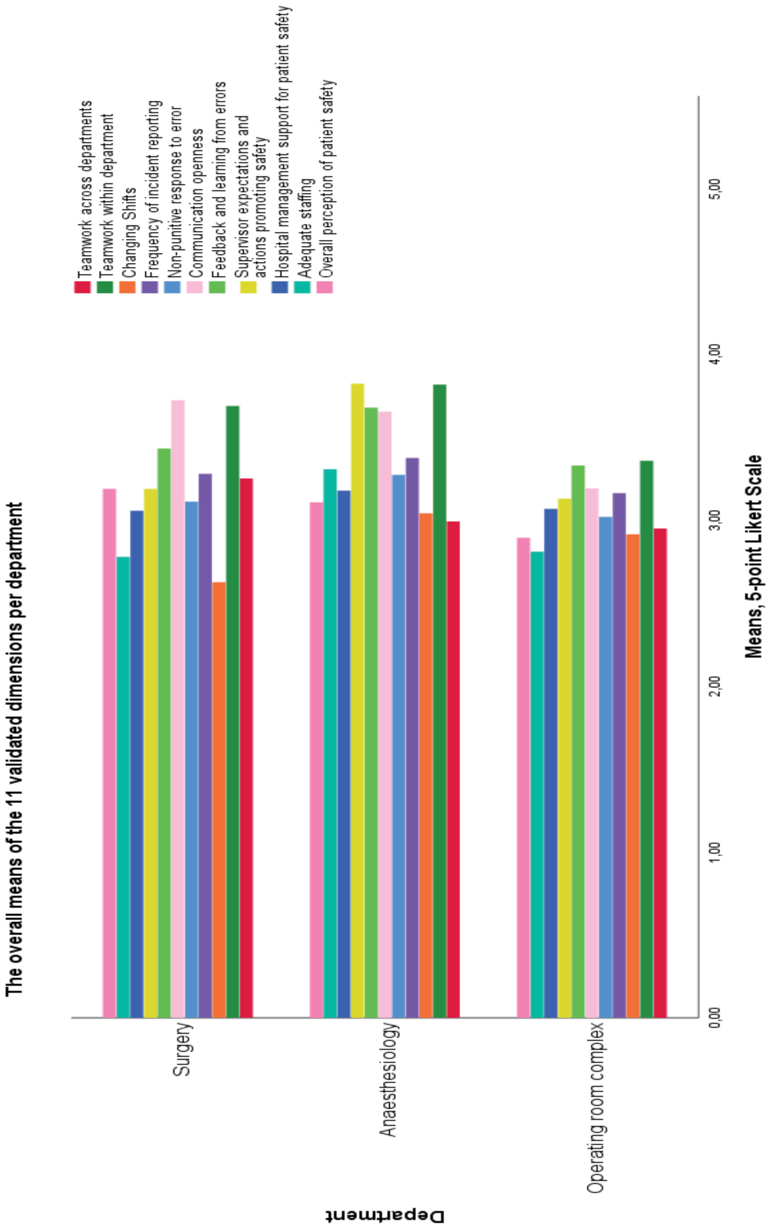
The overall means of the 11 validated dimensions per department
Teamwork across departments
Teamwork within department
Changing Shifts
Frequency of incident reporting
Non-punitive response to error
Communication openness
Feedback and learning from errors
Supervisor expectations and actions promoting safety
Hospital management support for patient safety
Adequate staffing
Overall perception of patient safety
Surgery
Anaesthesiology
Operating room complex
Department
0,00
1,00
2,00
3,00
4,00
5,00
Means, 5-point Likert Scale

Table 2. Patient Safety Dimension Means per Role in the Operating Room (5-point Likert scale)

Patient Safety Dimensions	Operating Nurses (N 29)	Anaesthesiologists (N 22)	Anaesthesiology Residents (N 7)	Anaesthesia Nurses (N 22)	Surgeons and 1 fellow (N 32)	Surgical residents (N 4)	Other (N 10)	Total (N 117)	P-value (One way ANOVA)	Positive Reponse Rate (mean >3.5)
1.Teamwork across departments	2.95 (SD 0.30)	3.05 (SD 0.46)	2.80 (SD 0.40)	3.02 (SD 0.50)	3.14 (SD 0.50)	3.15 (0.25)	2.80 (SD 0.65)	3.02 (SD 0.46)	P 0.290	11.90%
2.Teamwork within department	3.34 (SD 0.58)	3.70 (SD 0.73)	3.93 (SD 0.19)	3.90 (SD 0.60)	3.93 (SD 0.40)	3.75 (0.65)	3.25 (SD 0.94)	3.69 (SD 0.64)	P 0.001	73.02%
3.Changing Shifts	2.91 (SD 0.44)	3.14 (SD 0.38)	2.79 (SD 0.64)	2.98 (SD 0.60)	2.72 (SD 0.44)	2.75 (0.50)	2.85 (SD 0.24)	2.90 (SD 0.48)	P 0.060	21.43%
4.Frequency of incident reporting	3.28 (SD 0.92)	3.36 (SD 1.03)	3.67 (SD 0.69)	3.32 (SD 0.69)	3.46 (SD 0.70)	3.42 (0.69)	2.63 (SD 0.94)	3.33 (SD 0.85)	P 0.181	42.86%
5.Non-punitive response to error	2.98 (SD 0.64)	3.00 (SD 0.69)	3.52 (SD 0.33)	3.38 (SD 0.54)	3.29 (SD 0.49)	2.92 (0.50)	2.90 (SD 0.52)	3.16 (SD 0.60)	P 0.016	28.57%
6.Communication openness	3.15 (SD 0.66)	3.48 (SD 1.00)	4.19 (SD 0.38)	3.70 (SD 0.78)	3.91 (SD 0.41)	3.83 (0.33)	3.47 (SD 0.97)	3.60 (SD 0.76)	P 0.001	63.49%
7.Feedback and learning from errors	3.32 (SD 0.55)	3.49(SD 0.78)	4.00 (SD 0.51)	3.78 (SD 0.59)	3.51 (SD 0.45)	3.42 (0.40)	3.32 (SD 0.87)	3.52 (SD 0.62)	P 0.045	60.32%
8.Supervisor expectations and actions promoting safety	3.05 (SD 0.76)	3.67(SD 0.87)	3.89 (SD 0.35)	3.95 (SD 0.62)	3.63 (SD 0.69)	3.50 (0.29)	3.15 (SD 0.88)	3.54 (SD 0.78)	P < 0.001	62.70%
9.Hospital management support for patient safety	3.06 (SD 0.30)	3.15 (SD 0.47)	3.29 (SD 0.23)	3.16 (SD 0.31)	3.08 (SD 0.44)	3.08 (0.50)	3.00 (SD 0.54)	3.11 (SD 0.40)	P 0.713	14.29%
10.Adequate staffing	2.70 (SD 0.48)	3.14 (SD 0.67)	3.38 (SD 0.52)	3.40 (SD 0.65)	2.82 (SD 0.62)	2.67 (1.19)	3.00 (SD 0.96)	2.99 (SD 0.69)	P 0.003	21.43%
11.Overall perception of patient safety	2.89 (SD 0.45)	3.00 (SD 0.53)	3.39 (SD 0.32)	3.05 (SD 0.49)	3.20 (SD 0.40)	3.06 (0.55)	2.95 (SD 0.26)	3.06 (SD 0.46)	P 0.058	23.81%

The ORBB

The question “Do you believe that the use of a Black Box- a medical data recorder- in the OR could contribute to the patient safety” was answered with an overall mean of 3.05 (SD 1.12, 5-point Likert scale, N=126). Eighteen subjects (out of 81 total participants in the ORBB trial) participated in the Black Box trial of which 6 operating nurses, 5 anaesthesiologists, 4 anaesthesia nurses, and 3 surgeons.

Concerning the means of the 11 patient safety dimensions, overall perception of patient safety was the only dimension for which the overall mean was significantly different (P-value 0.03) between those who did participate in the ORBB Trial (mean 2.85, SD 0.43) and those who did not participate (mean 3.09, SD 0.45). Table 3 demonstrates the means of all the 11 dimensions between participants and non-participants of the ORR trial.

Working more than 40 hours per week seems to influence the attitude towards patient safety. Overall, 44.4% of the ORBB participants work 20-40 hours per week and 38.9% of them work more than 40 hours per week. Participating in ORBB trial and hours working per week both appeared to be significantly correlated with the overall attitude towards patient safety, when correcting for possible confounders (Table 4).

Table 3. Differences in attitudes towards the 11 patient safety dimension between participants of theBlack Box Trial (N = 18) and those who did not (N = 108) participate (Means 5-point Likert scale)

Patient Safety Dimensions	Worked with ORBB (Mean,SD) N= 18	Did not work with ORBB (Mean, SD) N=108	P-value (One way ANOVA)
1.Teamwork across departments	2.92 (0.42)	3.03 (0.46)	*P* 0.35
2.Teamwork within department	3.68 (0.75)	3.69 (0.62)	*P* 0.93
3.Changing Shifts	2.78 (0.52)	2.92 (0.47)	*P* 0.24
4.Frequency of incident reporting	3.43 (1.02)	3.30 (0.82)	*P* 0.59
5.Non-punitive response to error	3.13 (0.67)	3.17 (0.59)	*P* 0.81
6.Communication openness	3.56 (0.67)	3.60 (0.78)	*P* 0.80
7.Feedback and learning from errors	3.73 (0.54)	3.48 (0.63)	*P* 0.12
8.Supervisor expectations and actions promoting safety	3.63 (0.74)	3.52 (0.79)	*P* 0.60
9.Hospital management support for patient safety	3.20 (0.31)	3.10 (0.41)	*P* 0.29
10.Adequate staffing	2.87 (0.66)	3.01 (0.70)	*P* 0.42
11.Overall perception of patient safety	2.85 (0.43)	3.09 (0.45)	*P* 0.03

Table 4. Multivariable regression analysis model‡ evaluating factors associated with the overall attitude towards the overall patient safety.

Question	P-value*	95% CI	Bèta-coefficient
Have you participated in the OR Black Box surgical cases and following team debriefings? (yes vs no)	0.024	0.034 – 0.474	0.196
Overall, how many hours are you working per week? (≤39 hours vs >40 hours)	0.003	0.085 – 0.393	0.263

‡ Using backward stepwise regression

*corrected for the in simple linear regression analysis found significant variables (see Appendix)

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DISCUSSION

Principal findings

The results of this study show that the operating nurses rated the overall perception of safety the lowest, while the anaesthesiology residents rated it the highest. Overall, teamwork and communication openness were rated the most positive (PRR >63%) by the participants. Participating in the ORBB trial and hours working per week both appeared to be correlated with the overall attitude towards patient safety, when correcting for possible confounders.

Interpretation within the context of the wider literature

In line with previous (HSOPSC) studies, this study indicates there is a variety in perception of the safety culture in the OR between the different OR professionals. (10, 19) This remains to be a significant challenge for safety improvement initiatives, as a strong safety culture is based on a shared mental model of peri-operative situations. A shared mental model can only be established when beliefs, opinions, needs and attitudes on surgical safety can be safely expressed and discussed amongst all the members of the OR team.[7,20]

Nurses rated overall perception of safety, communication openness, supervisor expectations and action promoting safety, significantly lower compared to the rest of the team. This may indicate that their perception of their colleagues' safety behaviour is lower. Studies have shown that nurses usually have higher levels of intended engagement in safety behaviour (such as incident reporting) than doctors.[7,21] Surgeons are often the cause of conflict communication and nurses are most often the recipient of conflict-provoking behaviour.[22] Traditionally, OR teams are hierarchical and divided by role which has often discouraged nurses to speak up to or confront a surgeon.[22,23] However, the willingness to speak up about a safety concern is a key factor of safety in the OR.[23]

Surgical residents rated non-punitive response to error significantly lower compared to the rest of the team. Junior doctors are more likely to perceive blame as a result of an incident and are less likely to speak up when an error is made.[7] This may be caused by the fact that there is still a take-the-blame culture in the OR, where surgeons are urged from the first days of training to step up to the plate and own sole responsibility for their actions.[24] Yet, errors ought to be managed in a 'just culture' instead, where all team members feel confident to report events (even their own mistakes), and by promoting collective accountability.[6,25] The concept of 'collective accountability' entails that all providers work collaboratively and share responsibility for transparency, error prevention, and error management.[26] Healthcare organization have therefore the responsibility to implement non-punitive reporting systems and to support clinicians when errors occur.[11,27]

The results of this study may also suggest that, perhaps unexpectedly, the attitude of participants of the ORBB trial towards the overall patient safety was possibly less positive compared to those who did not participate. Besides that, working full-time seemed to have a positive impact on attitudes towards patient safety. It may be the case that professionals already having high standards in this domain, many of them working more than full-time, are the ones most critical. This may reflect in them expressing a lower overall perception on patient safety. Also, whilst working more, and also night-time hours, they may have been more involved in cases negatively impacting patient safety and therefore especially want to participate (i.e positive safety behaviour). Moreover, participants in the ORBB trial may have been faced with more aspects of safety behaviour during the team debriefings, compared to those who did not participate, and therefore have created -unconsciously- more awareness concerning patient safety improvement gaps. One way or another, early adopters or 'believers' already having a mind-set positive towards an innovation such as ORBB were of great value in organizations tilting towards a culture shift. Indeed, such mind-sets need to be cherished and nourished.

Implications for policy, practice and research

The goal of improving safety culture is aimed at encouraging all OR team members to be transparent about issues that may impact patient safety, as highlighted by the safety dimensions in the HSOPSC survey.[23] Healthcare professionals take care of patients as teams, err as teams, and need a way to accept accountability as teams.[27] Organizations need to consider the behaviour of the healthcare professionals as well as the complex interrelationships between culture, technology, and achieving reliable, high-quality patient outcomes. Because, there are still significant challenges to provide safe patient care in the high technology environment of the OR.[28,29] Implementation of an ORBB, or other video- and medical data recorders, may improve safety behaviour by facilitating team debriefing, coaching and training.[30-32] Understanding safety behaviour is fundamental to developing the teamwork and robust communications that are essential to create a high-reliability organization focused on improving patient safety.[28,33] During (video-assisted) team debriefings, with our without the use of an ORBB, differences in safety behaviour perceptions may be discussed, emphasizing collective accountability for errors in a safe, blame-free, non-hierarchical environment.[5,34]

Successful implementation of novel safety and quality improvement interventions, like an ORBB will require a collective understanding of the importance of transparency concerning safety improvement gaps, as well as a strong commitment to communication openness during both the surgical procedures and debriefings.[5,35] For a strong safety culture, all OR team members ought to be engaged and believe change in behaviour can actually improve patient safety. When implementing a video- and medical data recorder or team debriefing, it may hence be considered important to firstly assess its impact on safety needs, beliefs and perceptions of all professionals working in the OR, irrespective of experience, hours and years working in the hospital. Promoting positive safety behaviour may also help healthcare organizations to implement quality and safety improvement systems more broadly and in a sustainable manner.

Future multi-centre studies, on larger scale, across settings using (different types of) medical data recorders providing output supporting team debriefing and team training are recommended. Patient related outcome data should be included to evaluate whether improved safety behaviour actually leads to a reduction of preventable errors. Also, to strengthen the degree to which suitable inferences can safely be drawn about the impact of behavioural monitoring using medical data recorders under strict and safeguarded conditions on patient safety culture and behaviour.[36]

Strengths and limitations

The strength of this study is that, to the authors' knowledge, it is the first study to use the HSOPSC survey to assess the impact of participation in video-assisted team debriefings, on perceived patient safety. Also, the survey was sent to all staff working at the OR complex, instead of just the surgical department, as it may be considered important to include the entire team when implementing a safety improvement tool such as the ORBB.[1,37]

This study has some limitations as well. Firstly, the response rate was lower than expected, as only general invites could be sent out respecting new privacy laws. Even though, the survey was sent out by OR management, instead of the study coordinator, to increase the response rate. Yet, even with the new privacy regulations preventing sending out personal reminders, still almost 1 out 4 invited completed the questionnaire. Also, in comparison to other studies, the sample size and response rate in this study remains above the average lower limit.[38]

Secondly, regardless of the single-centre design and the sample size, safety behaviour (e.g. reporting incidents and communication openness) is often covert and difficult to measure. Safety behavioural intention may be influenced by many factors such as job satisfaction, hospital support, and beliefs. Even though surveys remain an important method in measuring culture, caution should be exercised in reliance on survey methods alone to measure safety culture.[7] Moreover, it was not possible to evaluate the safety behaviour of the non-responders. It is generally known that physicians are more likely to not take the time to complete a survey, when the relevance of the survey subject is perceived to be low or no direct 'benefits' for the individual are perceived.[39] This may emphasize why it is even more important to discuss the subject.[35,36]

Conclusions

Differences in perceptions between professionals working in the OR concerning safety behaviour exist and these are important to address when improving patient safety culture. Healthcare organizations may promote support for patient safety by implementation of a reporting system like the ORBB. Differences in safety behaviour, such as communication, teamwork and incident reporting may be discussed during the ORBB team debriefings, in a safe environment and transparent non-punitive manner. Future larger studies are needed to assess the impact of the use of the ORBB for team debriefing on safety behaviour in the OR.

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APPENDIX

Sectie A – Uw werkomgeving (18 vragen, 1 = helemaal niet mee eens - 5 = helemaal wel mee eens)

zeer mee oneens =1

mee oneens =2

neutraal (geen van beide) =3

mee eens =4

zeer mee eens =5

1. Mensen steunen elkaar op deze afdeling
2. We hebben genoeg personeel om de werklast aan te kunnen
3. Wanneer er veel werk snel verricht moet worden, werken we als een team samen om het werk af te krijgen
4. Op deze afdeling behandelen mensen elkaar met respect
5. Het personeel op deze afdeling maakt langere werktijden dan goed is voor de patiëntenzorg
6. Wij zijn actief bezig met het verbeteren van de patiëntveiligheid
7. We gebruiken meer invalkrachten dan goed is voor de patiëntenzorg
8. Het personeel heeft het gevoel dat hun fouten tegen hen gebruikt worden
9. Fouten hebben hier tot positieve veranderingen geleid
10. Dat de ernstigere fouten hier niet vaker gebeuren, berust eigenlijk op toeval
11. Als het ergens op de afdeling heel druk is, helpen anderen mee
12. Wanneer een incident wordt gemeld, voelt het alsof de aandacht naar de melder gaat en niet naar het probleem
13. Nadat veranderingen zijn aangebracht om de patiëntveiligheid te verbeteren, wordt hun effectiviteit geëvalueerd
14. We werken volgens een ‘crisis model’: we proberen veel snel te doen
15. Patiëntveiligheid wordt nooit opgeofferd voor het maken van meer productie
16. Het personeel vreest dat de fouten die zij maken in hun personeelsdossier worden bijgehouden
17. We hebben problemen met de patiëntveiligheid op onze afdeling
18. Onze procedures en systemen zijn adequaat om vergissingen te voorkomen

Sectie B – Uw supervisor/leidinggevende (4 vragen; 1 = helemaal niet mee eens - 5 = helemaal wel mee eens)

1. Mijn supervisor/leidinggevende geeft een compliment als hij/zij ziet dat werkzaamheden volgens de vastgestelde patiëntveiligheid procedures worden verricht
2. Mijn supervisor/leidinggevende neemt suggesties van het personeel met betrekking tot patiëntveiligheid serieus in overweging
3. Telkens wanneer de druk toeneemt, wil mijn supervisor/leidinggevende dat wij harder werken, zelfs als dit er toe leidt dat we stappen in procedures overslaan
4. Mijn supervisor/leidinggevende ziet problemen die zich keer op keer voordoen over het hoofd

Sectie C – Communicatie (6 vragen; 1 = nooit, 2 = zelden, 3 = soms, 4 = meestal, 5 = altijd)

1. We krijgen feedback over de veranderingen die ten gevolge van het melden van incidenten zijn ingevoerd
2. Het personeel voelt zich vrij om te spreken als zij iets ziet dat mogelijk een negatief effect heeft op de patiëntenzorg
3. We worden geïnformeerd over de vergissingen die op deze afdeling voorkomen
4. Het personeel voelt zich vrij om beslissingen of acties van personen met meer bevoegdheden ter discussie te stellen
5. Op deze afdeling bespreken we mogelijkheden om te voorkomen dat vergissingen zich herhalen
6. Het personeel is bang om iets wat niet juist lijkt aan de orde te stellen

Sectie D – Melden van incidenten (3 vragen; 1 = nooit, 2 = zelden, 3 = soms, 4 = meestal, 5 = altijd)

1. Als een vergissing wordt gemaakt, maar wordt ontdekt en gecorrigeerd voordat deze de patiënt heeft bereikt, hoe vaak wordt dit gerapporteerd?
2. Als een vergissing wordt gemaakt, die niet tot schade aan de patiënt kán leiden, hoe vaak wordt dit gerapporteerd?
3. Als een vergissing wordt gemaakt, die de patiënt had kunnen schaden maar niet geschaad heeft, hoe vaak wordt dit gerapporteerd?

