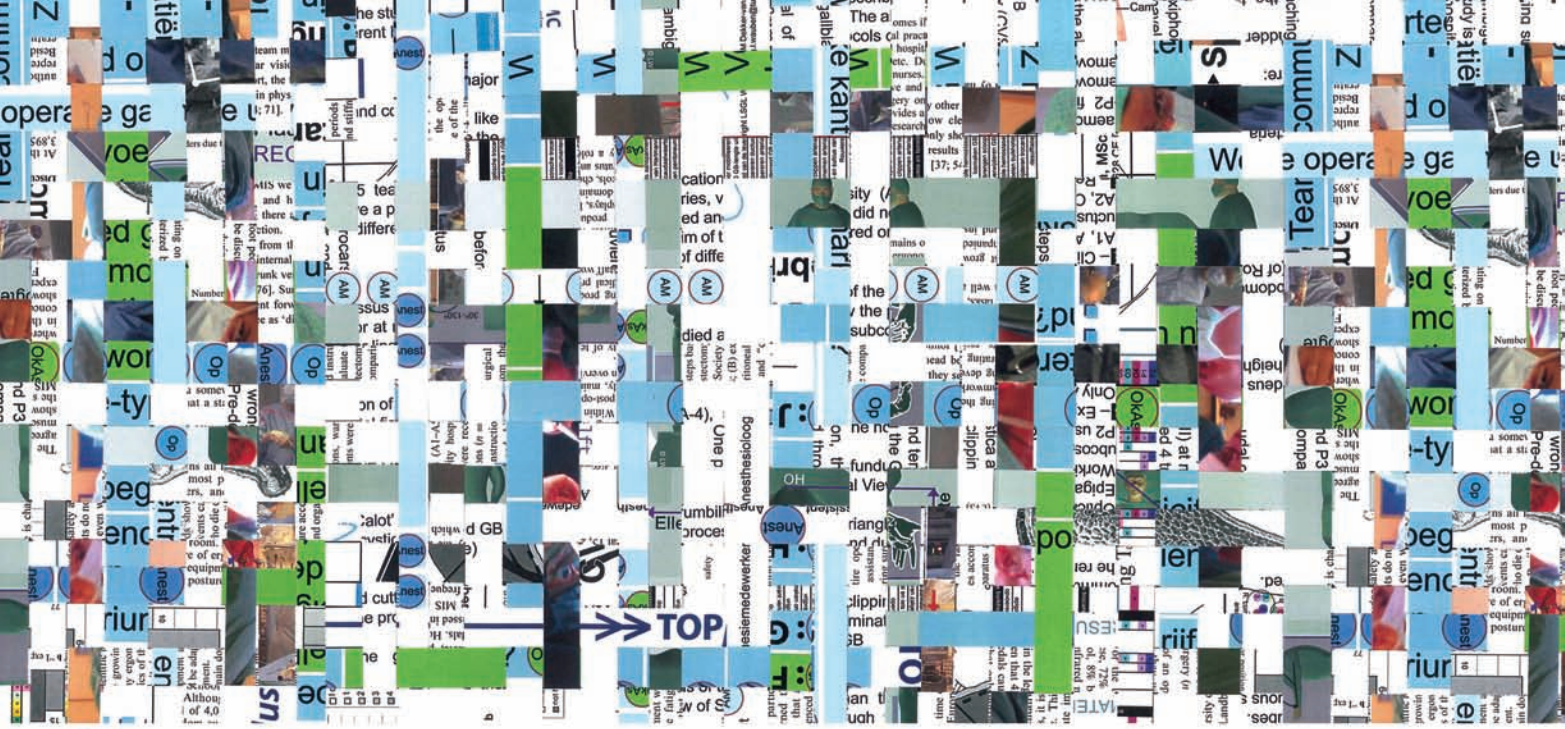

Safety in the Operating Theatre

a Multi Factor Approach for Patients and Teams

Linda SGL Wauben

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a Multi Factor Approach for Patients and Teams

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‘Every day you may make progress.
Every step may be fruitful.
Yet there will stretch out before you
an ever-lengthening, ever-ascending, ever-improving path.
You know you will never get to the end of the journey.
But this, so far from discouraging,
only adds to the joy and glory of the climb.’

Sir Winston Churchill

Table of content

Chapter 1. Introduction

In 2008 approximately 3.7 million people visited a hospital in the Netherlands.[205] In the same year approximately 50% of them underwent surgery, varying from relatively 'simple' outclinic procedures to complex procedures like open-heart surgery.[205] Surgery involves activities between humans, and between specialized medical equipment and humans in a specialized room, the operating theatre (operating room). During surgery several persons are involved and present in the operating theatre (OT), all with their own profession, tasks and responsibilities. Table 1.1 provides an overview of the OT and the persons involved during a surgical procedure.