Sectie E – Patiëntveiligheid waardering

1. Geef uw afdeling/werkomgeving een algemene waardering voor de patiëntveiligheid
   (A = uitstekend, B = heel goed, C = acceptabel, D = matig, E = slecht)

Sectie F – Uw ziekenhuis (11 vragen; 1 = helemaal niet mee eens - 5 = helemaal wel mee eens)

1. Het ziekenhuismanagement zorgt voor een werkklimaat waarin patiëntveiligheid gestimuleerd wordt
2. Ziekenhuisafdelingen stemmen onderling niet goed af
3. Er vallen zaken 'tussen wal en schip' als patiënten van de ene naar de andere afdeling worden overgeplaatst
4. Er is een goede samenwerking tussen de ziekenhuisafdelingen die met elkaar moeten samenwerken
5. Belangrijke informatie over patiëntenzorg gaat vaak verloren tijdens wisseling van diensten
6. Het is vaak onplezierig om met personeel van andere ziekenhuisafdelingen te werken
7. Problemen ontstaan vaak bij uitwisseling van informatie tussen ziekenhuisafdelingen
8. Uit de activiteiten die het ziekenhuismanagement verricht blijkt dat patiëntveiligheid topprioriteit heeft
9. Het ziekenhuismanagement lijkt alleen geïnteresseerd in patiëntveiligheid als zich een incident met schadelijk gevolg heeft voorgedaan
10. Ziekenhuisafdelingen werken goed samen om patiënten de beste zorg te verlenen
11. Wisselingen van diensten is problematisch voor de patiënten in dit ziekenhuis

Sectie G – Aantal incidenten gemeld

1. Hoe vaak heeft u in de laatste 12 maanden een incidentmeldingsformulier ingediend?
   (A = 0, B = 1-2, C = 3-5, D = 6 – 10, E = 11 – 20, F = 21 of meer)

Sectie H – Achtergrondinformatie

1. Wat is de primaire afdeling binnen het ziekenhuis waar u werkzaam bent?
   A = anesthesiologie, B=chirurgie, C=OK-complex
2. Hoe lang bent u werkzaam in het Amsterdam UMC, locatie AMC?
   (A = minder dan 1 jaar, B = 1 – 5 jaar, C = 6 – 10 jaar, D = 11 – 15 jaar, E = 16 – 20 jaar, F = 21 of meer jaar)
3. Hoe lang bent u werkzaam op uw huidige afdeling?
   (A = minder dan 1 jaar, B = 1 – 5 jaar, C = 6 – 10 jaar, D = 11 – 15 jaar, E = 16 – 20 jaar, F = 21 of meer jaar)
4. Hoeveel uur per week bent u werkzaam in het Amsterdam UMC, locatie AMC?
   (A = minder dan 20u/week, B = 20 – 39u/week, C = 40 – 59u/week, D = 60 – 79u/week, E = 80u/week of meer
5. Welke functie bekleedt u binnen het Amsterdam UMC, locatie AMC?
   (A= operatiekamer-assistent, B = Physician Assistent, C = staf anesthesioloog, D = anesthesioloog in opleiding (AIOS), E = anesthesiemedewerker, F = staf chirurg, G = chirurg in opleiding (AIOS), H = fellow chirurgie, I = anders, namelijk…….)
6. Hebt u wel/geen interactie met patiënten?
   JA / NEE
7. Hoe lang werkt u al binnen uw huidige specialisme/functie?
   (A = minder dan 1 jaar, B = 1 – 5 jaar, C = 6 – 10 jaar, D = 11 – 15 jaar, E = 16 – 20 jaar, F = 21 of meer jaar)

Sectie I – Ervaring met de Operatiekamer Black Box en team nabespreking

1. Denkt u dat het gebruik van een medische datarecorder (‘Black Box’) op de operatiekamer kan bijdragen aan de patiëntveiligheid?
   (1 = helemaal niet mee eens - 5 = helemaal wel mee eens)
2. Heeft u meegedaan aan de ‘Black Box TOPPER-trial (onderzoek waarin operaties op OK-20 werden opgenomen met de Black Box, en met het hele operatieteam werden nabesproken)?
   - Ja dan verder
   - Nee dan ‘hartelijk dank’ en onderstaande vragen niet laten zien.

3. Hebt u het toestemmingsformulier voor de Black Box TOPPER-trial gelezen?
   Ja / Nee, niet gekregen / Nee, wel gekregen maar niet gelezen
4. Hebt u het toestemmingsformulier voor de Black Box TOPPER-trial ondertekend?
   JA / NEE
5. Hoe vaak heeft u deelgenomen aan een operatie die met de 'Black Box' werd opgenomen?
   (A= 1 – 4 keer, B = 5 – 9 keer, C= 10 – 14 keer, D = 15 of meer keer)
6. Hoe vaak bent u uitgenodigd voor een teamnabespreking van een operatie waarin gebruik gemaakt werd van het 'Black Box performance report?
   (A= 1 – 4 keer, B = 5 – 9 keer, C= 10 – 14 keer, D = 15 of meer keer)
7. Hoe vaak heeft u een teamnabespreking bijgewoond waarin gebruik gemaakt werd van het 'Black Box performance report'?
   (A= 1 – 4 keer, B = 5 – 9 keer, C= 10 – 14 keer, D = 15 of meer keer)
8. Hoeveel maanden geleden heeft u voor het eerst meegedaan met een Black Box operatie?
   (A = deze maand nog, B = 1 – 3 maanden geleden, C = 4 – 6 maanden, D = 7 – 9 maanden geleden, E = 10 of meer maanden geleden)
9. Heeft u een presentatie door de onderzoekers waarin de resultaten van de Black Box TOPPER-trial werden gepresenteerd bijgewoond?
   JA / NEE
10. Wat miste u bij de teamnabesprekingen, of wat zou u willen verbeteren?
    -open veld-

<u>Sectie J – Uw opmerkingen</u>

Indien gewenst, geef hier alstublieft uw opmerkingen over patiëntveiligheid, fouten, incident meldingen of de operatiekamer Black Box in het Amsterdam UMC, locatie AMC.

-open veld-

PART IV

Future use of the OR Black Box in the operating room

CHAPTER 8

A review on the current applications of artificial intelligence in the operating room

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Surgical Innovation. 2021
doi.org/10.1177/1553350621996961

ABSTRACT

Background: Artificial intelligence (AI) is an era upcoming in medicine and, more recently, in the operating room (OR). Existing literature elaborates mainly on the future possibilities and expectations for AI in surgery. The aim of this study is to systematically provide an overview of the current actual AI applications used to support processes inside the OR.

Methods: PubMed, Embase, Cochrane Library, and IEEE Xplore were searched using inclusion criteria for relevant articles up to August 25th, 2020. No study types were excluded beforehand. Articles describing current AI applications for surgical purposes inside the OR were reviewed.

Results: Nine studies were included. An overview of the researched and described applications of AI in the OR is provided, including procedure duration prediction, gesture recognition, intraoperative cancer detection, intraoperative video analysis, workflow recognition, an endoscopic guidance system, knot-tying, and automatic registration and tracking of the bone in orthopedic surgery. These technologies are compared to their, often non-AI, baseline alternatives.

Conclusions: Currently described applications of AI in the OR are limited to date. They may, however, have a promising future in improving surgical precision, reduce manpower, support intraoperative decision-making, and increase surgical safety. Nonetheless, the application and implementation of AI inside the OR still has several challenges to overcome. Clear regulatory, organizational, and clinical conditions are imperative for AI to redeem its promise. Future research on use of AI in the OR should therefore focus on clinical validation of AI applications, the legal and ethical considerations, and on evaluation of implementation trajectory.

INTRODUCTION

The last few years have seen a tremendous growth in the use of sensors, video, and digital devices in the operating room (OR).[1–3] These applications generate large amounts of data in various formats, often referred to as “big data.”[4] Big data sets are complex and may be analyzed computationally to reveal patterns, trends, and associations, especially relating to human behavior and interactions. Big data has the potential to become progressively useful in both guiding surgical care and optimizing clinical patient outcomes, if handled well.[5-8] A limitation often overseen in analyzing big data is that traditional data processing techniques are not able to handle these vast amounts of complex data.[9] The solution may lie in a research area that became popularly known as “artificial intelligence (AI).” The term AI is often used to describe the study of algorithms that enables machines to reason and perform cognitive functions such as learning, problem-solving, and decision-making.[10,11] Recently, AI has made its introduction into medicine and, even more recently, into the OR.[2] This is of interest as these high-risk environments are considered to be one of the most error-prone areas in the hospital, where outcome is highly dependent on use of modern technology generating multisource data.[12,13] As such, if properly used, AI may have great impact on surgical workflow and outcome. It may provide context-aware perioperative decision support, predict patterns in patient parameters, monitor progress, and develop new in situ training tools.[14–17] These are just a few examples. To date, AI applications are painting and predicting a promising future surgical landscape. Yet, as is often the case with new innovations, AI may become lost in its promise when it is unclear what the actual baseline and best use case is.[18–20]

The current medical literature fixates predominantly on the future possibilities of AI in surgery, or more specifically, inside the OR. However, it is important to know the current situation—where does AI in the OR stand?—in order to validly decide on areas worthy of further exploration. The aim of this study is to systematically provide an overview of the current AI applications in surgery, used to support various processes inside the OR.

METHODS

Literature Search

A systematic literary search was performed up to August 25th, 2020 using the following online databases: PubMed, Embase, Cochrane Library, and IEEE Xplore. The terms AI, OR, and surgery, including synonyms or equivalent terms, were used in certain combinations to obtain the relevant literature. The full search strategy can be found in the online Supplemental Appendix A (http://journals.sagepub.com/doi/suppl/10.1177/1553350621996961).

Article screening was done independently by 2 reviewers (DCB and AvD). The inclusion criteria were as follows: (1) AI, (2) in surgery, and (3) in the OR. The exclusion criteria, next to duplicates and articles older than 10 years, were the following: (1) articles published in any language other than Dutch or English, (2) articles containing future applications of AI only, (3) AI used outside the OR, and (4) no full-text availability. Any study design may benefit the study, so no specific study designs were excluded beforehand. Disagreement between the two reviewers in study selection was resolved by healthy discussions concluding in consensus.

The studies that were included after full-text screening were critically appraised, with the use of an Evidence-Based Medicine Critical Appraisal Checklist (see Supplemental Appendix B).

Data Extraction

The included articles were extracted of data on study design, publication year, country of origin, and the specific researched applications of AI. The outcomes of these studies were analyzed and described and, if possible, defined in numbers. A clear overview of the different studies, their applications of AI and their specifically used subfield of AI, and their data type/source is provided. AI, while not easily defined, is a machine's capability to mimic intelligent human behavior.[21] AI is a broad field to be distinguished by multiple subfields. In order to better understand the analyses and outcomes of the studies, it was decided to explain some of the different subfields in AI beforehand. The subfields that are of importance to this systematic review are explained and elaborated on in Table 1.

Subfield	Definition
Machine learning (ML)	Gives computers via algorithms the ability to modify its processing when exposed to more information, without being specifically programmed to do so.[57,58] In this way, computers are capable of "learning from experience."[21,58,59] ML is considered to be promising in pattern recognition in large cohorts of data by using more complex techniques than traditional statistical analysis does.[60,61]
Artificial neural networks (ANNs)	Are tools used in ML. In function, they are imitating the human brain by connecting and finding interrelated complex relationships and patterns between data.[2] Basically, ANNs are composed of many computational units (neurons) that receive inputs, perform calculations, and direct output to the next computational unit. In other words, the input is being processed as signals through layers of algorithms that create certain patterns as final output; these patterns are interpreted and used in decision-making.[62] ANNs are commonly composed of simple 1- or 2-layered neural networks.
Deep learning	Deep learning networks consist of many layers and are able to recognize and learn more subtle and complex patterns.[63] Deep learning networks may take one or more datasets into account, which are evaluated multiple times in many different layers, until reaching the desired output.[21]
Convolutional neural networks (CNNs)	A convolutional neural network (CNN) is a class of ANNs that specializes in processing data in visualized imagery. In deep learning, "convolution" is a specialized kind of linear operation used in analyzing images, and in CNNs, the ANN employs this mathematical operation in at least one of its layers, hence the name convolutional.[64]
Computer vision (CV)	Focuses on how computers can gain high-level understanding of digital images and videos such as object and scene recognition, comparable to the human visual system.[25,65,66] The processed data may consist of video sequences, views from multiple cameras, or multidimensional data from a medical scanning device.[67,68]

Abbreviations: ML = machine learning; ANN = artificial neural networks; CV = computer vision; CNN = convolutional neural network

Table 1. Definitions of major subfields in artificial intelligence.

RESULTS

The literature search yielded 193 articles from PubMed database, 50 articles from Embase database, 5 articles from the Cochrane Library, and 27 articles from IEEE Xplore database. Finally, 9 articles were included. The flowchart with a more detailed description of the selection procedure may be viewed in Figure 1. The nine included studies are the following: Bodenstedt et al.,[22] Cho et al.,[23] Devi et al.,[24] Hashimoto et al.,[25] Jermyn et al.,[26] Kassahun et al.,[27] Padoy,[17] Zhao et al.,[28] and Liu et al.[29]

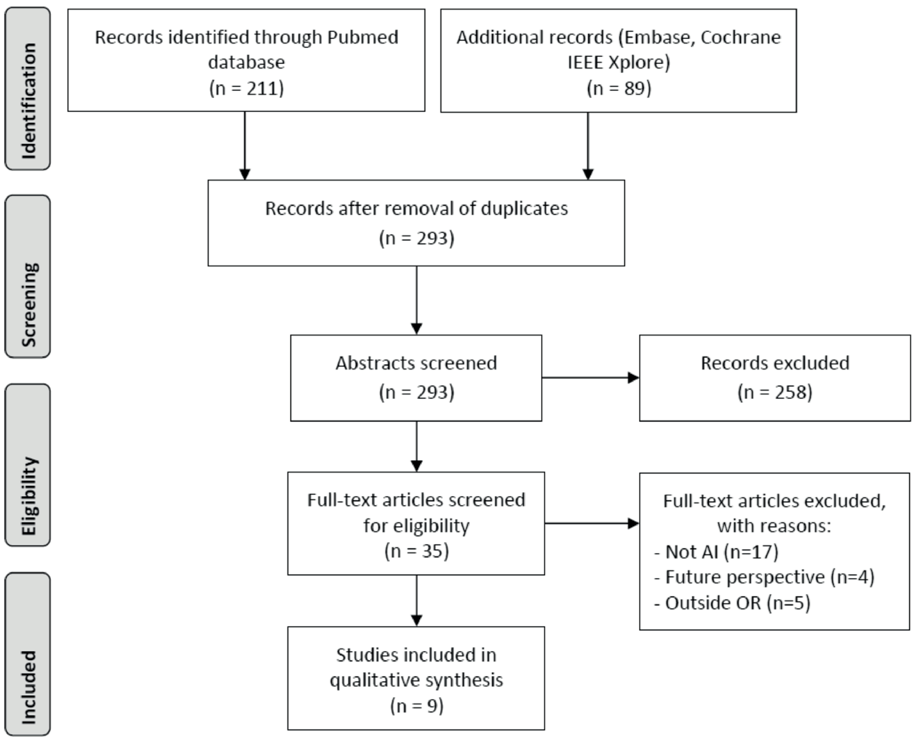

Figure 1. Flowchart of literature search.

Critical Appraisal

Only the 2 included review studies by Padoy[17] and Kassahun et al.,[27] were critically appraised. As a consequence of inhomogeneity in study design, the additional seven included studies did not contain a sufficient amount of checklist characteristics and were therefore not suitable for critical appraisal. Although both review studies scored negatively on many criteria, indicating that the quality of the studies should be considered relatively low, these studies were not of a regular review design either and were therefore difficult to classify.

Applications of AI

The included articles respectively researched one or multiple applications of AI in surgery. Table 2 shows an overview of the different studies, their researched application(s), and the specific AI subfield(s) the application is based on. Additionally, Table 2 specifies the data type/source that was used by the AI application.

Application(s)	Study	AI Subfield(s) [a]	Data Type/Source
Procedure duration prediction	Bodenstedt et al.[22]	CNN, deep learning, and ML	Video stream
	Zhao et al.[28]	ANN and ML	Case characteristics[b]
	Devi et al.[24]	ANN and ML	Surgical environment[c]
Gesture recognition	Cho et al.[23]	CNN and ML	Depth video stream and radiological images
Intraoperative cancer detection	Jermyn et al.[26]	ANN and ML	Spectral light
Intraoperative video analysis	Hashimoto et al.[25]	ANN, CV, and ML	Video stream
Workflow recognition	Padoy[17]	CNN, CV, RNN, deep learning, and ML	Video stream and images
Endoscopic guidance system and knot-tying	Kassahun et al.[27]	RNN and ML	Video stream
Automatic registration and tracking of the bone in orthopedic surgery	Liu et al.[29]	ANN, deep learning, and ML	Depth camera images

[a]Abbreviations: CNN = convolutional neural network, ML = machine learning, ANN = artificial neural network, CV = computer vision, RNN = recurrent neural network.
[b]Scheduled duration, age, gender, and comorbidities of the patient, tumor location, month of year, time of day, day of the week, etc.
[c]Experience of surgeon in years, experience of anesthetist in years, staff experience in years, type of anesthesia, etc. The actual set of environment variables depends on the type of surgery.

Table 2. Overview of included studies with specific AI application(s).

Procedure Duration Prediction

Due to the high density and non-singularity of information in a video stream, extracting its data for evaluation purposes is a challenging process. In comparison to the video stream, data from surgical instruments provide information that is easier to quantify. Whether or not such data provide sufficient information to make presumptive predictions on surgery duration is uncertain to date. Bodenstedt et al.[22] proposed and compared methods, based on CNNs to predict procedure duration based on data from surgical devices or video streams. The input was acquired from 80 recorded laparoscopic interventions of which the necessary data were available. Overall, the combined method (both video and surgical device data) performed best with an average error of 37% and an average halftime error of approximately 28%. This is an improvement to the baseline method with an average error and average halftime error of both 124%.[22]

Zhao et al. sought to accurately predict procedure duration of robot-assisted surgery cases using multiple machine learning (ML) models, using case characteristics (scheduled duration, age, gender, and comorbidities of the patient, tumor location, month of year, time of day, day of the week etc.) as data input. They compared the ML models to the baseline model, which is the time scheduled for the procedure determined by former case duration averages and changes by the surgeon. The following ML models were used: (1) multivariable linear regression, (2) ridge regression, (3) lasso regression, (4) random forest, (5) boosted regression tree, and (6) ANNs. The average root-mean-squared error (RMSE), a measure for the imperfection of the fit of the estimator to the data, was lower for all the ML models than the baseline model. The average RMSE was lowest with the boosted regression tree (80.2 minutes, 95% confidence interval 74.0–86.4), which was significantly lower than the baseline model (100.4 minutes, 95% Confidence interval 90.5–110.3). The use of a boosted regression tree, a predictive modeling approach used in ML, increased the amount of correctly booked procedures from 148 to 219 (34.9% to 51.7%, $P < .001$).[28]

Devi et al. researched several techniques to estimate procedure duration in an ophthalmology department by taking the surgical environment into account (experience of surgeon in years, experience of anesthetists in years, type of anesthesia, etc.).

Three techniques were researched, namely, adaptive neuro-fuzzy inference systems (ANFISs), multiple linear regression analysis (MLRA), and ANNs. However, ANFIS is a fusion between the adaptive learning capability of ANNs and the intuitive logic of human reasoning, formulated as a feed-forward neural network. The results of procedure duration prediction were compared between the three techniques, and the ANFIS model came out to be performing better than the other 2 as portrayed in Table 3.[24]

	Root-Mean-Squared Error (RMSE)		
Type of Surgery	ANFIS	ANN	Regression
Corneal transplant	.1557	.1895	.2755
Cataract	.0697	.1427	.1768
Oculoplastic	.1431	.1668	.2123

Abbreviations: ANN = artificial neural networks; ANFIS = adaptive neuro-fuzzy inference systems.

Table 3. Comparison of techniques to estimate procedure duration.[24]

Gesture Recognition

To decrease the risk of contamination during surgical procedures, Cho et al.[23] researched a noncontact interface based on ML models in order to enhance the accuracy of gesture recognition. Support vector machines (SVMs) and naive Bayes classifiers, ML models with associated algorithms used for classification, were used in the study.[30] Cho et al. used 30 features, including hand and finger data, as input for these ML models to predict and train 5 types of gestures. The overall accuracy of the 5 gestures was 99.58% ± 0.06 and 98.74% ± 3.64, respectively, for SVM and naive Bayes classifiers. Self-training methods of SVMs and naive Bayes classifiers improved accuracies by about 5–10%.[23]

Intraoperative Cancer Detection

During brain tumor removal it is important yet very difficult to detect and remove all cancer cells. As a consequence, when not completely removed, the patient is at risk for recurrence of cancer. With certain types of brain cancer in vivo, Raman spectroscopy can detect these invasive cancer cells. A downside to this technique is the fact that the Raman signal is weakened by spectral artifacts generated by the regular lights in the OR.

Jermyn et al. found that ANNs are able to improve the detection of invasive brain cancer cells by overcoming the negative impact of spectral artifacts. Despite the inclusion of light artifacts, ANNs keep the detection of invasive cancer cells at almost the same level, improving sensitivity by 19% and specificity by 7% compared to the standard technique.[26]

Intraoperative Video Analysis

Video data of laparoscopic procedures are used for both education and quality improvement purposes. In order to decrease the required time for analysis and review of video data, Hashimoto et al. investigated the possibility of automatic video segmentation using CV and ML techniques. Their research demonstrated that CV and ML techniques were able to differentiate between specific steps of laparoscopic surgery procedures with an accuracy of 82% ± 4%.[25]

Workflow Recognition

The long-term vision of Padoy[17] is to develop a surgical control tower (SCT) that, using AI, can monitor and support many processes, providing overall awareness of what is happening in the OR. Key for such an SCT is the requirement of an AI system that can recognize the surgical workflow and is aware of the surgical context. Workflow is often described as the sequence of tasks, interactions, or other processes through which a piece of work passes from initiation to completion.[31] In their review, Padoy[17] researched several recent ML and deep learning applications that can add to the workflow recognition system. These applications include phase recognition, tool detection and localization, and human detection and pose estimation and are described below.[17]

Phase Recognition

Phase recognition, the task of instantly determining the current phase of surgery at any time t from video data, was researched both in laparoscopic videos and external videos. In laparoscopic videos, a study showed that the combination of a CNN and a recurrent neural network (RNN) was able to recognize the different phases automatically and in real time, with an accuracy of 86%. In a study using external videos, a combination of a

CNN and hidden Markov models (HMMs), a popular application for ordinal or temporal data within AI, recognized different phases in the surgical procedure with an accuracy of 90%.[17]

Tool Detection and Localization

Tool detection and localization adds to the precision of phase recognition. By recognizing more subtle and detailed activities, tool detection and localization may be informative for predicting operative steps and length of operation. Deep learning techniques were used to research tool detection and localization in laparoscopic images and videos. Using a CNN, results show a mean average precision of 87% in tool detection and 88% in tool localization.[17]

Human Detection and Pose Estimation

Since the people are the main actors in the OR, detecting their position and estimating their poses by localizing their body parts can provide useful information for optimizing workflow. With the use of external videos, the ability to estimate the specific body poses of the people in the OR was investigated. The mean per joint position error (MPJPE) was used as a quantitative measure for 2D and 3D body part localization. Deep learning approaches yielded the best results in both 2D and 3D pose estimation with an average MPJPE of 17 and 5 cm, respectively.[17]

Endoscopic Guidance System

Weede et al. described an autonomous endoscopic guidance system based on ML. The system is capable of collecting and processing data on the movements of surgical instruments in recorded videos of surgical procedures. Subsequently, with the use of trajectory clustering, maximum likelihood classification, and HMMs, the system uses this information to predict trajectories that are used to guide the endoscope. The results show a hit rate of over 89% for predicting the movement of the surgeon's instruments, leading to 29.2% less camera movements and improved visibility.[27,32]

Knot-Tying

Although in open surgery, knot-tying is part of basic skills and a relative fast procedure, in minimally-invasive surgery, laparoscopic knot-tying can take up to three minutes for a single knot to complete. Mayer et al.[32] described a system to speed up the knot-tying based on RNNs in robotic heart surgery. The surgeon presents a sequence (eg, examples of human-performed knot-tying) to the network and, an RNN with long-term storage learns the task. The preprogrammed controller was able to construct a knot in 33.7 seconds, whereas the use of an RNN provided—after learning from 50 previous runs—a speed improvement of almost 25%, producing a knot in 25.8 sec.[27,33]

Automatic Registration and Tracking of the Bone in Orthopedic Surgery

In computer-assisted orthopedic surgery, registration of the bone plays a vital role as it describes the position of the patient in regard to the surgical system. This way, the surgical site can be correctly aligned according to the preoperative plan. Therefore, the precision of the registration has influence on all the following steps in the procedure. Liu et al.[29] describe a new way of automatic registration and tracking of the bone, based on depth imaging and deep learning. During surgery, a depth camera repeatedly captures depth images of exposed bone. Using these images, deep neural networks learn to localize, segment, and extract the surface geometry of the target bone. The extracted surface geometry is then compared to a preoperative model of the same bone for registration, making surgical intervention or invasive optical markers superfluous. Ex vivo experiments show a mean translational and rotational error of 2.74 mm and 6.66°, respectively. However, these accuracies are currently lower than conventional intraoperative registration methods based on optical markers.[34,29]

DISCUSSION

The results of this systematic review study provide an overview of various AI applications currently used for surgical purposes inside the OR. The great majority, of the AI applications have shown superior results in comparison to their non-AI alternatives. However, studies are set up in various pilot settings. The various applications are an indication of multi-field interest in finding use cases for AI in the OR, paired with a need for more clinical research across user settings. Many studies have shown significant technological performance in the field of AI, but only a small minority has been able to situate their impacts and associated changes in current health systems.[35]

According to Rogers'[36] widely used Diffusion of Innovations theory, adoption of innovative technology always involves early and late adopters. During the innovation process, where an individual is motivated to reduce uncertainty about the advantages and disadvantages of an innovation, it is important to emphasize the ethical and legal challenges.[37,38] Yet, sufficient political, regulatory, organizational, and clinical conditions for AI development and ethical use of sensitive information are still lacking and hence needed to implement AI applications safely and sustainably in the future.[35,39,40] Additional barriers for the widespread implementation of AI in health care may be unawareness on the topic or solutions, lack of user or implementation knowledge by the medical professionals and their workplace supporters, unresolved questions about ethics or privacy from management, or an insufficient IT infrastructure. Most likely, it will be a combination of these barriers.[41]

While AI, and ML in particular, is receiving more attention in surgery, it is obviously not the only field of medicine in which the use of AI is growing.[27] The surgical field may be able to learn from the use of AI in other medical fields. For example, in oncology, research has demonstrated that ML applications can be of great help for the diagnosis or detection of cancer.[42-44] In cardiology, AI techniques are capable of reading electrocardiograms, and by integration with electronic medical records of patients, heart failure can be detected early on with reduced mortality as outcome.[45–47] In anesthesiology, ANNs are used to monitor the depth of anesthesia, and ML techniques are able to predict hypotension during surgery.[48,49] And now, during the current COVID-19 pandemic, more AI applications and studies have been initiated.[19,50,51] The Guangdong Second Provincial General Hospital, for example, plans to incorporate AI image recognition into their infection control system to provide real-time monitoring and an aid for minimizing the risk nosocomial COVID-19 infection. The observing system aims to enhance the sensitivity and accuracy of instant detection in negative pressure isolation wards, which offers creative assistance to combat the COVID-19 outbreak.[50] This application may also be used in the OR to minimize the risk of surgical infection.

Indeed, AI in health care has presented some promising and impressive results and is a fertile area of research, as Challen et al.[52] concluded in their review. However, as this study shows the multilingual character of AI in surgery, AI is a complicated and comprehensive field of study. The rapid pace of change, diversity of different techniques, and multiplicity of tuning parameters make it difficult to get a clear picture of how accurate these systems might be in clinical practice or how reproducible they are in different environments.[52] A realistic perspective is needed, balancing the potential for improvement against the risk of negative outcomes. As Yu et al.[8] also concluded, we need to acknowledge the brittleness of these systems, the importance of defining the correct frameworks for their application, and ensure rigorous quality control, including human supervision, to unwanted outcomes. Rigorous prospective trials in a diverse patient population and clinical review of atypical feature statistics are needed, to safeguard the value and coherency of the collected data.[8,52] It is therefore wise to attract knowledge coming from ML experts, ethicists, and lawyers, next to healthcare professionals, to decide on proper fit of use case and safety of AI systems.

This study has some limitations to take into account. First, as this is a review study, unpublished data and gray literature, such as technical reports, are not included, which may have strengthened the results. Moreover, the results may have been influenced by a publication bias, especially, because—as this is study shows—AI assistance in the OR is still in its infancy. Park et al.[53] acknowledged the problem of irregular research designs in medical AI studies. This is also displayed by the significant variability in the way results are reported, making it very difficult to combine and compare data across studies.

This results in the realization that before any AI tool can be used in clinical practice, it requires confirmation of its clinical utility by undergoing thorough research. In their article, they therefore described and reviewed essential methods on the design of such studies, like the importance of using an adequate external dataset, crucial to the clinical evaluation of AI in medicine.[53]

Second, the applications of AI discussed in this study are, although interesting in their pilot effort, not ready for large-scale clinical practice.[54] AI is not yet able to detect causal relationships in data at a necessary level for clinical implementation to rely on, nor is it able to produce truly automated interpretations of its analyses.[54] Before these implications can be clinically and safely applied in the OR on a bigger scale, future studies should focus on clinical studies, with data from actual patients.[39]

Conclusion

AI systems inside the OR, if well-designed, embedded, and researched, may have a promising future in the OR environment. It may support surgical decision-making, improve surgical precision, reduce manpower, improve workflow, increase surgical safety, and some day it may even carry out some autonomous functions.[6–8,16,21] In the not so distant future, evolving technology like the OR black box, with integrated deep learning algorithms, may prove to be of great help in analyzing and optimizing workflow and outcome in real time.[55] Indeed, the application and implementation of AI inside the OR still has several challenges to overcome. However, evidence-based research adding to the body of knowledge concerning applications of AI inside the OR is moving quickly. Healthcare professionals ought to accept the fact that we need AI in order to optimize future circumstances in the OR and ultimately, surgical quality and safety.[14,55,56]

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CHAPTER 9

Six Sigma in surgery: how to create a safer culture in the operating theatre using innovative technology

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British Journal of Anaesthesia. 2021
doi.org/10.1016/j.bja.2021.08.023

SUMMARY

Safe delivery of patient care in the operating theatre is complex and co-dependent of many individual, organisational, and environmental factors, including patient, task and technology, individual, and human factors. The Six Sigma approach aims to implement a data-driven strategy to reduce variability and consequently improve safety. Analytical data platforms such as a Black Box ought to be embraced to support process optimisation and ultimately create a higher level of Six Sigma safety performance of the operating theatre team.

The operating theatre is a high-performance and high-stress environment, and an environment where a culture of blame andshame is stillprevalent.[1] This,despite the fact that errors are rarely the result of individual failure, but are the consequence of an uninterrupted chain of multiple and multifactorial events. Safe delivery of surgical care is complex and co-dependent of many organisational and environmental factors, including patient, task and technology, individual and teamfactors.[1] Human factors are known to have a major impact on surgical outcome.[1]

Multiple strategies aim at improving surgical safety and can therefore be categorised into two routes; technological/managerial/engineering related or non-technical/human factors related.[2] The first involves the higher levels in an organisation and the latter is at the workers' level, including job satisfaction, motivation, and attitudes, all influencing safety behaviour. Both routes, however, impact the same outcomes and influence or even complement each other. Safety culture combines the technical, social, and scientific dimensions of safety management, which encompasses all ideas, beliefs, and habits that affect how safety is managed at different organisational levels.[1,2] Organisations with a positive safety culture are characterised by communications founded on mutual trust, shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.[1] Safety culture is hence a very broad and inclusive high-order construct, founded on the individual attitudes and values of everyone involved.[1,2] This editorial highlights the importance of improving safety culture and discusses an innovative strategy to reach a higher safety level in the operating theatre.

Six Sigma safety level

Before the COVID-19 pandemic, more than 100 000 flights a day were safely executed. The risk of an airplane being involved in a fatal accident is one in 16 million flights. Key to this success has been the implementation of a system approach, in which 'errors' are addressed without blame, yet proactively, to diminish the consequences before they escalate into serious adverse events.[3] Causes are searched for within the system rather than blaming one individual. As a result, safety improvement gaps within the system and their consequences can be identified and resolved.[4] Using this approach, aviation was able to reach the Six Sigma level of system performance.[3] The term 'Six Sigma' comes from statistics, specifically from the field of statistical quality control, which evaluates process capability. The concept of Six Sigma was originally developed by Motorola engineers in the 1980s, to provide greater resolution in measuring and decreasing defects in every product, service, and transactional process. It helped to optimise operational processes, by reducing process output variation.[5] In statistical terms, Six Sigma refers to 3.4 defects per million opportunities (i.e. nearly perfect). The formula repre- sents the variation about the process average (mean), hence the expectation that the first six standard deviations (sigma) of production variability fall within acceptable failure limits.[5,6]

The fundamental objective of the Six Sigma methodology is the implementation of a structured data-driven strategy, focusing on reduction of variation and process improvement.[6,7] A balance between error prevention, detection, handling, and learning is crucial. The operating theatre remains an environment that often lacks comprehensive data capture, robust monitoring strategies, and process evaluation, causing a knowledge gap on perioperative process optimisation.[8] Currently, most quality and safety improvement ap- proaches in healthcare focus on retrospective data and post hoc error analysis to identify poor quality, resulting in recall bias, low compliance, and a lack of detail. Objective multisource data monitoring systems are needed.

The Six Sigma framework includes five steps: define, measure, analyse, improve, and control (DMAIC).[6] In healthcare, organisations need first to recognise that human error cannot be completely avoided. Instead, events that may lead to errors ought to be spotted early, analysed, and reduced. Using a system approach, procedures are standardised so that, for example, specific protocols (e.g. use of name stickers or the WHO Surgical Safety checklist) help minimise the chance of human error occurring.[9,10] It is important, as well, that operating theatre teams using this approach are often able to overcome unexpected events and deviations, achieving good outcomes. This is termed system resilience, meaning that the team is able to adapt successfully before, during, or after safety threats occur, despite conditions that could lead to failure.[11,12] The positive consequences of increased transparency about errors ought to be highlighted, such as longterm learning, improving team performance, and innovation, known as error management.

Transparency regarding errors in healthcare is needed, but has proved difficult to achieve.[3,13] Healthcare is complex because of the diversity of professionals, each with their own educational background, attitudes, and standard procedures.[14] Regardless, a shared mental model is essential in high-risk environments such as the operating theatre. A shared mental model indicates that all members of the operating theatre team have a common understanding of the plan for patient management, and of the roles and responsibilities of each individual, ensuring a psychologically supportive and safe environment.[15] One in which every team member feels respected, encouraged, and safe to speak up.[3,4] This appears to be difficult to accomplish, even when teams work together regularly, and therefore requires leadership, communication, commitment, resources, and awareness from both the entire operating theatre team and the organisation.[1,2,15]

How can we use the Six Sigma approach?

Measurement and understanding the team's current performance, where the team can improve, and the ability to learn, are essential components of ensuring safe patient care.[16] Six Sigma performance might be achieved by creating a continu- ously monitored operating theatre, capturing natural behaviour and standard operative processes, in order to define both the technical (i.e. technology, managerial, or engineering) and non-technical (i.e. human) factors possibly affecting safety. Comprehensive data capture systems such as an Operating Room Black Box are therefore becoming more widely implemented in high-risk environments such as the operating theatre, trauma bays, and in simulation training centres to measure, analyse, and train teams.[17] These devices collect complex real-time quality data obtained from views of the surgical field, nursing station, laparoscopic camera, and anaesthesia monitoring devices using privacy-by-design principles.[10] Visual data analytics based on big data may facilitate perioperative outcomes research, quality improve- ment efforts, and real-time clinical decision-making.[16,18]

Video recordings of the entire operating theatre allow an unbiased and de-identified evaluation of patient anatomy, the operating theatre team, and perioperative activities.[7,17]

Artificial intelligence (AI) and machine learning are used to facilitate efficient analysis of the multisource big data achieved from the operating environment based on validated rating scales.[19,20] The Operating Room Black Box system our research group uses, creates a video-assisted outcome report that pro- vides comprehensive, detailed, and objective feedback including annotated video segments of interest while pro- tecting user privacy (i.e. faces are blurred, voices are altered).[10,21] A report such as this can be used to apply the Six Sigma strategy (DMAIC) to improve perioperative team performance and processes, for example by team debriefing, coaching, and simulation training.[8,11,17,21]

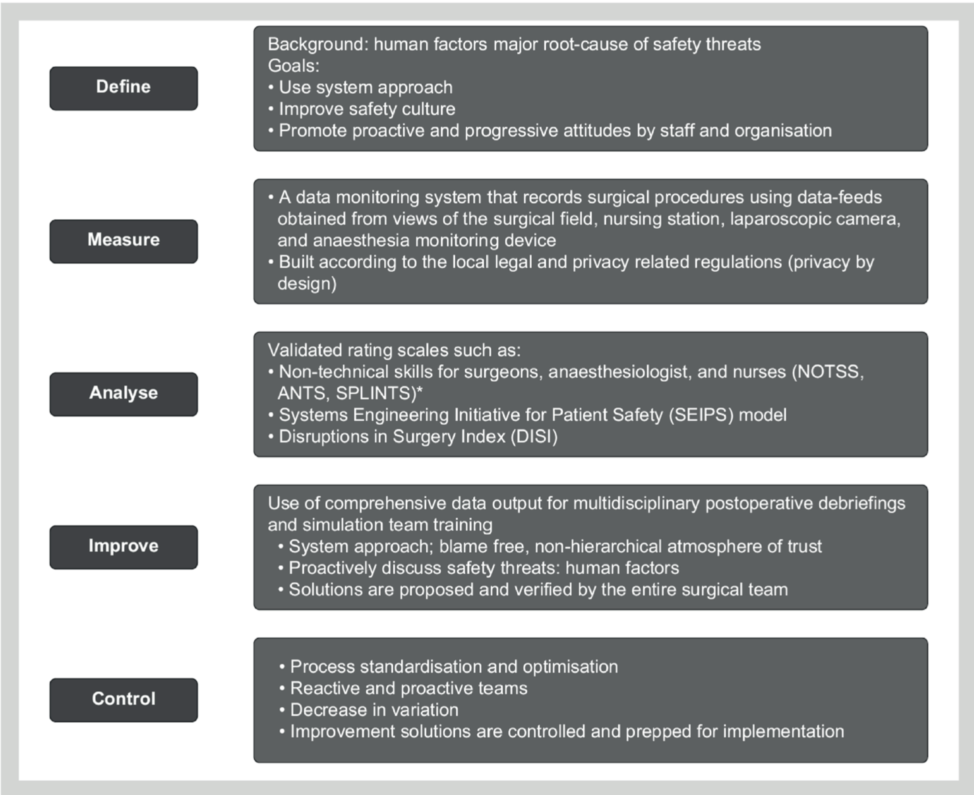

Figure 1. How to use a data monitoring system in the operating theatre following the Six Sigma Strategy. *Non-Technical Skills for Surgeons (NOTSS), Anaesthetists' Non-Technical Skills (ANTS), Scrub Practitioners' List of Intraoperative Non-Technical Skills (SPLINTS).

The Black Box to improve safety culture

Implementation of a platform such as an Operating Room Black Box is an important tool to facilitate transparency, carefully balancing legal restrictions whilst respecting patient interests.[17] Use of such a system may be very valuable in creating a sustainable culture managing error responsibly.[4,7,13] Use of a data monitoring system such as the Operating Room Black Box in the operating theatre following the Six Sigma approach is summarised in Figure 1.

All healthcare professionals working in the operating theatre should be involved to define what the purpose of a safety improvement initiative really is; 'what is in it for them?'. Indeed, healthcare professionals need the chance to develop a more proactive and progressive attitude towards safety culture and improvement.[22] Changing safety culture in healthcare can only be achieved by those working in it. They need and deserve the tools to do so. Proactive and progressive healthcare organisations prioritise safety, actively invest in safety improvement initiatives, and staff raising safety-related issues are rewarded, not blamed.[22] Changing an established working culture in the operating theatre is perceived as being difficult, and therefore a basis of trust, responsibility, and accountability is essential.[1,9]

The Operating Room Black Box precisely measures and analyses how the team interacts and responds to unexpected events, by collecting and analysing objective multisource data from within the operating theatre, which offers a vast new field of data concerning system factors affecting surgical safety.[6,11] Using multisource big data, relevant safety threats, which are often unforeseen, are now identified whilst focusing on resilience and support. In multidisciplinary debriefings, safety threats are proactively discussed in a blame-free atmosphere of trust, where the conventional hierarchical mode is flattened. Solutions are introduced, and the team verifies that the proposed improvements are able to solve the issue at hand. This exchange of data may help foster trust, more responsible attitudes, and enhance risk awareness to increase safety. Next, these teams report more errors, allowing them to talk about errors, in turn increasing timely error detection and correction. These highly performing teams will indeed have a proactive attitude towards error reporting, management, and prevention. Suggested safety improvement solutions by the team are consequently controlled and prepared for implementation. In this 'circle of safety', suggested improvements may be tested in a simulation setting and then applied in the real world. The focus of this last step is process standardisation and optimisation. Indeed, Six Sigma focusses on reducing process variability, yet we ought to accept that healthcare is different from the aviation and car industries, as human variability plays a much bigger role. Resilience results in good outcomes in the presence of adverse conditions by positive adaptability within systems, and to this end human variability is essential.[23] However, by using an objective data monitoring system such as the Operating Room Black Box and following the above-mentioned DMAIC approach, variability in the safety of healthcare can be reduced, which may ulti- mately result in a higher Six Sigma safety level.[6,11]

Conclusions

While it is laudable that healthcare professionals accept responsibility for their actions, their behaviour resonates with and results from the context, organisation and culture in which they act. In most operating environments, even if the atmosphere is constructive, identifying and acknowledging error is difficult. More transparency concerning error management and shared belief that engagement leads to safety improvement are of utmost importance. To reduce the incidence of errors in the operating theatre, quality and safety improvement initiatives ought to involve the entire team, promoted and supported by the organisation. The use of innovative analytical platforms such as an Operating Room Black Box should therefore be embraced, as they may support process optimisation and help healthcare organisations reach the level of a progressive, sustainable, and Six Sigma safety culture in the operating theatre.

Authors' contributions

Contributed substantially to the conception and drafting of the article or revising it critically for important intellectual content: all authors

Approved the final version of the manuscript: all authors Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: all authors

Declarations of interest

TPG holds intellectual property ownership of Surgical Safety Technologies Inc., is the founder of the OR Black Box®, and is supported by research grants from Medtronic Canada, Ethicon Canada, Baxter Canada, Olympus Canada, Takeda Canada, and Intuitive Canada. The other authors declare that they have no conflicts of interest or financial ties to disclose.

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SUMMARY AND GENERAL DISCUSSION

SUMMARY

This thesis describes the implementation process of a video- and medical data recorder in the operating room (OR), named the OR Black Box. This system was used as a data-driven surgical safety and quality improvement initiative by using the outcome report for post-operative structured team debriefing.

Part I: Implementation of the OR Black Box in the operating room

The OR Black Box® (ORBB) is implemented in one OR at our academic medical centre. As is often the case with relatively new technology, clear legal guidelines and methods on how to use such a system were lacking.

In **Chapter 1** the privacy law concerns, medicolegal considerations and universal legal requirements regarding the use of a video- and medical data recorder (MDR) were reviewed. Regardless of the national differences in legislation, the general privacy principles are quite clear on how to implement such a quality improvement system. It is important to ensure clear consensus and openness between participants and researchers about the methods and purpose of the MDR. When the MDR is used as a quality improvement tool, the patient is not the object of the study itself, which means that written informed consent, does not necessarily have to be obtained. An opt-out option is sufficient, with their decision clearly noted in the medical record. The MDR outcome data can therefore never become part of the patient's medical record. Staff, including medical students, are asked formally, to volunteer to work with the MDR. An official informed consent stating the purpose of the data recordings, where the data recordings are analysed, what the expected benefits for the participants are, and how the data are stored securely, is obtained. Following the general privacy principles, the safety and personal privacy of the staff and patients is protected, when using the privacy-by-design principles and ensuring full transparency of the methods used. To this end, the patient's personal identifiers are stripped from the file as soon as possible (deidentification), faces of the staff are scrambled and voices are altered, and the data is kept safe and secure. The outcome report is anonymised and the original data is deleted as soon as the report is generated. Only the outcome report is presented to the team, and hence used for quality

improvement purposes, such as team debriefing. If a severe adverse event occurs during the recorded procedure, video recordings usually help rather than harm the healthcare professionals involved. If he or she has provided reasonable quality standard of care, no punitive measures can be imposed. In conclusion, the fear that use of the MDR bears an increased risk of medical negligence litigation, limited performance or loss of professional status is unjustified, as long as good professional standards of patient medical record keeping and reporting of adverse events are maintained. Yet, clear legislation on the use of MDRs in the OR for quality improvement purposes is needed.

In **Chapter 2** we combined relevant findings from a literature review, experience with team debriefing in simulation settings, and implementation of the ORBB and its outcome report to develop a novel debrief model to be used for video-assisted team debriefing. A standardized debrief model is needed to debrief the surgical team in an efficient and effective manner, taking into account the busy working schedules of all the healthcare professional involved. Structured debriefing minimizes resource, effort, and motivational constraints.[1 2]

Powerful status- and role-based hierarchies often characterize healthcare teams. It is important to realize that hierarchy and status may affect group dynamics negatively during the debriefing session.[3] Creating the correct conditions is hence key to a successful team debriefing.[4] Therefore we recommend to organize the debriefing in a neutral environment, outside the OR, and let the team members sit at a round table. When reflecting upon actions, participants should share the feeling of being safe and respected in their individual roles and privacy. This may help participants to open up and speak their mind freely. An independent moderator to lead team debriefing may be essential, safeguarding aforementioned conditions.

It may be recommended to focus on the non-technical human factor aspects, such as communication and teamwork rather than individual technical skills to improve surgical outcomes.[5 6] Video-assisted debriefing is believed to be more objective, effective and educational.[7 8] The outcome report used in the debriefing can be automatically analysed with the use of artificial intelligence and machine learning software, based on validated human factors related rating scales. The independent facilitator of the debriefing uses the outcome report, augmented with objective video-assisted feedback, to moderate the session and ensure the process of a safe, efficient and educational debriefing for the entire surgical team. Future studies are needed to evaluate whether the use of the debrief model in video-assisted team debriefing may actually change the behaviour of the participating team members and consequently have a positive impact on the number of adverse events in operating room.

Part II: Increasing transparency in the operating room

The ORBB was used to record 35 laparoscopic abdominal surgical cases, performed by 4 staff surgeons. The ORBB obtained all intra-operative data feeds, including audio-visual and patient physiologic data from views of the surgical field, nursing station, laparoscopic camera, and anaesthesia station, including the anaesthesia patient-monitoring device. Recording began just after the anaesthesia was administered to the patient and ended after skin closure, just before the sterile drapes were removed. The ORBB outcome report comprised video segments of all relevant identified safety threats and resilience support events, coded according to the validated Systems Engineering Initiative for Patient Safety (SEIPS) framework.[9] The video segments included qualitative descriptions of the event.

In total, 18 fundoplications, 6 diaphragmatic hernia repairs, 3 elective appendectomies, 3 subtotal colectomies, 2 unilateral adrenalectomies, 2 bilateral adrenalectomies and 1 sigmoid resection were recorded. In these surgical cases, 4 surgeons, 2 surgical fellows, 12 surgical residents, 6 anaesthesiologists, 5 anaesthesiology residents, 9 anaesthesiology nurses, 27 theatre nurses and 16 medical interns participated (N = 81). All 35 cases were debriefed with the team and on average, 4 (out of 7–8) team members (median, IQR 3) was able to attend their team debriefing.

After each debriefing, the team members were asked to complete a survey. In **Chapter 3** the participants' satisfaction with the ORBB and its outcome report used for structured the postoperative multidisciplinary debriefings was assessed with the use of this survey. In total, 151 surveys were completed. This outcome was chosen because, in order to be able to adopt such an innovative system, people working in the OR need to feel comfortable and secure.[10] The team has to be satisfied with a system that ‘watches’ and ‘judges’ them, to learn from unnoticed or differently perceived errors that may have taken place. Moreover, to implement this system sustainably, mutual confidence in its efficacy is key and therefore needs to be assessed.

The mean score on the question: “How important do you feel it is to be able to structurally debrief surgical procedures with the entire team” was 8.44 (SD 1.2, 10-point Likert scale). Altogether, satisfaction of the surgical team with the use of the ORBB and corresponding outcome report for postoperative structured team debriefing was very high. The participating team members have considered the team debriefings to be important, useful, and educational.

As participation was voluntary, it was expected that the participants would be satisfied with the outcomes of the project. This may have introduced a positive selection bias in our study. Yet, at the start of the project, only a few anaesthesiologists and nurses felt comfortable enough to participate. However, over time, the number of participants kept on growing steadily. The second group of adopters overcame their initial scepticism and reverted their opinion due to positive user experience shared by their peers. They came to better understand how their privacy was protected and experienced the benefits by themselves. Eventually, in 148 out of 151 times (98.0%) the participants recommended participating in the ORBB team debriefings to their colleagues. Future studies are needed to determine the effect of including the recording of the entire procedure (start when patient enters the OR and stop when patient leaves the OR) and subsequent anaesthesiology data analysis feedback embedded in the outcome report on satisfaction of the team concerning the ORBB system.

The intra-operative events recognized by the ORBB and discussed during the team debriefings were assessed in **Chapter 4**. Each of the 6 SEIPS categories; person, tasks, tools and technologies, organization, internal (physical) environment, and external environment were included. Both most identified resilience support events and safety threats were mostly related to the SEIPS category person. Most resilience support events were regarded as events subcategorized as effective communication (n = 77). Most safety threats were regarded as events subcategorized as unsafe acts (n = 236).

The multidisciplinary debriefing sessions following the recorded cases most often discussed events related to communication and situational awareness.

Effective teamwork is a strong predictor of effective communication and our results may once again highlight the importance of clear communication in the OR. Participants in this study indicated that debriefing provided them with the opportunity to "speak up" more easily. Cultural, professional, and organizational factors predispose people to avoid speaking up, and is often the final barrier to an adverse event in the making.[11-13] Speaking up to raise concerns about a perceived safety threat or behaviour may therefore have a direct and preventive effect on adverse outcomes.[12 14] Besides, it has been acknowledged that simply describing adverse events in surgery and reporting their frequency does not suffice when it comes to preventing them from happening again in the future. Explicit clarification and a shared perception of the situation is needed. Therefore, research that adds to the growing body of knowledge concerning relevant safety threats and resilience support mechanisms in the OR is valuable for future surgical quality improvement initiatives.

The results of our study may make surgical teams realize the important effect that miscommunication and incorrect assumptions may have on team performance and surgical safety. The postoperative debriefings may be considered an especially valuable intervention to clarify safety threats caused by ineffective communication. 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.[15-17] Promoting these human factors is key when it comes to improving safety culture.[15-18] To this end, team debriefing with the use of the ORBB outcome report may be applied as an approach to improve safety behaviour of the surgical team. We therefore may recommend to invite staff working in the OR to participate in about 1 to 3 team debriefings per year to continue evaluating and improving their safety behaviour and the safety culture in the OR. The patient itself was not the main subject of this study. Therefore, future larger studies are needed to evaluate the direct or indirect positive impact of the use of the ORBB used for team debriefing on postoperative patient outcomes.

Part III: Improving surgical quality and patient safety in the operating room

Delivering safe surgical care can be extremely complex. It requires a combination of technical skills, professional conduct and interpersonal communication. Multiple factors have been recognized to influence surgical safety.[19 20] These may include the surgical team, social interactions, technology, organizational and environmental factors, patient characteristics, and the complexity of the procedure itself.[21] Yet, human factors, such as teamwork and communication, have been identified as major elements affecting surgical safety.[19 22] Consequently, substantial data exist regarding the impact of improving human factor skills through the use of checklists, briefings and debriefings, coaching and simulation training.[20 23-25] However, the OR is an unique high-stress environment comprised of professionals from multiple specialities, who's training may differ widely. Tailored safety improvement interventions, including the entire team, have thus been recommended. Yet, greater detail regarding the varying etiologies of safety improvement gaps is needed.[26-28]

In **Chapter 5** differences in perception among operating staff regarding human factors in the OR are evaluated. We carried out an international multi-centre survey study in St. Michael's Hospital (Toronto, Canada) and the Amsterdam UMC, location AMC (The Netherlands). In both locations, the ORBB was in use. Between September 2016 and July 2018, 117 elective laparoscopic procedures were recorded using ORBB. The Surgical Team Assessment Record (STAR) questionnaire was administered in both centers.[29] This questionnaire investigates the Human Factors Analysis and Classification System (HFACS)'s four levels of human failure, including organizational influences, unsafe supervision, preconditions for unsafe acts, and unsafe acts.[30] In total, 507 questionnaires were completed, of which 230 (91 cases) were completed at St. Michael's Hospital (SMH) and 277 (35 cases) at the Amsterdam UMC. In total for both sites, 119 questionnaires were completed by staff surgeons, 96 by surgical residents, 76 by surgical fellows, 78 by the anaesthesiology team members (including anaesthesia nurses), 41 by scrub nurses, 44 by circulating nurses, and 53 by medical students.

Surgical fellows rated their personal readiness significantly lower, compared to the rest of the team. This may be in part caused by stress surrounding career choices and stability. Other factors known to influence staff well-being include workload, climate, or perceptions of teamwork. Negatively affected personal well-being, expressed by for example emotional exhaustion, fatigue and an inability to concentrate, may hinder one's capacity to ensure surgical safety.[15 31 32] Hence, promoting staff well-being may serve to improve teamwork, organizational outcomes and consequently surgical safety.

Staff surgeons identified distractions (51.3%, n = 61) and aberrations (60.5%, n = 72) during surgery more often, compared to the other team members. These were usually related to technological issues. Although distractions or aberrations during surgery are inevitable, they can be detrimental to overall team performance. Each team member may have a different sense of what is a distraction or aberration, and thus act differently in identifying or reporting these. Yet, highly cohesive teams may support the expression of individual opinions, which may promote identification of these distractions or unsafe acts.[33] If unsafe acts are identified pro-actively, this may mitigate peri-operative errors, as these are usually the result of a cumulation of minor aberrations resulting from different factors in the OR.[12]

The crew resource management principles are adopted from the aviation industry and incorporated in the HFACS model, as these principles emphasize the importance of using the closed-loop communication (CLC) technique in order to prevent unsafe acts.[34] The CLC technique includes 3 components; 1) an initial message that starts with stating the name of the recipient, known as directed call out, 2) verification by the named recipient, including repeating the critical aspect of the message, known as check back, and 3) verification by the message sender that the recipient has interpreted the sent message correctly, known as closing the loop. Accordingly, the WHO Surgical Safety Checklist briefing includes an introduction stating name and role of all team members before start of the surgical procedure.[35] During the ORBB team debriefings, the participating professionals realized how difficult it is to recall one another's name. Even when they had worked with the same team members multiple times before. In **Chapter 6** we introduced a simple solution to support the use of the CLC technique. As we discovered that just "checking the box" of the Surgical Safety Checklist does not mean the check has actually been performed and may not suffice to remember the roles and names. We therefore joint the Theatre Cap Challenge, initiated an Australian anaesthesiologist.[36] This initiative emphasizes the importance of visible staff identification, by putting your name and role on your surgical cap while working in the high-risk operating environment. The name and role sticker stations have been placed at the dressing rooms in the operating complex. The OR staff was notified accordingly and were asked to wear the name stickers on their surgical caps. Participation was voluntary. Board members and team leaders acted as role models.

About one year after implementation, we evaluated how many were actually wearing the name stickers. We found that on average almost half of the OR staff (44.8%, n=103 out of 230 observations) was now wearing the stickers and of this randomly observed sample, 17 (16.5%) were a surgeon, 29 (28.2%) were OR nurses, 31 (30.1%) anaesthesia nurses, and 15 (14.6%) were medical interns. Staff may have been derisive at first, throwing remarks upon colleagues "So you can't even remember your own name, can you?" or "That looks silly, I am not going to do that". Nevertheless, those eventually did wear them commented; "it looks silly, but it works", "I feel more part of the team when I am certain that everybody is able to use my name", and "it is useful, because especially during stressful situations names are forgotten". Although some may not see or understand the power of something as simple as using one another's name, it is generally known that people feel more appreciated and are happier to help if you call them by their name, enhancing coherency of the team and improve surgical safety.[37] Patience and role modelling by leaders showing the way with using the name stickers is important.[38 39] Future studies are needed to evaluate the impact of putting your name on your surgical cap on the use of the CLC technique and subsequently the incidence of adverse events caused by miscommunication in the OR.

Overall, a deeper understanding of the etiology and effect of personal factors (i.e. crew resource management and personal well-being) on team performance may lead to more targeted and sustainable quality improvement initiatives. A supportive team-based approach is therefore recommended, to limit the amount of unnecessary safety threats during a surgical procedure.[26 40] Future studies are needed to elucidate the impact of human factor behaviour in the OR, such as closed-loop communication and leadership, on team performance. Also, to define what type of human factors are most relevant and valuable to incorporate in team-based training focusing on improving surgical safety.

Lastly, **Chapter 7** assessed the OR staff's attitudes towards our patient safety culture, and whether participation in the ORBB team debriefings may have affected their safety behaviour. Understanding the needs, attitudes and perceptions amongst healthcare professionals working in the OR is key in improving future surgical safety.[38 41] The Dutch version of the validated Hospital Survey on Patient Safety Culture was used and ten questions regarding the use of the ORBB were added.[42] In total, 126 professionals working in our OR complex completed the survey. Overall attitude towards patient safety was scored with a mean of 3.06 (SD 0.46), 5-point Likert Scale, PRR 23.81%). The operating nurses rated the overall perception of safety the lowest (mean 2.89 (SD 0.45)) while the anaesthesiology residents rated it to be the highest (mean 3.39 (SD 0.32)). Teamwork within the department was rated the most positive with an overall mean of 3.69 (SD 0.64), Positive response rate 73.02%), followed by communication openness (mean 3.60 (SD 0.76) Positive response rate 63.49%). Overall, the attitude of professionals who participated in surgical team debriefings using the ORBB was positively correlated with the overall perception on patient safety (P-value < 0.024, 95% CI 0.034-0.474, Bèta-coefficient 0.196).

In line with previous (HSOPSC) studies, this study indicates there is still a variety in perception of the safety culture in the OR between the different OR professionals.[43 44] A strong safety culture is based on a shared mental model of peri-operative situations, but can only be established when beliefs, opinions, needs and attitudes on surgical safety can be safely expressed and discussed amongst members of the OR team.[38 45] Errors ought to be managed in a 'just culture' instead, where all team members (from residents to nurses) feel confident and are encouraged to report events (even their own mistakes).[46 47 48] Collective accountability needs to be promoted, as healthcare professionals take care of patients as teams, err as teams, and need a way to accept accountability as teams.[49] Healthcare organizations have therefore the responsibility to implement non-punitive reporting systems and to support clinicians when errors occur.[49] Yet, to create a strong safety culture, all OR team members -irrespective of experience, hours and years working in the hospital- ought to be engaged and believe change in behaviour can actually improve patient safety.[50 51] To this end, implementation of the ORBB may improve safety behaviour by facilitating team debriefing and consequently providing the team with the opportunity to discuss communication and teamwork issues affecting safety. During the team debriefings, differences in safety behaviour perceptions may be discussed, in a safe, blame-free, non-hierarchical environment.[51 52]

Future studies with the ORBB or other medical data recorders -on larger scale and across different settings- are needed to evaluate whether improved safety behaviour actually leads to improved patient outcomes. Also, to strengthen the degree to which suitable inferences can safely be drawn about the impact of behavioural monitoring using medical data recorders on patient safety culture.

Part III: Future use of the OR Black Box in the operating room

The last few years have indeed seen a tremendous growth in the use of sensors, video and digital devices in the OR.[53] These applications generate large amounts of data in various formats, often referred to as 'big data'.[54] A limitation in analyzing big data is that traditional data processing techniques are not able to handle these vast amounts of complex data.[55] The solution lies in artificial intelligence (AI) software. This term used to describe the study of algorithms that enables machines to reason and perform cognitive functions such as learning, problem solving, and decision-making.[56 57] As a result, AI has made its introduction into medicine and is expanding its footprint in surgical care.[53] This is of interest, as these high-risk environments are considered to be one of the most error-prone areas in the hospital, where outcome is highly dependent on use of modern technology generating multisource data.[20 58] The unique nature of surgical practice leaves healthcare professionals working in the OR therefore well-positioned to take the next step in the use of AI in the OR.[53] Using multiple data sources, including audio and video, AI could be a powerful tool for intra-operative decision support, used in warning systems to help the team predict and avoid adverse events that may lead to complications.[57]

In **Chapter 8** the use of artificial intelligence (AI) applications in the OR is systematically reviewed. Pubmed, Embase, Cochrane library, and IEEE Xplore were searched and this yielded 193 articles. Finally, 9 studies were included. The identified applications of AI in the OR included; procedure duration prediction, gesture recognition, intra-operative cancer detection, intra-operative video analysis, workflow and phase recognition, human detection and pose estimation, an endoscopic guidance system, knot-tying, and automatic registration, and tracking of the bone in orthopaedic surgery. The great majority, if not all, of the AI applications have shown superior results in comparison to their non-AI alternatives. However, studies are set up in various pilot settings and only a small minority has been able to situate their impacts and associated changes in current health systems. According to Rogers' widely-used Diffusion of Innovations theory, adoption of innovative technology always involves early and late adopters. During the innovation process, where an individual is motivated to reduce uncertainty about the advantages and disadvantages of an innovation, it is important to emphasize the ethical and legal challenges.[46 59] Yet, sufficient political, regulatory, organizational, and clinical conditions for AI development and ethical use of sensitive information are still lacking, and hence needed to implement AI applications safely and sustainably in the future.[60-62] Additional barriers for the widespread implementation of AI in healthcare may be unawareness on the topic or solutions, lack of user or implementation knowledge by the healthcare professionals and their workplace supporters, unresolved questions about ethics or privacy from management, or an insufficient IT infrastructure. Most likely, it will be a combination of these barriers.[63] Indeed, the application and implementation of AI inside the OR still has several challenges to overcome. However, in the not so distant future, evolving technology like the ORBB, with integrated AI and machine software, may prove to be of great help in analysing and optimizing workflow and outcome in real-time. The ORBB team is currently working on developing applications of AI in surgical practice: identifying intraoperative events like bleeding, hypothermia, aberrant anatomy, or tool use, using patient, team, and surgeon factors. The team's attention can then be drawn to warnings and they can decide whether to take action based on the by the ORBB provided explanations: to modify risk factors by, for instance, reviewing imaging, changing the surgical approach, or requesting different instruments.[57]

In **Chapter 9** the importance of improving the safety culture in the OR is highlighted. Strategies aiming to improve the safety culture can be categorized into two routes; technological/managerial/engineering versus non-technical/human factors related.[64] The first relates to the higher level in an organization and the latter at the workers' level, including job satisfaction, motivation and attitudes, all influencing safety behaviour. Both routes, however, impact the same outcomes and are likely to influence or even complement each other.[21 64]

The aviation industry has reached an impeccable level of safety by using the six sigma approach. The concept of Six Sigma has originally been developed by Motorola engineers in the 1980's, to provide greater resolution in measuring and decreasing defects. It helped to optimize operational processes.[65] This Six Sigma approach guarantees ultra-high-quality systems, in which only 3-4 defects occur per 1 million opportunities (i.e. nearly perfect).[65 66] The fundamental objective of the Six Sigma methodology is the implementation of a structured data-driven strategy, focusing on reduction of variation and process improvement.[66] To date, most safety improvement strategies in healthcare still focus on retrospective data and post-hoc error analyses to identify poor quality. Moreover, the use of technology to objectively monitor and analyse human factors affecting safety remains suboptimal, causing a knowledge gap on perioperative process optimization. The Six Sigma strategy includes five steps: define, measure, analyse, improve and control (DMAIC).[66] If we want to apply the Six Sigma strategy optimally, a continuously monitored OR, capturing natural behaviour and standard operative processes, is required. Implementation of a platform like an ORBB is an important tool to facilitate more transparency concerning error management and culture.[67] Following the DMAIC steps, safety improvement initiatives ought to involve the entire team, promoted and supported by the organization. The ORBB may be used in accordance with the Six Sigma Strategy, to support process optimization and to ultimately create a sustainable safety culture in which errors are managed responsibly.[12 50]

GENERAL DISCUSSION

Legal and privacy concerns

As is often the case with relatively new technology, legal guidelines on the use of a Black Box are currently lacking.[46] Lessons are learned from the aviation industry, and the main issues that should be addressed are related to the privacy and legislation perspectives. Regardless of the national differences in legislation, the importance of the general privacy principles, to ensure clear consensus and openness between participants and researchers about the methods and purpose of the Black Box, are to be underlined. The key dimensions to address are; "what is the purpose?', "who and what to the data cover?", "what about the privacy and privacy-by-design-principles?', "who is responsible for the data?", and "which format should the data be in?". Most importantly, written informed consent does not necessarily have to be obtained from the patients. That their safety and personal privacy is protected needs to be pointed out, ensuring full transparency of the methods used.[46] This thesis concluded that the fear that a Black Box bears an increased risk of medical negligence litigation, limited performance or loss of professional status is unjustified, as long as good professional standards of patient medical record keeping and reporting of adverse events are maintained. To help dissipate any remaining fear, resistance or doubt, an official agreement on confidentiality can be signed and supported by the hospital directorate. The researchers and the institute are then, in accordance with the official agreement, bound to refuse the disclosure of any data obtained by the Black Box. Yet, it is important to emphasize that, if a severe adverse event occurs, video recordings usually help rather than harm the healthcare professionals involved. The chain of (re)actions and decisions resulting in the unwanted event are better understood with the objective help of the Black Box, as it helps in augmenting the analysis of a calamity or near miss when constructing a public calamity report.[10 26] The data source itself is protected by law. Besides, if the healthcare professional has provided reasonable quality standard of care, no punitive measures can be imposed anyway.[46 67 68]

Team debriefing

There is a large variety of approaches to team debriefing available in the current medical literature.[69] However, healthcare professionals arrive to the OR with various sets of experiences, ingrained personality traits, and established relationship patterns. All of them may benefit from team debriefing considerably, but most of them often do not yet have sufficient or any experience in structured team debriefing.[70 71] Moreover, team debriefing usually takes place in a simulation setting, but is considered to be an even more powerful learning experience for the OR team when it takes place following the real clinical setting instead, such as after actual surgical procedures.[25] For this, the use of a standardized debrief model is recommended. Using video recordings during the debriefings is recommended as well, as they provide objective feedback.[72] However, peer-reviewed articles on how to actually debrief with the use of a Black Box and especially on how to optimally translate it into clinical practice appeared to be lacking. No debrief model suitable for postoperative video-assisted team debriefing was found in the current medical literature.[69] Therefore, the identified approaches, elements, and methods on how to debrief the OR team with the use of a Black Box were summarized in the structured Amsterdam Black Box debrief model. The participants who experienced the use of this debrief model believed the Black Box debrief sessions were useful and educational, and believed that their time was well spent.[51]

The establishment of a safe environment, facilitating an open, honest, and positive discussion, characterizes a good team debriefing session.[86] As summarized in this thesis, honest participation means that the participants can safely ask themselves and each other "what went well, what could be better, and what should we do differently next time?"[69 73] Participants develop a high level of reflection by creating their own conclusions and motivation for change.[71] The team debriefings should be scheduled outside the immediate OR environment on a round table setup, so the team can sit comfortably, on eye level, and on neutral ground.[71] Hospital directorates who support participation of debriefings should facilitate in allocating time, making it possible to attend the debriefings preferably in normal working hours. It is also advised to plan the debriefing not immediately after the surgical procedure, but within a time-span of some days, as direct “hot” debriefing is often not practical in the workplace and it gives the team some time to process and “wind down”.[74]

A summarized performance report based on validated rating scales (such as the NOTSS[75], ANTS[76] and SPLINTS[77]) is recommended for both logistic and informational reasons. Therefore, the Black Box performance report that was used includes specific and condensed feedback on all identified relevant positive and negative events.[26] It is recommended to focus on the non-technical aspects, such as communication rather than individual technical events, as this is considered more educational for the team than debriefing individual technical skills.[78-80] By integrating AI and machine learning software, the video and medical data output can be largely automatically analysed, sparing the involved healthcare professionals hours of looking back at video footage.[57 81]

Perspectives of the participants

For people working in the OR it is vital to feel comfortable and secure, in order to be able to adopt an innovative system such as the Black Box. The team has to be satisfied with a system that “watches” and “judges” them. Only then, the team can learn from unnoticed or differently perceived errors.

This thesis concluded that the overall satisfaction of the OR team with the use of the Black Box and corresponding performance report for postoperative structured team debriefing was high. Ninety-eight percent of participants would recommend postoperative multidisciplinary debriefing with the use of the Black Box and its performance report to their colleagues.[51]

As to be expected, the primary surgeons, drivers of the initiative, were significantly more satisfied than the participating assisting surgeons, anaesthesiologist sand OR nurses. The phenomenon of perceived difference of perception about the same situation between the surgeon and other team members has been highlighted in the current literature.[82,83] The so-called ‘Rashomon’ effect may have been of influence as well, which occurs when the same event is described in significantly different ways by different people who were involved.[84] Indeed, based on the respective roles of the team members in the OR, disagreements exist regarding the evidence of possible adverse events. Subjectivity versus objectivity in perception, memory and reporting is in play as well, when looking back upon situations.

Besides that, participants were asked to voluntarily participate in the Black Box project, so it was to be expected that they would be satisfied with the Black Box debriefings. This may have introduced a positive selection bias. However, at the start of the project, only a few anaesthesiologists and nurses felt comfortable enough to participate. Interestingly, their participation numbers kept on growing steadily in the study over time. An effect that can be contributed to the fact that several healthcare professionals who were initially unsure or even quite sceptical towards the initiative decided to participate in the team debriefings during the trial based on positive experiences shared by their colleagues. When these second group of adopters overcame their initial scepticism and came to understand how their privacy was protected, they reverted their opinion due to actual user experience.[85] Eventually, initial laggards became the most important drivers and advocates for the Black Box project.[51]

Observations by the OR Black Box

This thesis highlights the importance of clear communication in the OR, as the most often discussed events during the team debriefings were related to communication and situational awareness.[86] These results are in line with other studies that used video recording in the OR, also demonstrating that communication is generally the root-cause of adverse events.[87-89] Therefore, team debriefing appears to be vital, as it was only during the postoperative debriefings that the team members realised the important impact of miscommunication.[86] Moreover, team debriefing can drive the quality improvement process by identifying, and most importantly, addressing and discussing recurring, new or unrecognized safety issues.[3,90]

Traditionally, OR teams are hierarchical, often discouraging team members to speak up to or confront a team member.[48,91] Yet, participants indicated that the Black Box debriefings provided them with the opportunity to “speak up” more easily. Other factors that prevent a person from speaking up have been examined in many fields outside of healthcare, including psychology, business, and aviation.[11] Cultural, professional, and organisational factors predispose people to avoid speaking up, and is often the final barrier to a safety threat.[11-13] Speaking up to raise concerns about a perceived safety threat or behaviour has therefore a direct and preventive effect on adverse events.

The OR team members also indicated that participating in the debriefings made them feel "more valuable" and "part of the team", which has a positive impact on the personal well-being of the team members, job satisfaction, and organisational commitment.[15-17] Promoting these human factors is hence very important when it comes to improving team performance and thus the safety culture.

The evidence on the impact of the team's non-technical skills on patient outcomes is still limited, as it is difficult to analyse these factors with traditional research methods.[89 92] Just describing adverse events and reporting their frequency does not adequately capture the complex, independent factors surrounding intra-operative events. Explicit clarification is necessary and objective multisource data, as provided by the Black Box, are hence needed.[89 92] Video recording surgical procedures using a Black Box has consequently multiple benefits, as 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.[27 72]

Human factors in the operating room

The OR is a unique and high-stress environment, where professionals from various specialties, disciplines and level of seniority are required to work closely together as a team. As emphasized, it is important to ensure that a shared mental model is perceived by all members of the OR team.[38 45] Highly cohesive teams support the expression of individual opinions, which promotes identification of an active or latent unsafe acts.[33] Unsafe acts need to be identified and managed pro-actively, in order to mitigate peri-operative errors, as these are often the result of a cumulation of minor aberrations resulting from different factors in the OR.[12] Pro-active error management requires a supportive and safe environment in which the entire OR team is able and willing to speak up, and team members know what is to be expected.[40] For this, a high level of individual human factor skills is required. Several important human factor skills may lead to peri-operative unsafe acts, such as personal readiness, distractions, and communication between the team members.[12 30] However, the impact of such unsafe acts is not always evident nor apparent to the team, and OR team members may have discrepant attitudes about the level of human factor skills exhibited from one another. Discrepancies may be caused by differences in status or authority, responsibilities, and culture.[12 22 30 93]

Surgical fellows rated their own well-being significantly lower than the surgical residents, which may be caused by stress surrounding career choices and stability. Other factors known to influence staff well-being include workload, mental stress, climate, or perceptions of teamwork.[94] These human factor elements are associated with burnout symptoms, job satisfaction and organisational commitment. Burnout symptoms, such as emotional exhaustion, fatigue and an inability to concentrate, hinder one's capacity to ensure high performance.[15] Hence, it is important to promote staff well-being, as it improves human factor skills, organisational outcomes and consequently patient safety.

Distractions or aberrations during surgery are inevitable, but they can be detrimental to overall team performance. Each team member has a different sense of what is a distraction or aberration, and thus act differently in identifying these possible threats to patient safety. Therefore, individuals vary in feeling the urge or responsibility to alert the team on a perceived distraction or aberration.

The importance of awareness of communication skills in the OR ought not to be underestimated either. Increased use of the CLC technique (i.e. using each other's name) reduces unnecessary miscommunication, provides opportunities for clarification of safety-critical information, and enhances the OR team's shared mental model.[95] Yet, participants of the Black Box study realised how difficult it apparently is to remember each other's names. There are many reasons why people find it difficult to remember each other's names, even when the names are introduced prior to start of the procedure, are written on a whiteboard and when team members have worked with one another multiple times before. Therefore, implementation of the use of name stickers or plates in the OR is recommended, as it may facilitate the CLC technique in a simple manner.

Improving human factor skills in the OR requires a change in safety culture, which takes time and commitment. In line with previous studies, this thesis indicated there is a variety in perception of the safety culture in the OR between the different OR professionals.[43 44] This remains to be a significant challenge for safety improvement initiatives. A strong safety culture is indeed based on a shared mental model, which can only be established when beliefs, opinions, needs and attitudes on surgical safety can be safely expressed and discussed amongst all the members of the OR team.[38 45] The goal of improving the safety culture is aimed at encouraging all OR team members to be transparent about issues that may impact patient safety.[33 48] Therefore, healthcare organisations need to consider not only the behaviour of the OR team, but also the complex interrelationships between culture, technology, and achieving reliable, high-quality patient outcomes.[96 97]

Future perspectives

In the future, society may decide to choose transparency over the medicolegal and privacy concerns of the OR team and demand full legal access for the patient to the information generated by a Black box.[27 98] In the USA[99] and Korea[100], legislation is begin drafted to require continuous video recording in the OR and to allow patients to access these video recordings, aiming to prevent malpractice. If future legislation were to support the position that video recordings become part of standard care, healthcare professionals are bound to work in a continuously monitored OR, where all results are accessible to patients. This is an argument for healthcare professionals and organisations to start exploring optimal use of a Black Box, to secure optimal conditions for both patient and providers, as soon as possible.

To secure optimal conditions, future studies are needed to evaluate the feasibility, deployment and generalizability of such video recording systems across different operating environment settings. AI and machine learning software needs to be used to facilitate efficient analysis of the multisource big data achieved from the OR, based on the before mentioned validated rating scales.[101] The OR Black Box system that was implemented and used in this thesis, now creates a video-assisted and AI-based outcome report that provides comprehensive, detailed, and objective feedback including annotated video segments of interest while protecting user privacy (i.e. faces are blurred, voices are altered). To date, the OR Black Box® user network has grown to various other medical centres world-wide.[102] External or hospital funding should support the educational project, as the use of a Black Box for postoperative team debriefing is a data-driven quality improvement initiative. New research lines should focus on change of safety behaviour (i.e team debriefing and training), how to build stronger teams based on the identified safety threats (e.g. human factor skills, distractions, equipment failure), and its impact on patient outcomes.

The Six Sigma methodology also emphasizes the need for a structured data-driven strategy, focusing on reduction of variation and process improvement.[66] Nevertheless, the OR remains an environment that often lacks comprehensive data capture, robust monitoring strategies, and process evaluation. Consequently, OR professionals are not able to fill the knowledge gap on perioperative process optimisation.[10] Yet, Six Sigma performance may only be achieved by creating a continuously monitored OR, capturing natural behaviour and standard operative processes, in order to define both the technical (i.e. technology, managerial, or engineering) and non-technical (i.e. human) factors possibly affecting patient safety.[103]

Future studies should evaluate whether the use of the proposed debrief model in video-assisted team debriefing may actually change the behaviour of the participating team members. Scheduling the multidisciplinary debriefings for such an amount of consecutive surgical cases with so many different OR team members proved to be challenging. Although the results of this thesis showed that neither the number of team members attending the team debriefing, nor number of workdays between the procedure and debriefing was significantly associated with the satisfaction scores, it is recommended to invite OR personnel to participate in about 1-3 multidisciplinary debriefings per year. Besides that, the team itself should be able to request a Black Box debriefing if wanted or needed. If a calamity occurs, the team should also be able to request the anonymous Black Box performance report, to augment to the calamity analysis. Whether or not it is widely generalizable to have an independent person, such as a professor of psychiatry, moderate the sessions and the cost-effectiveness remains open to discussion as well.

Multi-centre studies, on larger scale, across settings using (different types of) medical data recorders providing output supporting team debriefing and team training are therefore needed. Patient related outcome data ought to be included. Also, to strengthen the degree to which suitable inferences can safely be drawn about the impact of behavioural monitoring using video recorders on human factor skills, patient safety behaviour and safety culture.

Conclusions

Being able to look back on shared performance in a safe, neutral and moderated setting helps all team members to get a clearer perspective on peri-operative situations. This ensures a productive, healthy and safe working environment, which focusses on education and rehabilitation rather than blame and shame. Systematic postoperative team debriefing using a Black Box, led by an independent facilitator, supports objective assessment of safeety threats that have traditionally been ignored, creating an unique opportunity to discuss appropriate solutions with the entire OR team. Quality improvement initiatives, such as the Black Box system, therefore need to be supported by the healthcare organisation, and above all involve the entire OR team, to create more transparency concerning error management and a shared belief that engagement leads to an even better safety culture in the operating room.

KEY POINTS OF THIS THESIS

- It is possible to implement a video- and medical data recorder in the operating room in accordance with the local legal, ethical and privacy related guidelines
- A debrief model was developed and may be used to facilitate video-assisted postoperative debriefing in a structured, non-hierarchical and safe manner
- The participants of the Black Box procedures and following debriefings considered it to be both beneficial and important and would highly recommend participation to their peers
- Both safety threats and resilience support events identified by the Black Box were most often related to the interaction between members of the team
- During the postoperative multidisciplinary debriefings, events related to communication and situational awareness were most often discussed by the team
- The use of name stickers on the surgical cap may help use the closed-loop communication technique to improve communication skills in the operating room
- Participation in the Black Box debriefings may have a positive impact on safety behaviour by providing the opportunity to discuss differences in perception concerning patient safety
- A team-based approach, with full support of the organization, is recommended when implementing a quality improvement initiative such as the Black Box
- Artificial intelligence software, integrated in the Black Box, may help optimise surgical decision making, improve workflow, and ultimately surgical quality and patient safety
- The use of the Black Box following the Six Sigma strategy may support process optimisation and therefore help improve the safety culture in the operating room

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APPENDICES

NEDERLANDSE SAMENVATTING

Dit proefschrift beschrijft de implementatie van een video- en medische data recorder (MDR) in de operatiekamer (OK), genaamd de OR Black Box. Dit systeem is gebruikt als een data-gedreven kwaliteitsinstrument waarbij we het uitkomstenrapport van de MDR hebben gebruikt voor postoperatieve gestructureerde team nabesprekingen.

Deel 1: Implementatie van de OR Black Box in de operatiekamer.

De OR Black Box® (ORBB) is geïmplementeerd in een OK van ons academische medische centrum. Zoals vaak het geval is bij implementatie van nieuwe technologie, ontbraken duidelijke juridische richtlijnen en methoden over hoe zo'n systeem gebruikt moet worden.

In **Hoofdstuk 1** werden de privacy, medische aansprakelijkheid, juridische overwegingen en voorwaarden met betrekking tot het gebruik van een MDR beoordeeld. Ondanks dat er verschillen zijn wat betreft wetgeving tussen verschillende landen, is de algemene privacywetgeving behoorlijk duidelijk over hoe je een kwaliteitsinstrument moet implementeren. Het is daarbij met name belangrijk dat er overeenstemming en openheid is tussen de deelnemers en onderzoekers over de methoden en het doel van de MDR. Als de MDR als kwaliteitsinstrument gebruikt wordt, is niet de patiënt het onderwerp van de studie, maar het operatieteam. Dit betekent dat de patiënt geen officiële toestemming hoeft te geven voor het gebruik van de MDR. Een "geen bezwaar" is voldoende, wat uiteraard duidelijk in het patiëntendossier genoteerd moet worden. De data uit de MDR en het MDR-uitkomstenrapport kan daarom nooit onderdeel worden van het patiëntendossier. Het operatieteam, inclusief medische studenten, moet wel officieel om toestemming gevraagd worden voor deelname aan de pilotstudie en dus ermee akkoord gaan om te werken in een OK waar een MDR gebruikt wordt. Het team wordt daarbij eerst goed ingelicht over het doel van de MDR opnames, waar en hoe de data geanalyseerd wordt, wat de voordelen van deelname zijn en hoe de data veilig wordt bewaard. Volgens de officiële privacywetgeving is de privacy van de deelnemers en patiënt beschermd, als je de privacy-by-design principes opvolgt en daarover transparant bent naar alle betrokkenen. Dit betekent dat patiëntgegevens direct van het opnamebestand worden verwijderd (de-identificatie), de gezichten van de deelnemers worden geblurd, de stemmen worden vervormd en de data wordt beveiligd verstuurd en bewaard. Het uitkomstenrapport is geanonimiseerd en de originele data wordt verwijderd zodra het uitkomstenrapport gegenereerd is. Alleen het uitkomstenrapport wordt gepresenteerd aan het team en wordt gebruikt met als doel de kwaliteit van de perioperatieve zorg te verbeteren, door middel van de team nabesprekingen. Als zich een calamiteit voordoet tijdens de operatie die wordt opgenomen met de MDR, zullen de videobeelden de teamleden eerder helpen dan schaden. Als het team gehandeld heeft volgens de normale standaard, kunnen er geen bestraffende maatregelen door het bestuur genomen worden. Concluderend kan gesteld worden dat angst voor het medisch aansprakelijk gesteld worden voor fouten als gevolg van het gebruik van een MDR onterecht is, zo lang er sprake is van goede documentatie van de operatie in het patiëntendossier en rapporteren van ongewenste gebeurtenissen, volgens de lokale ziekenhuis protocollen. Duidelijke wetgeving voor het als kwaliteitsinstrument gebruiken van een MDR in de OK is wel nog nodig.

In **Hoofdstuk 2** worden de bevindingen van een literatuurstudie, ervaring met team nabesprekingen in de simulatiesetting en de implementatie van de ORBB met bijbehorend uitkomstenrapport gecombineerd om een nieuw model voor de video-geassisteerde team nabesprekingen te creëren. Een gestructureerd nabespreekmodel is nodig om het operatieteam op een efficiënte en effectieve manier te debriefen. Daarbij wordt ook het drukke werkschema van alle teamleden in acht genomen. Gestructureerd nabespreken zorgt ervoor dat het team zo min mogelijk belast wordt, stimuleert de motivatie en minimaliseert de noodzaak tot gebruik van extra hulpbronnen. In operatieteams is vaak nog sprake van een sterke hiërarchie. Het is belangrijk om te realiseren dat dit een negatief effect kan hebben op de dynamiek in het team tijdens de nabesprekingen. Om een succesvolle nabespreking mogelijk te maken, is het daarom belangrijk om de juiste condities te creëren. Wij raden daarom aan om de nabespreking te organiseren in een neutrale omgeving, buiten de OK en om het team aan een ronde tafel te laten zitten. Alle teamleden moeten zich veilig en gerespecteerd voelen wat betreft hun individuele rol en privacy. Dit helpt het team om tijdens de nabespreking

makkelijker open te praten over wat er gebeurd is gedurende de operatie. Het is aan te raden om een onafhankelijk persoon de nabespreking te laten leiden, dus niet de chirurg of anesthesioloog, om op die manier de bovengenoemde condities optimaal te maken.
Het doel is de chirurgische patiëntuitkomsten te verbeteren, daarom is het ook aan te raden om tijdens de nabespreking te focussen op de niet-technische vaardigheden, zoals communicatie en samenwerking, in plaats van de technische vaardigheden van de teamleden. Nabesprekingen die ondersteund worden middels videobeelden worden beoordeeld als zijnde meer objectief, effectief en leerzaam.

Het uitkomstenrapport kan automatisch geanalyseerd worden met behulp van kunstmatige intelligentie software, gebaseerd op gevalideerde scoringssystemen. De onafhankelijke debriefer gebruikt het objectieve MDR uitkomstenrapport om de nabespreking te begeleiden en ervoor te zorgen dat het team feedback krijgt op een veilige, efficiënte en leerzame manier. Op deze manier kan er ook gediscussieerd worden over wat goed gegaan is en wat de volgende keer beter kan. In vervolgstudies zal geanalyseerd moeten worden of het gebruik van het MDR-uitkomstenrapporten en de bijbehorende nabesprekingen daadwerkelijk een positief effect hebben op de dynamiek tussen de teamleden en zo ook op de veiligheid in de OK.

Deel II: Vergroten van de transparantie op de operatiekamer.

De ORBB heeft voor deze pilotstudie 35 laparoscopische buikoperaties opgenomen, die uitgevoerd zijn door 4 verschillende chirurgen. De ORBB verzamelde alle data in de OK door middel van camera's in het plafond gericht op de operatietafel en de kant van de anesthesiologen, de laparoscopische camera en de anesthesiemonitor. De opname werd pas gestart als de patiënt in slaap was en werd afgedekt met steriele doeken en werd gestopt zodra de huid weer gesloten was, vlak voordat de steriele doeken weer werden verwijderd. Op die manier werd de privacy van de patiënt gewaarborgd.

Het MDR uitkomstenrapport bestond uit videoclips van alle relevante ongewenste gebeurtenissen (safety threats) en ook gebeurtenissen waaruit blijkt dat het team goed is omgaan met deze gebeurtenissen (resilience support events). Al deze gebeurtenissen werden gecodeerd volgens een gevalideerd scoringssysteem: The System

Engineering Initiative for Patient Safety (SEIPS) Framework.

In totaal hebben 81 verschillende medewerkers meegedaan aan de MDR operaties en nabesprekingen, waarvan 4 chirurgen, 2 chirurgische fellows, 12 chirurgische arts-assistenten, 6 anesthesiologen, 5 anesthesiologie arts-assistenten, 9 anesthesiemedewerkers, 27 operatieassistenten en 16 coassistenten. Alle 35 operaties werden nabesproken met het team, waarbij gemiddeld 4 (van de 7 à 8) teamleden (median, IQR 3) aanwezig konden zijn bij de nabespreking. Na elke nabespreking werden de teamleden gevraagd om een vragenlijst in te vullen.

In **Hoofdstuk 3**, werd de tevredenheid van de deelnemers met betrekking tot de MDR en het gebruik van het MDR uitkomstenrapport in de nabesprekingen gemeten. Er zijn totaal 151 vragenlijsten ingevuld. Het is belangrijk om bij de implementatie van nieuwe innovatieve technieken de tevredenheid van de deelnemers te meten omdat zij zich comfortabel en veilig moeten voelen om zich te kunnen aanpassen aan zo'n nieuw systeem dat hen beoordeelt op hun prestaties. Alleen dan kan men ervan leren. Bovendien moet iedereen die eraan deelneemt vertrouwen hebben in de werking van het systeem, om het systeem op de lange termijn ook duurzaam in werking te houden.
De vraag; "Hoe belangrijk vindt u het in teamverband en gestructureerd kunnen nabespreken van operaties?", werd beantwoord met een gemiddelde van 8.44 (SD 1.2, 10-punts Likert schaal). Alles samengenomen, was de tevredenheid van het operatieteam met het gebruikt van de ORBB en bijbehorende uitkomstenrapport in de team nabesprekingen zeer hoog. De deelnemers vonden de team nabesprekingen belangrijk, nuttig en leerzaam.

Deelname was vrijwillig en daarom was te verwachten dat deelnemers eerder tevreden zouden zijn. Aan het begin van de studie voelden slechts een paar anesthesiologen en operatieassistenten zich comfortabel genoeg om deel te nemen. Desalniettemin, werden dat steeds meer deelnemers. De tweede groep adopters besloten om toch mee te doen, ondanks dat ze in eerste instantie sceptisch waren, naar aanleiding van de positieve ervaringen van hun collega's. Uiteindelijk zouden 148 van de 151 deelnemers (98%) deelname aan de ORBB operaties en nabesprekingen aanraden. Vervolgstudies zijn wel nodig om te bepalen wat het effect op de tevredenheid van het operatieteam is, als de gehele operatie wordt opgenomen (vanaf dat de patiënt de OK binnenkomt tot en met het verlaten van de OK) en daarmee de gehele anesthesie data-analyse en bijbehorende feedback verwerkt wordt in het uitkomstenrapport.

In **Hoofdstuk 4** werden de intra-operatieve events die door de ORBB werden geïdentificeerd en tijdens de team nabesprekingen werden besproken, geanalyseerd. Alle 6 SEIPS categorieën werden geïncludeerd; persoon, taak, tools en technologie, organisatie, interne (fysieke) omgeving, externe omgeving. Zowel de meest geïdentificeerde resilience als de safety threat events waren bijna altijd gerelateerd aan de categorie persoon. De meeste resilience support events vielen onder de subcategorie; effectieve communicatie (n = 77). De meeste safety threats vielen onder de subcategorie; onveilige handeling (n = 236). Tijdens de team nabesprekingen werden meestal events besproken die te maken hadden met communicatie en situational awareness.

Goede samenwerking zorgt voor goede communicatie en andersom. De resultaten van onze studie benadrukken wederom hoe belangrijk duidelijke communicatie in de OK is. Deelnemers van deze studie gaven aan dat ze door de nabesprekingen de mogelijkheid kregen om makkelijker hun mening hardop uit te spreken. Culturele, professionele en organisatorische factoren kunnen dit moeilijker maken en dit is vaak de laatste druppel voor het ontstaan van een ongewenste gebeurtenis. Het bevorderen van het uitspreken van je mening over mogelijke safety threats of verbeterpunten middels de nabesprekingen kan daarom een direct effect hebben op voorkomen van toekomstige fouten tijdens de operatie. Bovendien is algemeen erkend dat het alleen beschrijven van ongewenste gebeurtenissen tijdens de operatie en het rapporteren van de incidentie hiervan niet voldoende is om ervoor te zorgen dat ze worden voorkomen in de toekomst. Het verduidelijken en het creëren van een gezamenlijke perceptie van de gebeurtenis is nodig. Daarom is al het onderzoek dat kennis deelt over relevante safety threats en resilience support mechanismen in de OK van belang voor toekomstige initiatieven die de perioperatieve veiligheid willen vergroten.

De resultaten van onze studie kunnen ervoor zorgen dat operatieteams zich beter realiseren wat voor negatief effect miscommunicatie en verkeerde aannames kunnen hebben op de prestaties van het team en dus de veiligheid in de OK. De teamleden gaven bovendien zelf aan dat ze zich door deelname in de nabesprekingen “waardevoller” en meer “onderdeel van het team” voelden. Dit kan een positief effect hebben op het persoonlijke welzijn van de teamleden, werktevredenheid en organisatorische betrokkenheid. Het promoten van deze human factors is van groot belang als het gaat om het verbeteren van de veiligheidscultuur. Concluderend kunnen team nabesprekingen met behulp van het ORBB uitkomstenrapport toegepast worden om het veiligheidsgedrag van de operatieteamleden te verbeteren. We kunnen daarom aanraden om werknemers die in de OK werken uit te nodigen om deel te nemen aan ongeveer 1 tot 3 team nabesprekingen per jaar om op die manier continue hun veiligheidsgedrag en de veiligheidscultuur te blijven evalueren en verbeteren.

De patiënt zelf was niet de focus van deze studie. Daarom zijn nieuwe grotere vervolgstudies nodig om de directe of indirecte impact van het gebruik van de ORBB voor de team nabesprekingen op de postoperatieve uitkomsten voor de patiënt te evalueren.

Deel III: Het verbeteren van de kwaliteit van de zorg en patiëntveiligheid in de operatiekamer.
Het leveren van veilige chirurgische zorg kan extreem complex zijn. Het vergt een combinatie van technische vaardigheden, professioneel gedrag en interpersoonlijke communicatie. Meerdere factoren beïnvloeden de chirurgische veiligheid, zoals het operatieteam, sociale interactie, technologie, organisatorische en omgevingsfactoren, patiëntkarakteristieken en de complexiteit van de operatie zelf. Ondanks dat, zijn human factors, zoals teamwork en communicatie, geïdentificeerd als een van de grootste elementen die de chirurgische patiëntveiligheid beïnvloeden. Derhalve bestaat er nu veel wetenschappelijk bewijs over de impact van het verbeteren van human factor vaardigheden met behulp van checklists, briefings en debriefing, coachen en simulatietraining. Maar, de OK is een unieke stressvolle omgeving, waar professionals van verschillende specialisaties en met verschillende opleidingen, samenwerken. Het wordt daarom aangeraden om veiligheidsinterventies hierop aan te passen en daarbij het hele operatieteam te betrekken. Maar meer duidelijkheid is nodig om uit te zoeken wat precies de etiologie is van de hiaten in het verbeteren van de veiligheid in de OK.

In **Hoofdstuk 5** worden de verschillen in perceptie onder de operatieteamleden met betrekking tot human factors in de OK geëvalueerd. We hebben een internationale multicenter studie opgezet in het St. Michael's Hospital (Toronto, Canada) en het Amsterdam UMC, locatie AMC (Nederland). Op beide locaties was de ORBB in gebruik. Tussen september 2016 en juli 2018 werden 117 electieve laparoscopische operaties opgenomen met de ORBB. De Surgical Team Assessment Record (STAR) vragenlijst werd gebruikt in beide centra. Deze vragenlijst onderzoekt de 4 levels die kunnen leiden tot menselijk falen volgens het Human Factor Analysis and Classification System (HFACS); organisatie, onveilige supervisie, precondities voor onveilige gebeurtenissen en onveilige gebeurtenissen. In totaal zijn 507 vragenlijsten ingevuld, waarvan 230 (91 operaties) vanuit het St. Michael's Hospital (SMH) en 277 (35 operaties) vanuit het Amsterdam UMC (AMC). In totaal, vanuit beide locaties samen, zijn 119 vragenlijsten ingevuld door staf chirurgen, 96 door chirurgen in opleiding, 76 door chirurgie fellows, 78 door leden van het anesthesie team (anesthesiologen of anesthesiemedewerkers), 58 door OK-assistenten (41 assisterend aan tafel, 44 circulerend) en 53 door coassistenten. Chirurgie fellows scoorden hun eigen persoonlijke welzijn significant lager in vergelijking met de rest van het operatieteam. Dit zou kunnen komen door stress rondom het krijgen van een vaste plek als staflid en bijbehorende carrière keuzes. Andere factoren die het persoonlijke welzijn beïnvloeden zijn; werkdruk, werkklimaat, of perceptie van teamwork. Negatief persoonlijk welzijn, dat zich uit als emotionele uitputting, oververmoeidheid, en concentratiestoornissen, zorgt ervoor dat iemand niet de nodige chirurgische veiligheid kan waarborgen. Het is dus zeer belangrijk om het persoonlijke welzijn van de stafleden te bevorderen om op die manier te zorgen voor beter teamwork, organisatorische uitkomsten en uiteindelijke de veiligheid van de patiënt.

De staf chirurgen bemerkten meer afleidingen (51.3%, n = 61) en afwijkingen (60.5%, n = 72) tijdens de operatie in vergelijking met de rest van het team. Deze waren volgens hen meestal gerelateerd aan technische events. Afleidingen en afwijkende gebeurtenissen zijn niet te voorkomen tijdens een operatie, maar kunnen wel grote impact hebben op de performance van het team. Voor elk teamlid worden afleidingen of afwijkende gebeurtenissen anders geïnterpreteerd. Elk teamlid zal daarom ze daarom

eerder of niet bemerken en ze wel of niet benoemen. Goed samenwerkende teams steunen het geven van een individuele mening, wat weer het benoemen van relevante afleidingen of onveilige gebeurtenissen bevordert. Als afleidingen of ongewenste gebeurtenissen proactief benoemd worden door alle leden van het team, kan dit onveilige gebeurtenissen voorkomen, aangezien deze meestal het resultaat zijn van een keten van kleinere gebeurtenissen die veroorzaakt worden door verschillende factoren in de OK.
De Crew Resource Management principes, afgeleid van de luchtvaartindustrie, zijn verwerkt in het HFACS model, omdat deze principes benadrukken hoe belangrijk de closed-loop communicatie (CLC) techniek is om onveilige gebeurtenissen te voorkomen. De CLC techniek bestaat uit 3 onderdelen; 1) het initiële bericht start met het door de zender noemen van de naam van de ontvanger, ook wel directed call out, 2) verificatie van de benoemde ontvanger, inclusief het herhalen van het belangrijkste onderdeel van het bericht, ook wel check back, en 3) verificatie van de zender dat de ontvanger het verzonden bericht goed begrepen heeft, ook wel closing the loop. Daarom bestaat de WHO Surgical Safety Checklist briefing ook uit een introductie ronde waarin alle namen en rollen van de leden van het operatieteam worden benoemd voor de start van de operatie.

Tijdens de ORBB team nabesprekingen realiseerden de deelnemers zich hoe moeilijk het is om elkaars namen te onthouden en gebruiken. Zelfs wanneer je al heel vaak met elkaar had samengewerkt. In Hoofdstuk 6 wordt daarom een simpele oplossing geïntroduceerd om het gebruik van de CLC techniek te bevorderen. Ook omdat we erachter kwamen dat gewoon het ´hokje aanvinken' niet betekent dat de introductieronde daadwerkelijk goed uitgevoerd wordt en vaak ook niet voldoende is om de namen te onthouden en gebruiken. Daarom hebben we ons aangesloten bij de Theatre Cap Challenge¸ geïntroduceerd door een Australische anesthesioloog. Deze challenge benadrukt hoe belangrijk het kan zijn om de namen van de teamleden visueel te maken door een sticker met je naam en rol op je operatiemuts te plakken als je aan het werk bent in de OK. De sticker stations werden geplaatst in de kleedkamers van het OK complex en iedereen werd hierover officieel geïnformeerd en gevraagd om de stickers te dragen. Deelname was vrijwillig. De afdelingshoofden gaven het voorbeeld door als eersten de stickers te gebruiken.

Ongeveer 1 jaar na implementatie hebben we geëvalueerd hoeveel personeelsleden de stickers daadwerkelijk droegen. We vonden dat gemiddeld bijna de helft de stickers droeg (44.8%, n = 103 van de 230 observaties). Er werd op 2 willekeurige dagen geobserveerd en geteld en van dit sample waren er 17 (16.5%) chirurg, 29 (28.2%) OK-assistent, 31 (30.1%) anesthesiemedewerker, en 15 (14.6%) coassistent. In eerste instantie reageerden men wat minachtend en hoorde je opmerkingen zoals; "dus jij kan niet eens je eigen naam onthouden hè?", of "dat ziet er stom uit, dat ga ik niet dragen." Desalniettemin benadrukten diegenen die de stickers wel droegen dat; "het ziet er misschien stom uit, maar het werkt wel", "Ik voel me meer onderdeel van het team wanneer ik zeker weet dat iedereen mijn naam weet", en "het is nuttig, want vooral in stressvolle situaties is het extra moeilijk om elkaars naam te onthouden." Ook al was nog niet iedereen overtuigd van het nut van het gebruik van de naamstickers, is het wel algemeen bekend dat men zich meer gewaardeerd voelt en het fijner vindt om te assisteren als je de desbetreffende persoon bij naam noemt. Dit vergroot de coherentie van het team en verbetert op die manier de team performance.

Samenvattend, kan uitgebreidere kennis over de etiologie en het effect van persoonlijke factoren (i.e. crew resource management en persoonlijk welzijn) op team performance resulteren in meer gerichte en duurzamere initiatieven die kwaliteit en veiligheid in de OK verbeteren. Het wordt daarom aangeraden om te focussen op initiatieven die het hele operatieteam ondersteunen, om op die manier het aantal onnodige onveilige gebeurtenissen tijdens operaties te limiteren. Meer studies zijn nodig om uit te zoeken wat de daadwerkelijke impact van human factor gerelateerd gedrag in de OK, zoals bijvoorbeeld het gebruik van de CLC techniek en sterk leiderschap, op team performance zal zijn. Daarnaast zijn er studies nodig om te definiëren welke human factors het meest relevant en waardevol zijn om op te nemen in de team trainingen die focussen op het verbeteren van de veiligheid in de OK. Hoofdstuk 7 bespreekt de houding van de operatieteamleden ten opzichte van de patiëntveiligheidscultuur en of deelname aan de ORBB team nabesprekingen hun veiligheidsgedrag beïnvloed zou kunnen hebben. Het begrijpen van de behoeftes, houdingen en percepties van het zorgpersoneel dat in

de OK werkt is uiterst belangrijk wanneer je de veiligheid in de OK wil verbeteren. De Nederlandse versie van de gevalideerde Hospital Survey on Patient Safety Culture werd gebruikt en er werden 10 vragen die betrekking hadden op de ORBB aan toegevoegd. In totaal werd de patiëntveiligheid gescoord met een gemiddelde van 3.06 (SD 0.46), op een 5-punts Likert Scale. De OK-assistenten scoorden de gemiddelde perceptie van patiëntveiligheid het laagst (mean 2.89, SD 045), terwijl de anesthesiologen in opleiding dat het hoogst scoorden (mean 3.39, SD 0.32). Teamwork binnen de afdeling, werd door iedereen het hoogste gescoord met een gemiddelde van 3.69 (SD 0.64), gevolgd door; open communicatie (gemiddelde 3.60, SD 0.76). Deelname aan de ORBB team nabesprekingen, was positief gecorreleerd aan de gemiddelde perceptie van de patiëntveiligheid (P-waarde < 0.024, 95% CI 0.034 – 0.474, Bèta-coëfficiënt 0.196).
In overeenkomst met eerdere studies die deze vragenlijst hebben gebruikt, laat deze studie zien dat er nog steeds een verschil is in perceptie van patiëntveiligheidscultuur binnen de verschillende leden van de operatieteams. Een sterke veiligheidscultuur is gebaseerd op een shared mental model met betrekking tot situaties in de OK, maar kan alleen gecreëerd worden als overtuigingen, meningen, behoeftes en houdingen ten opzichte van chirurgische patiëntveiligheid veilig benoemd en besproken kunnen worden door alle leden van het operatieteam. Onveilige acties moeten daarom gemanaged worden in een just culture, waarin alle teamleden (van coassistent tot arts-assistent tot OK-assistent) zich zelfverzekerd voelen en worden aangemoedigd om onveilige gebeurtenissen (ook als ze door henzelf worden veroorzaakt) bespreekbaar te maken. Gezamenlijke aansprakelijkheid voor fouten moet benadrukt worden, aangezien zorgpersoneel in de OK voor de patiënt zorgt als een team, fouten maakt als een team en dus verantwoording voor incidenten neemt als een team. Zorginstellingen hebben daarom de verantwoordelijkheid om een niet-bestraffend incident melding systeem te implementeren dat personeel steunt en niet straft als er fouten zijn ontstaan. Om een sterke veiligheidscultuur te creëren, moeten daarom alle operatieteamleden, ongeacht hun ervaring, werkuren en dienstjaren in het ziekenhuis, betrokken worden en ook allen moeten geloven dat verandering in hun veiligheidsgedrag daadwerkelijk zal leiden tot meer patiëntveiligheid. Implementatie van de ORBB zou op deze manier het veiligheidsgedrag kunnen verbeteren door de team

nabesprekingen mogelijk te maken en daarmee de operatieteamleden de mogelijkheid te geven om communicatie en teamwork gerelateerde gebeurtenissen die mogelijk impact hebben op de patiëntveiligheid te bespreken. Tijdens de team nabesprekingen worden ook verschillen in perceptie met betrekking tot veiligheidsgedrag besproken in een veilige, niet-hiërarchische en niet-bestraffende omgeving.

Toekomstige studies met de ORBB, of andere medische data recorders, op een grotere schaal en in verschillende settingen, zijn nodig om te evalueren of verbeterd veiligheidsgedrag daadwerkelijk leidt tot verbeterde uitkomsten voor de patiënt. Ook zijn meer studies nodig om de conclusie dat het monitoren van veiligheidsgedrag met behulp van medische data recorders inderdaad een positief effect heeft op de patiëntveiligheidscultuur in de OK, te versterken.

Deel IV: Toekomstig gebruik van de OR Black Box in de operatie kamer

Over de afgelopen jaren is er een enorme groei geweest wat betreft het gebruik van sensors, video en digitale apparaten in de OK. Deze toepassingen genereren grote hoeveelheden data in verschillende formats, ook wel big data genoemd. Een beperking van het analyseren van big data is dat traditionele data-analyse technieken meestal niet in staat zijn om te gaan met deze grote hoeveelheden complexe data. De oplossing ligt bij kunstmatige intelligentie software, ook wel artificiële intelligentie (AI). Deze term wordt gebruikt om software de beschrijven die met behulp van algoritmes, machines de mogelijkheid geeft te denken en te handelen als mensen, door ze te laten leren, problemen op te lossen en keuzes te laten maken. AI is daarom geïntroduceerd in de gezondheidszorg en wordt langzaam steeds meer gebruikt binnen de chirurgische zorg. Dit is interessant, omdat de OK wordt beschouwd als de meest fout-gevoelige omgeving in het ziekenhuis, waar de uitkomsten erg afhankelijk zijn van het gebruik van moderne technologie dat data vanuit meerdere bronnen tegelijk genereert. De unieke aard van de chirurgische zorg geeft het zorgpersoneel dat in de OK werkt daarom een goede positie om het gebruik AI in de zorg naar het volgende level te brengen. Het gebruik van meerdere databronnen, inclusief geluid en video, zorgt ervoor dat AI een krachtig instrument kan zijn voor het ondersteunen van perioperatieve besluitvorming en ontwikkelen van alarmsystemen die het team kan helpen met het voorspellen en voorkomen van ongewenste gebeurtenissen die kunnen leiden tot complicaties voor de patiënt.

In **Hoofdstuk 8** wordt het gebruik van AI toepassingen in de OK systematisch beoordeeld. De Pubmed, Embase, Cochrane library, en IEE Xplore databases werden afgezocht en dit resulteerde in 193 artikelen. Hiervan zijn uiteindelijk 9 geschikte artikelen geïncludeerd. De hieruit geïdentificeerde toepassingen van AI in de OK waren; het voorspellen van de duur van de procedure, herkennen van gebaren, detecteren van mensen en inschatten van hun houding, een endoscopisch sturingssysteem, beoordelen van chirurgisch knopen en het identificeren van botten tijdens orthopedisch chirurgische ingrepen. De meerderheid, al dan niet alle AI toepassingen lieten superieure resultaten zien in vergelijking met de daarbij horende non-AI alternatieven. Echter, de meeste studies waren alleen opgezet en toegepast in een pilot-setting.

Gedurende het innovatieproces is het dus belangrijk om ethische en juridische aspecten te beoordelen en te bespreken, omdat voor diegenen die er gebruik van moeten gaan maken dit kan meespelen in hun motivatie en het maken van de afweging tussen de voor- en nadelen van het implementeren van de nieuwe techniek. Helaas is er nog niet voldoende bekend over de regulerende, organisatorische en klinische voorwaarden voor de ontwikkelingen van AI. Net zoals over de ethische overwegingen voor het gebruik van AI software van de benodigde privacygevoelige informatie. Wet- en regelgeving is nodig om de toepassingen van AI veilig en duurzaam te kunnen implementeren. Andere barrières voor brede implementatie van AI in de zorg kunnen zijn; de onwetendheid over het onderwerp en de mogelijkheden, een gebrek aan kennis van de gebruikers en de verschaffers van de werkplek, onopgeloste vragen over ethische en privacy gerelateerde vraagstukken van het management, of een ontoereikend IT netwerk. Waarschijnlijk zal het een combinatie van al deze punten zijn. De toepassing en implementatie van AI in de OK heeft dus inderdaad nog heel wat uitdagingen te overwinnen. Alhoewel in de niet zo verre toekomst de zich steeds verder ontwikkelende ORBB technologie, met nu geïntegreerde AI and machine learning software, veel hulp kan bieden in het analyseren en optimaliseren van workflow en resultaten in de OK in real-time. Het ORBB team is momenteel bezig met ontwikkelen van applicaties van AI gericht op chirurgische handelingen. Namelijk, met behulp van patiënt- team- en chirurg-gerelateerde factoren identificeren van intra-operatieve gebeurtenissen zoals; een bloeding, hypothermie, afwijkende anatomie, gebruik van instrumenten. De aandacht van het team kan getrokken worden door het geven van een waarschuwing en op die manier kan het team besluiten of hier iets mee gedaan moet worden of niet, op basis van de door de ORBB geleverde informatie. Op die manier kan er ingespeeld worden op risico factoren door bijvoorbeeld het bekijken van radiologie beelden, de chirurgische techniek aan te passen of het inzetten van andere instrumenten.

Tot slot, wordt in **Hoofdstuk 9** het belang van het verbeteren van de veiligheidscultuur in de OK belicht. Strategieën om de veiligheidscultuur te verbeteren kunnen gecategoriseerd worden in 2 routes; technologisch/management/engineering versus non-technisch/human factors gerelateerd. De eerste route is gerelateerd aan het hogere level van een organisatie en de tweede route aan het level van het zorgpersoneel, wat ook werktevredenheid, motivatie en houding inhoudt. Beide routes beïnvloeden dezelfde uitkomsten en zullen waarschijnlijk ook elkaar beïnvloeden of zelfs versterken.
De luchtvaartindustrie heeft een bijna perfect level van veiligheid bereikt door het toepassen van de Six Sigma aanpak. Het concept van Six Sigma is oorspronkelijk ontwikkeld door Motorola engineers in de jaren ’80, om beter te worden in het meten en verminderen van defecten in zowel hun producten, onderhoud en transactieprocessen. Het hielp hen om de operationele processen te optimaliseren door het reduceren van variatie in proces uitkomsten. In statische termen staat Six Sigma voor 3.4 defecten per miljoen mogelijkheden (i.e. bijna perfect). De formule representeert de variatie van de gemiddelde (mean) proces uitkomsten, dus de verwachting dat de eerste 6 standaarddeviaties (sigma) van de productie variabiliteit binnen de acceptabele fout limieten valt. Het fundamentele doel van de Six Sigma methodologie is de implementatie van een gestructureerde data-gedreven strategie, die focust op de reductie van variatie in het proces en dus procesverbetering.

Momenteel focussen de meeste veiligheidsverbeteringen strategieën in de gezondheidszorg nog steeds op retrospectieve data en post-hoc error analyses om slechte kwaliteitsuitkomsten te identificeren. Bovendien blijft het gebruik van technologie

om objectief human factors die impact kunnen hebben op de veiligheid te monitoren suboptimaal, wat resulteert in een kennishiaat met betrekking tot procesoptimalisatie.
De Six Sigma aanpak bevat 5 stappen; definiëren, meten, analyseren, verbeteren en controleren. Als we de Six Sigma strategie optimaal willen toepassen, hebben we een OK nodig die continue gemonitord wordt om op die manier het natuurlijke gedrag en de standaard operatieve processen te meten en op die manier zowel de technische als non-technische factoren die de veiligheid kunnen beïnvloeden te analyseren. We moeten alleen niet vergeten dat de gezondheidszorg uiteraard heel anders is dan de luchtvaart- of auto-industrie, waarbij menselijke variabiliteit een veel grotere rol speelt. Desondanks, door het gebruik van een objectief datamonitoring systeem zoals de ORBB en het hierbij toepassen van de bovengenoemde 5 stappen, kan variabiliteit in de operatieve zorg mogelijk verkleind worden, wat uiteindelijk zal resulteren in een hoger Six Sigma veiligheidslevel.

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LIST OF PUBLICATIONS

In this thesis

van Dalen ASHM, Jung JJ, Nieveen van Dijkum EJM, Buskens CJ, Bemelman WA, Grantcharov TP, Schijven MP. Analyzing and discussing human factors affecting surgical patient safety using innovative technology: creating a safer operating culture. ***Journal of Patient Safety***, 2022

van Dalen ASHM, Swinkels JA, Coolen S, Hackett R, Schijven MP, Improving communication in the operating room: introducing the theatre cap challenge. ***Journal of Perioperative Practice***, 2021

van Dalen ASHM, Strandbygaard J, van Herzeele I, Boet S, Grantcharov TP, Schijven MP, Six Sigma in Surgery: how to create a safer culture in the operating theatre using innovative technology. ***British Journal of Anaesthesia***, 2021

Birkhoff DC, van Dalen ASHM, Schijven MP. A review on the current applications of artificial intelligence in the operating room. ***Surgical Innovation,*** 2021

van Dalen ASHM, Goldenberg M, Grantcharov TP, Schijven.MP. Assessing the team's perception on human factors in the operating room environment. ***American Journal of Surgery***, 2020

van Dalen ASHM, Jansen M, van Haperen M, van Dieren S, Buskens CJ, Nieveen van Dijkum EJM, Bemelman WA, Grantcharov TP, Schijven MP. Implementing structured team debriefing using a Black Box in the operating room: surveying team satisfaction. ***Surgical Endoscopy***, 2020

van Dalen ASHM, van Haperen M, Swinkels J, Grantcharov TP, Schijven MP. Development of a model for video-assisted postoperative team debriefing. ***Journal of Surgical research***, 2020 van Dalen ASHM, Legemaate J, Wolfgang S, Legemate DA, Schijven MP. A review of current legal perspectives and recommendations on the use of a Black Box in the operating theatre. ***The British Journal of Surgery***, 2019

Other publications

GlobalSurg Collaborative, Global variation in postoperative mortality and complications after cancer surgery:a multicentre, prospective cohort study in 82 countries. ***The Lancet***, 2021

Kempeneers MA, Issa Y, et al. Pain patterns in chronic pancreatitis: a nationwide longitudinal cohort study. ***Gut***, 2020

Barsom EZ, van Dalen ASHM, et al. Comparing video consultation and telephone consultation at the outpatient clinic of a tertiary referral centre: patient and provider benefits. ***BMJ Innovations***, 2020

Jansen M, Barsom EZ, van Dalen ASHM, et al. Identification of Meaningful Data for Providing Real-Time Intraoperative Feedback in Laparoscopic Surgery Using Delphi Analysis. ***Surgical Innovation***, 2020

EuroSurg Collaborative. Timing of nasogastric tube insertion and the risk of postoperative pneumonia: an international, prospective cohort study. ***Colorectal Disease***, 2020

EuroSurg Collaborative. Safety of hospital discharge before return of bowel function after elective colorectal surgery. ***British Journal of Surgery***, 2020

EuroSurg Collaborative. Safety and efficacy of non-steroidal anti-inflammatory drugs to reduce ileus after colorectal surgery. ***British Journal of Surgery***, 2020

Adams-McGavin RC, Jung, JJ, van Dalen ASHM, Grantcharov TP, Schijven MP. System Factors Affecting Patient Safety in the OR. ***Annals of Surgery***, 2019 van Dalen ASHM, Ali UA, Murray AC, Kiran RP. Optimizing patient selection for laparoscopic and open colorectal cancer resections: a NSQIP matched analysis. ***The American Surgeon***, 2019

EuroSurg Collaborative, Ileus Management International (IMAGINE): Protocol for a multicentre, observational study of ileus after colorectal surgery.
Colorectal Disease, 2018

EuroSurg Collaborative, Body mass index and complications following major gastrointestinal surgery: a prospective, international cohort study and meta-analysis. ***Colorectal Disease***, 2018

PHD PORTFOLIO

EDUCATION

General courses

- AMC World of Science — 2016
- Project Management — 2017
- Practical Biostatistics — 2017
- BROK course — 2017

Specific courses

- Clinical Epidemiology 1: Evaluation of Medical Tests — 2017
- Clinical Epidemiology 2: Observational Epidemiology Effects & Effectiveness — 2017
- Advanced Topics in Biostatistics — 2018

Seminars, workshops, lectures and master classes

- Symposium Incidenten in de Patiëntenzorg , AMC — 2016
- De Anatomische Les, Concertgebouw, Amsterdam — 2016
- Medical Business Fundamentals and Masterclass, Amsterdam — 2017

Other

- Journal Club, Department of Surgery, AMC — 2016-2018
- Medical Business Project, LUMC — 2017
  Including consultancy training at Deloitte & Gupta Strategists

TEACHING AND TUTORING

Lecturing — 2018

- Workshop on virtual reality (reanimation) games at St. Michael's Hospital's Simulation Center

Tutoring, Mentoring — 2017-2018

- Mentoring second year medical students, University of Amsterdam (*Leerlijn Professionele Ontwikkeling*)

Supervising

- *Local Lead, team EuroSurg Research Collaborative* 2017-2018
  Supervising and coordinating mini-teams AMC, OLVG, Flevoziekenhuis, Tergooi ziekenhuis IMAGINE study
- Supervising Bachelor thesis Christiaan Birkhoff 2019
  Systematic review on artificial intelligence in the operating room

Other

- *National Lead The Netherlands, GlobalSurg 3 Collaborative* 2018-2019
  International cohort study. Initiate and coordinate data collection teams at Amsterdam UMC, location AMC and VUmc, ZaansMC, OLVG Oost and TerGooi hospital

SCIENTIFIC CONFERENCES

Oral presentations

- Video- and medical data recording in the OR; the legal framework outlined 2017
  EAES congress, Frankfurt, Germany
- Laparoscopic colorectal cancer resection in the elderly and obese is associated with more reduction of post-operative complications compared to the younger and non-obese patients (Master Thesis). *ESCP congress, Berlin, Germany* 2017
- Experience & perspective after 1 year OR Black Box (Key Note Lecture) 2018
  Beyond Gynecologic Surgery Congress, Clermont-Ferrand
- Structured team debriefing with the use of an OR Black Box 2018
  EAES congress, London, UK
- Analysing adverse events and potential threats with a “Black Box” in the operating room. *EAES congress, London, UK* 2018

- Implementing an OR Black Box and structured team debriefing to improve team performance and surgical safety 2018
  ESCP congress, Nice, France
- Results of the Transparency in the Operating Room Trial 2018
  OK Transparant congress, Amsterdam UMC, location AMC
- Situational Awareness in the operating room 2019
  Symposium Vereniging Chirurgie voor Medisch Studenten, Utrecht, The Netherlands
- Implementing a tool for structured postoperative team debriefing to improve surgical safety. Emerging Technology Session. 2019
  SAGES, Baltimore, USA
- The use of a Black Box in the OR: lessons learned observing safety threats and resiliency, 2019
  EAES congress, Sevilla, Spain
- Assessing human factors in the operating theatre: differences in perceptions within the surgical team 2019
  EAES congress, Sevilla, Spain
- Assessing human factors in the operating room 2019
  American College of Surgeons (ACS) Clinical Congress, San Francisco, USA
- Implementing the OR Black Box: lessons learned 2019
  American College of Surgeons (ACS) Clinical Congress, San Francisco, USA
- Surveying operating room staff attitudes: is working in a Black Box monitored operation room of influence on patient safety? 2021
  World Congress of Endoscopic Surgery (WCES), Barcelona, Spain

Poster presentations

- Innovatiebazaar Benchmarking *OK Symposium, Radboud UMC* — 2016
- Debriefing using a medical data recorder in the operating room: this is how we do it. *EAES congress, Frankfurt, Germany* — 2017
- Communication in the operating room; the name of the game *EAES congress, London, UK* — 2018
- Surveying theatre staff's attitude towards patient safety culture and the use of a Black Box at the operating room *EAES congress, Sevilla, Spain* — 2019
- A review on the current applications of artificial intelligence in the operating room. *WCES, Barcelona, Spain* — 2021

(Inter)national conferences

- NRC Live Zorgtechnologie, Amsterdam — 2016
- ESCP (European Society of Coloproctology), Milan, Spain — 2016
- Chirurgendagen, Veldhoven, The Netherlands — 2017
- EAES (European Association of Endoscopic Surgery), Frankfurt, Germany — 2017
- ESCP (European Society of Coloproctology), Berlin, Germany — 2017
- Beyond Gynaecologic Surgery Congress, Clermont-Ferrand, France — 2018
- EAES congress, London, UK — 2018
- ESCP congress, Nice, France — 2018
- OR Transparency, Amsterdam UMC, location AMC Amsterdam, The Netherlands. (organisation) — 2018
- EAES congress, Sevilla, Spain — 2019
- American College of Surgeons Clinical Congress, San Francisco, USA — 2019
- World Congress of Endoscopic Surgery, Barcelona, Spain — 2021

PARAMETERS OF ESTEEM

Grants

- Travel Grant by the *Amsterdams Universiteitsfonds* to visit and present at the American College of Surgeons Clinical Congress in San Francisco, USA — 2019

Awards and prizes

- Gerhard Buess Technology Award; 1 out of 7 best papers, EAES, London — 2018
- “Ideeplaats veiligheid” Price; Introducing the Theatre Cap Challenge Amsterdam UMC, location AMC — 2018
- Gerhard Buess Technology Award; 1 out of 7 best papers, EAES, Sevilla — 2019

DANKWOORD

Met veel plezier heb ik afgelopen jaren aan dit proefschrift gewerkt. Dit was niet mogelijk geweest met de steun, inspiratie en hulp van velen, zowel op als buiten de werkvloer. Een aantal van hen wil ik dan ook graag in het bijzonder bedanken voor de bijdrage aan de totstandkoming van dit proefschrift:

Prof. dr. M.P. Schijven, beste Marlies, bedankt dat jij mij als onervaren coassistent de kans hebt gegeven om dit uitdagende PhD-project op te zetten. Dit was zeker in het begin niet altijd even makkelijk, maar ik ben heel blij dat het ons gelukt is. Je hebt mij geleerd dat hoe gek een idee voor sommigen ook mag klinken, je er gewoon voor moet gaan. Daarbij blijf je wel altijd kritisch en stelde je vaak mijn geduld op de proef als ik weer een rood manuscript van je terugkreeg. Ik heb daarbij veel geleerd van je eindeloze discipline, positieve mentaliteit en chirurgische precisie. Je bent voor mij een echte mentor waarbij ik weet dat ik altijd op jouw steun kan rekenen. Trot ben ik dan ook dat ik jouw PhD-student ben geweest. Ik hoop dat we in de toekomst nog vaker mogen samenwerken, zowel in als buiten de operatiekamer.

Prof. dr. T.P. Grantcharov, dear Teodor, what an honour to be able to work with you. Your vision on the future of safe surgical care and innovative approach to improve it is very inspirational. It has been amazing to see how your Black Box team started as a small group and how it has now developed into a dedicated internationally evolving network. Thank you for introducing me to your Black Box team in both Toronto, during the ACS Congress in San Fransisco, and the EAES conferences. I'm proud to be part of the OR Black Box network and hope we can keep working together in the future.

Prof. dr. W.A. Bemelman, beste Willem, veel dank dat u vanaf het begin deel wilde nemen aan het Black Box project en mij als onderzoeker onder uw hoede hebt genomen. Uw kritische blik met betrekking tot het onderzoek en de bijbehorende artikelen waren van vitaal belang. Ook bedankt voor het er altijd met het volste enthousiasme voor zorgen dat er tussen het harde werken door ook wel genoeg feestjes georganiseerd werden, met als resultaat onvergetelijke avonden op de Vinkeveense plassen en de ESCP congressen.

De leden van mijn promotiecommissie, *Prof. dr. H.P. Beerlage, Prof. dr. N.D. Bouvy, Prof. dr. mr. J. Legemaate, Prof. dr. M.M. Levi, Prof. dr. J.A. Romijn, Prof. dr. W. Schlack,* hartelijk dank dat u zitting wilde nemen in de promotiecommissie en veel dank voor het beoordelen van mijn proefschrift.

Dank aan alle deelnemers van de TOPPER trial (OK-assisstenten, anesthesiemedewerkers, anesthesiologen, AIOSen, coassistenten), zonder jullie vertrouwen, openheid en bereidheid om als 'early adopter' mee te doen aan de Black Box operaties en nabesprekingen was het uiteraard niet mogelijk geweest om dit project uit te voeren.

Diederich Cornelisse, bedankt voor het mij introduceren op het OK complex en het zetten van de eerste stappen met betrekking tot de implementatie van de Black Box.

Peter Stoete, bedankt voor het mede mogelijk maken van de installatie van de Black Box met de rest van het technische team van het OK complex. Zonder jouw hulp en bereikbaarheid, op welke dag van de week of tijdstip van de dag dan ook, was het niet mogelijk geweest om de Black Box succesvol werkende te maken en alle operaties succesvol op te nemen.

Beste Hans, Ed en Erwin, bedankt voor het mogelijk maken van de installatie van de Black Box vanuit het ICT architecten team.
Martijn Broekhoff, bedankt voor het mede mogelijk maken van het integreren van de camera's voor de Black Box vanuit Olympus.

Dear Karthik, thank you so much for your support with the implementation of the OR Black Box at our centre. Moreover, thank you for always being available to help with the system during the procedures and providing us the performance reports on time for the team debriefings. Thank you for showing us a great time during our visits in Toronto and of course, for always making me laugh with your (bad) jokes during the sometimes stressful times. I hope to see you again sometime, and wish you all the best with your new career path and family.

Dear Amar, thank you so much for making the installation of the OR Black Box possible. I am impressed with how you were able to make it technically possible. Thank you for always being available and happy to help when the system was not working properly and of course always fixing it on time. It was a sincere pleasure working with you.

Dr. Goldenberg and Dr. Jung, dear Mitchell and James, thank you for welcoming me to your city and introducing me to your research group. Thank you both, for critically reviewing our manuscripts and checking the English grammar. It was a sincere pleasure working with you and I wish you all the best with your medical and scientific careers.

Drs. M. van Haperen, beste Maartje, heel erg bedankt voor het nemen van het voortouw vanuit de anesthesiologen. Bedankt voor je toewijding, enthousiasme en je waardevolle input tijdens zowel de operaties als de nabesprekingen. Uiteraard ook heel erg bedankt voor de onvergetelijke tijd tijdens ons bezoek aan Toronto, de ijshockeywedstrijd en de gezellige etentjes. Mede dankzij jou heb ik de keuze voor anesthesiologie gemaakt.

Beste Shirley Sussenbach, bedankt voor het steunen van het Black Box project vanuit de OK-assistenten. Bedankt voor het inroosteren van het juiste personeel en voor het helpen met het overtuigen van hen die twijfelden. Zonder jou was het niet mogelijk geweest om alle operaties succesvol uit te voeren en na te bespreken.

Beste Emil Hofstra, bedankt voor het telkens weer inroosteren van de juiste anesthesiemedewerkers. Zonder jou was het niet mogelijk geweest om alle operaties succesvol uit te voeren en nabespreken.

Prof. dr. J.A. Swinkels, beste Jan, heel erg bedankt voor het willen begeleiden van de team nabesprekingen. Zonder u was het niet mogelijk geweest om deze succesvol te laten verlopen en er voor te zorgen dat iedereen zich veilig voelde om deel te nemen aan de discussie.

Prof. dr. E.J.M. Nieveen van Dijkum en dr. C.J. Buskens, beste Els en Christianne, bedankt voor het willen meedoen met het Black Box project vanuit de chirurgen. Bedankt voor het enthousiasme tijdens de operaties en team nabesprekingen, mede daardoor zijn deze succesvol verlopen. Bedankt voor de kritische blik en adviezen met betrekkingen tot het opschrijven van de resultaten.

Alle mede-onderzoekers van de G4, Simone, Julia, Karin, Tara, Vivian, Emma, Nick, Stijn, Stijn, Joske, Sven, Lianne, Anouk, Fay, Rens, Jeroen, Charlotte, Robin, Robin, Daan, Deesje, Maarten, Sophie, Marthe, Fabienne, Frederique, Sapho, Eliza, Sarah, Stefan, Hamid, Reza, Timothy, Merel, Eran, Anna, Niels, Eline, Marianne, Thijs, Fadi, Joline, Saloomeh, Lotje, Fleur, Wernard, Siem, Marjolein, en de rest die ik nog vergeten ben, bedankt voor alle gezelligheid, vrijdagmiddagborrels, lunches, cola rondjes, congressen, weekendjes weg en feestjes.

Kamertje 7, lieve Marin en Syl, bedankt dat jullie mij verwelkomd hebben op G4, in het mooiste kamertje uiteraard. Bedankt dat jullie mij door die eerste maanden van mijn PhD hebben geholpen, met het checken van de mails, cover letters, en het ervoor zorgen dat ik niet te veel afgeleid werd. Wat leuk dat voor ons alle drie ons eerste manuscript in de British Journal of Surgery gepubliceerd is. En ik ben heel trots dat jullie allebei een mooie opleidingsplek hebben weten te bemachtigen.

Team Pokémon, bedankt voor al jullie hulp en advies tijdens onze vrijdagmiddag-overleggen, *Riëtte* bedankt voor het welkom heten en wegwijs maken in dit team, *Anneloek*, bedankt voor jouw inspirerende manier van je niet gek te laten maken en je eigen weg te durven kiezen, *Esther,* bedankt voor jouw inspirerende creativiteit en alles op je eigen originele manier aanpakken. *Marilou*, we begonnen als concurrenten maar gelukkig werden we snel hechte collega's. Bedankt voor al je gezelligheid op G4, de borrels en gelukkig ook in Toronto. Je bent een echte doorzetter en blijft wat er ook gebeurd altijd positief. *Tim*, bedankt dat jij met de TedTrial de Black Box toch nog draaidende weet te houden. *Sebas,* bedankt dat je samen met Tim wat mannelijkheid in de Pokémon groep hebt gebracht.

Beste secretaresses van G4, beste Ilse, Els, Jacq, Sophie, Nora, Indra, Ingrid en Joke, dank voor jullie hulp, ondersteuning en gezelligheid op de afdeling. Jacq, Sophie en Ilse, bedankt voor het ervoor zorgen dat alle administratieve zaken tijdens de afrondende fase van mijn promotietraject helemaal soepel verlopen zijn.

Collega's van de IC in het Flevoziekenhuis, bedankt voor de onvergetelijke en leerzame tijd in de dierentuin. Wat had ik toch gemoeten zonder jullie grappen, mentale support en selfies.

Cogroepje 72, bedankt voor de gezelligheid op het voetenplein en de steun tijdens de coschappen.

Mr. Wijffels, lieve Floor, Flora, knoet, Siamese, achterkleinkind, het begon eigenlijk allemaal dat eerste weekend in New York, samen de zonsondergang kijken bij de Williamsburg Bridge. Wat was ik blij dat ik in het begin bij jou op de bank kon logeren, totdat ik mijn eigen kamer geregeld had. De avonturen die we daarna samen hebben meegemaakt hebben zich als een sneltrein opgestapeld. Het zijn er te veel om zo op te noemen, maar gelukkig hebben we altijd nog de foto's als bewijs. Bedankt dat je altijd precies datgene weet te zeggen of vragen waar ik op dat moment behoefte aan heb, dat je altijd voor mij klaar staat als ik mijn ei kwijt moet, ook al heb je zelf al heel wat tegenslagen gehad, en bedankt dat je mijn vriendin bent met wie ik zo erg op een lijn zit qua kijk op het leven en de wereld.

Iris Bosch, lieve Ir, Siri, bedankt voor alle onvergelijkelijke roadtrip avonturen, hotel gym en honden knuffel sessies en natuurlijk mezcal margarita avondjes. Naast al dat harde werken moest er natuurlijk ook genoten worden.

Drs. Meulendijks, lieve Eva, mede PhD student, surfchick en lolo party animal, bedankt voor je nuchterheid, sportiviteit tijdens de COVID sportsessies en surfsessies in Sportugal, en natuurlijk je ongelofelijk goede dansmoves op alle feestjes die we samen hebben gepakt.

Drs. Gielis, lieve Wup, ook wij kennen elkaar ondertussen al meer dan 10 jaar. Als toekomstige echtgenoot van Paflov, verdien jij ook een plekje in deze lijst. Bedankt voor je oneindige grappen en sterke verhalen. Bedankt voor het organiseren van alle gezellige borrels op jullie dakterras, aan de nieuwe meer, en je enthousiasme op alle feestjes die we samen al hebben meegemaakt.

Drs. Panfilova, lieve Paflov, Natali, Pafmoes, bedankt dat je destijds bij mij kwam wonen op de Blokmakerstraat. Bedankt dat ik altijd jouw advies kon vragen over tentamens die jij al lang gehaald had. Bedankt voor alle goede gesprekken, je bent een huisarts in de dop. We hebben al heel wat samen meegemaakt. Van horror films met uilen kijken op de brakke dagen met een liter fles cola en jij natuurlijk met de sla en citroen. Van Schmeck Pony tot Lowlands. Van alto/toko borrels tot gala's/blind date diners. Van partyen in St. Tropez tot skiën in de Alpen. Ik weet zeker dat onze vriendschap voor altijd is.

Drs. Bom, lieve Wouter, bedankt voor alle gezelligheid op de G4, op de Swammerdamstraat, de ski weekendjes in Zwitserland, Renesse, en natuurlijk Lowlands. Bedankt dat je ervoor gezorgd hebt dat ik op tijd was voor mijn morning presentation in Nice. Bedankt voor het samen organiseren van de vrijmibo's. Bedankt voor het oprichten van team Fresh Pow Pow. Zonder jou was het allemaal, ondanks je eigenwijze koppigheid, toch een stuk saaier geweest! Bedankt dat jij altijd vrolijk, positief en vol energie bent en mij altijd op sleeptouw neemt. Er was even een break, maar gelukkig is alles nu weer goed. En wat zou het leuk zijn als we in de toekomst als team op de OK kunnen samenwerken, als je durft.

Dr. Stellingwerf, lieve Merle, Murl, cogenootje, collega, mede phd-er, bijna buurvrouw, party animal, vriendin, en Paranimf. Bedankt dat je mij hebt geïntroduceerd op de G4. Bedankt dat ik altijd bij jou kon afkijken met hoe ik mijn coschappen moest onderbreken voor mijn PhD, het regelen van congressen, me weer aanmelden voor mijn coschappen en uiteindelijk natuurlijk voor het afronden van deze PhD thesis. Dat was nooit gelukt zonder alle gezelligheid, serieuze maar ook niet serieuze gesprekken en vele buitenlandse maar ook Amsterdamse avonturen die we samen hebben beleefd in de afgelopen 7 jaar. Jij bent altijd overal voor in en zorgt dat elke activiteit een feestje wordt. Wat vliegt de tijd en wat is jouw oneindige energie altijd een inspiratie.

Stephanie Masson, lieve Stephamice, bedankt voor jouw altijd positieve mentaliteit, zorgzaamheid en je grote warme hart. Volgens mij heb ik jou nog nooit horen klagen of iets negatiefs horen zeggen. Je bent de gangmaker op elke borrel en staat altijd met een grote glimlach voor mij klaar, zelfs als je het zelf ook niet altijd even makkelijk hebt, en dat waardeer ik enorm.

Us Mestreechke, lieve Bent, Bien, Does, Kimmie, Masch, we kennen elkaar al bijna ons hele leven en hebben al heel wat pieken en dalen samen meegemaakt. Bedankt dat jullie al die tijd al in mijn leven zijn, vanaf de peuterspeelzaal tot aan nu. Dat is heel bijzonder en ik weet zeker dat onze vriendschappen voor altijd zijn, want jullie zijn als familie.

Dikke billen club, lieve Maan, Nien, Syl, bedankt dat ik in het eerste jaar van onze bachelor met jullie mee op avontuur mocht in Paramaribo, Suriname. Lekker billen wassen en in de weekenden het land verkennen. Bedankt dat jullie me bij de les hielden tijdens de colleges en werkgroepen van de bachelor. Bedankt voor de support later tijdens de coschappen waar ik toch wat op jullie achter liep, maar uiteindelijk konden we allemaal meepraten over de ups and downs van het leven als PhD student. Wat ben ik blij dat wij na al die (12?!) jaren nog steeds goede vriendinnen zijn en wat mooi om te zien dat we allemaal ons eigen pad hebben gevonden.

JC Bass, lieve Sas, Sooph, Marthy, wat een geweldige avonturen hebben wij samen meegemaakt in New York. Van party brunches in Manhattan tot book launch parties in Brooklyn. Van rooftop cocktails tot lattes met banana pancakes. Van wachten op de Subway met live music tot in de kou op een Citibike door de stad. Iedereen was altijd overal voor in! Zo leuk dat we allemaal met een ander soort stage naar deze stad toe gingen, maar toch elkaar gevonden hebben en elkaar natuurlijk nog steeds regelmatig zien. Sex and the city for life. Zonder jullie was dit nooit zo'n onvergetelijke tijd geworden en had ik die masterscriptie natuurlijk nooit met zoveel plezier geschreven.

The Edlin Family, Dear Janene and Rich, thank you so much for welcoming me into your family. Rich, thank you for once telling me "life is too short to be scared", Janene, thank you for being my "American mom". *Dan, Greg and Ben*, thank you for showing me such a great time every time we met up in some other city in The States.

Malouloouuuu, lieve Malou, bedankt dat jij mijn New York 2.0 tijd onvergetelijk gemaakt hebt en dat we daarna nog vele feestjes, borrels en brunches in Amsterdam hebben gehad en gelukkig zullen er nog velen volgen.

Mitra, lieve Miet, wie had dat gedacht toen wij samen een verdieping deelde in ons party paleisje op de Leidsekade. Bedankt voor alle gezelligheid en goede gesprekken. Wat ben ik blij dat ik jou destijds heb kunnen opzoeken in Barcelona tijdens jouw master en jij mij vervolgens bent komen opzoeken in New York tijdens mijn wetenschappelijke stage. Bedankt dat je nog steeds een geweldige gastvrouw bent die altijd alle etentjes, brunches en borrels tiptop geregeld heeft.

PN '09, het mooiste jaar, bedankt voor alle onvergetelijke herinneringen die we samen gemaakt hebben tijdens mijn studententijd. Ook al zien we elkaar niet meer zo vaak als toen we nog hard aan het studeren waren voor onze bachelors en daarnaast ook elke week borrelend op de Toko te vinden waren, onze jaarband zal voor altijd blijven bestaan.

VVV Dames 11, bedankt voor het begrip als ik weer eens niet aanwezig kon zijn op de trainingen of wedstrijden door congressen, coschappen, of diensten. Bedankt voor alle leuke zondagen op het hockeyveld, gezellige gesprekken op de fiets of in de auto onderweg naar de trainingen of wedstrijden, en natuurlijk ook alle TDs, borrels, feestjes, en wintersportvakanties.

Huize Hugo, lieve Rox, bedankt voor je luisterende oor en avondjes kletsen na onder andere al mijn diensten op de IC tijdens de 2e COVID golf. *Lieve Ariet*, bedankt voor je altijd positieve sfeer in huis en de heerlijke pokebowls. *Lieve Ideles,* bedankt voor al je ongevraagde, maar eigenlijk altijd zeer gewenste adviezen, inspirerende verhalen, kookkunsten en bovenal hulp bij het voorbereiden van mijn sollicitaties.

Lieve (tante/oma) Ans, bedankt voor je Brabantse gastvrijheid tijdens mijn baan bij de anesthesie in het JBZ. Wat voelde ik mij meteen welkom en wat werd ik toch verwend met lekker eten en bijpassende toetjes. Dat maakte het thuiskomen na werk elke keer een feestje en het vroege opstaan de volgende ochtend toch een stuk makkelijker.

Floor Wit, lieve Flo, je bent ondertussen meer een broer dan de vriend van mijn zusje. Bedankt voor jouw zorgeloosheid, dat je om kan gaan met de familie van Dalen planning, je beleggingsadviezen en waardevolle toevoeging aan mijn familie en vriendengroep.

Aimée, lieve Amy, wij zijn al vriendinnen zolang ik me kan herinneren. Ook al verhuisde jij in groep 3 naar boven de rivieren, bleven we toch penvriendinnen. Acht bloemetjes was het geheim. Ook al zagen we elkaar soms lange periodes niet, wisten we dat de vriendschap goed zat en was het altijd meteen weer als vanouds. Bedankt dat ik tijdens mijn eerste jaar in Amsterdam bij jou mocht logeren totdat ik mijn eigen plekje had gevonden. Ik ben heel blij dat we nu toch weer in dezelfde stad wonen. Bedankt voor de altijd heerlijk Bourgondische borrels en gezelligheid. Trots op onze Maastrichtse roots.

Lieve Hackeng's en Pinto's, lieve Framily, bedankt voor alle vakanties die we samen gehad hebben, van kamperen in Italië tot skiën in de Franse Alpen. Van kaasfondue food fights tot de jacuzzi laten overstromen met zeepsop. Bedankt voor de nieuwe december diner traditie, met of zonder extra aanhang, het is altijd een groot succes. Bedankt dat jullie er altijd waren op verjaardagen en afstudeerborrels. *Sara-Joan, Yigal en Tilman,* bedankt dat jullie altijd goed advies konden geven voor mijn studiekeuzes en sollicitaties.

Lieve Lou, sis, bedankt dat je niet alleen m'n zusje maar ook mijn beste vriendin bent. Sisters are flowers from the same garden. Je kent me door en door en woorden zijn meestal niet nodig om te begrijpen wat we denken, willen of nodig hebben. Bedankt dat je er altijd voor me bent, me altijd aan het lachen kan maken en me altijd het juiste advies geeft. En natuurlijk bedankt voor je creativiteit en het helpen ontwerpen van de layout van dit proefschrift.

Lieve Pieter, Piet, bro, broski, paranimf, bedankt voor je altijd scherpe opmerkingen, grappen en interessante discussies. Bedankt dat je me altijd aan het lachen kan maken. Je kent geen gêne, hebt geweldige dansmoves en bent een echte charmeur. Ondanks dat je niet altijd naar het vaak door jou zelf gevraagde (dokters)advies van je grote zus wil luisteren, krijg je op op je eigen manier toch altijd alles voor elkaar en komt het altijd allemaal goed.

Lieve familie, bedankt voor jullie warmte, liefde en gezelligheid. Bedankt dat jullie mij, als eerste arts in de familie, altijd het volste vertrouwen hebben gegeven dat ik alles met succes zou gaan afronden. *Thomas*, bedankt dat je het mij toevertrouwde om je hechtingen te verwijderen op eerste kerstdag. *Lara en Stephan*, bedankt voor het helpen regelen van mijn stage in Indonesië en dat we bij jullie mochten logeren op Bali. *David,* bedankt dat je als buurman altijd voor me klaar staat. *Ome Jan en tante Francis*, bedankt voor jullie altijd warme welkom en natuurlijk het organiseren van de kerstdiners. *Tante Esther*, peettante, bedankt dat ik in jouw huisje in Amsterdam mocht logeren tijdens mijn nachtdiensten. *Nina en Sanne*, lieve nichtjes, bedankt dat jullie altijd het voortouw nemen als er weer en neven&nichten borrel georganiseerd mag worden.

Hélène en Pleun, Lieve Mam en Pap, bedankt voor jullie onvoorwaardelijke steun tijdens alle keuzes die ik tot nu toe heb gemaakt. Van jongs af aan hebben jullie mij geleerd dat ik alles wat ik wil kan bereiken, als ik er maar mijn best voor doe. Jullie hebben er voor gezorgd dat ik niks tekort ben gekomen, ook al was dat niet altijd even makkelijk. Waar een wil is, is een weg. Ik ben super trots dat jullie mijn ouders zijn.

ABOUT THE AUTHOR

Anne S.H.M. van Dalen was born on December 31, 1989 in Zwolle, the Netherlands. She grew up in the south of Limburg, and obtained her gymnasium diploma at the *Sint Maartens College* in Maastricht. Hereafter, she travelled to Nicaragua and Guatemala to improve her Spanish skills and do volunteer work in a local hospital. In 2009, she moved to Amsterdam to start her bachelor in Medicine at the University of Amsterdam. In Amsterdam, she fully enjoyed being a student and building a new life with many new friends. After finishing her Bachelor degree, she decided she wanted to write her master thesis abroad and got in contact with prof. dr. Kiran, a surgeon at Columbia University Medical Center in New York, the United States of America. Under his supervision, she finished her master thesis about the differences between laparoscopic versus open surgery for colorectal cancer patients. She also ran the New York marathon for the Dutch Cancer Society (*KWF*). After finishing her first year of clinical rotations, she was given the unique opportunity to start this PhD project under supervision of prof. dr. Schijven, prof. dr. Bemelman, and prof. dr. Grantcharov. From June 2016 until December 2018 she was a fulltime PhD-student, during which was fortunate to present the results of this thesis at several international conferences. In January 2019, she continued her clinical rotations as part of her Master degree. During the last year of her clinical rotations, she was able to do an internship at the department of anaesthesiology (Amsterdam UMC, location AMC) and the department of surgery (OLVG hospital, location east). Due to the COVID-19 pandemic, she also worked as a nursing assistant at the Intensive Care Unit of the OLVG hospital, location east. In July 2020, she finished her Master degree after which she started working as a general resident at the Intensive Care unit of the Flevo hospital in Almere. After about a year, she started working as a general anesthesiology resident (not in training) at the Jeroen Bosch hospital in Den Bosch. In the summer of 2022 she will start her anaesthesiology training at the LUMC in Leiden.

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