Surgery can be divided into three phases: pre-operative, intra-operative, and postoperative phase. This thesis focuses on the *intra-operative phase* of surgery.

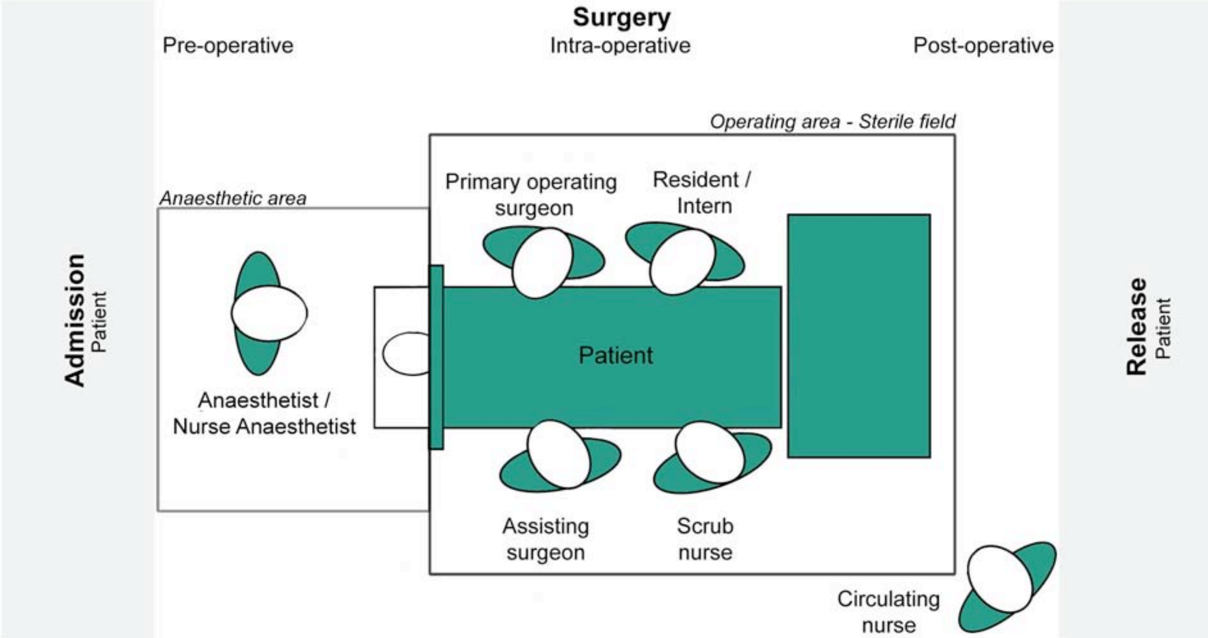
At present there are five types of surgery: 1) Open surgery, 2) Hand assisted (laparoscopic) surgery (a small incision makes it possible for the hand to touch the surgical field - haptic feedback), 3) Small incision surgery (a small incision by which the surgical field can be seen), 4) Minimally Invasive Surgery (MIS; surgery performed through small skin incisions or through the natural openings of the human body, in which the surgical field is projected on a monitor see paragraph 1.1.2), and 5) recently introduced NOTES (Natural Orifice Translumenal Endoscopic Surgery; similar to MIS, but only performed through the natural openings of the human body). As most of the procedures are performed by means of *open surgery* and *minimally invasive surgery,* this thesis focuses on these types of procedures.

1.1. Types of surgery

1.1.1. Conventional open surgery

Most surgical procedures are still performed by means of conventional open surgery (80-85% in the Netherlands). During open surgery a large incision in the patient's body gives direct access to the tissue and organs. The surgeons can feel temperature, inspect the shape, structure and consistency of the tissue and can touch the organs with their gloved hands.[234, 283] Besides this 'natural' haptic feedback, surgeons have direct vision on the operating field and they can move relatively freely.[234] However, occasionally the surgical field is too far away from the edge of the table or is perpendicular to the edge of the table, making the surgeon lean over or lean on the patient to obtain a clear view on the surgical field.[8] Sometimes the instruments or the team members' heads block the surgical field and light in the field. In addition, relatively simple and easy to use instruments are used.[234] A disadvantage of open surgery for the patient is the need for relatively large incisions and therefore cosmetic and functional results for the patient. Also convalescence is longer and often more complicated.

Table 1.1. Persons in the operating theatre



The operating theatre is divided into **three working areas**: 1) The **Sterile field** (within the operating area) is mainly around the operating table (which is mostly placed in the centre of the theatre underneath a clean airflow). The field is sterile from waist up to the surgical team's breast. 2) The **Anaesthetic area** is at the patient's head and is usually separated from the sterile area with a drape. The equipment, such as anaesthetic airway, monitoring, registration, and safety equipment are placed here. 3) The remaining part of OT is **non-sterile**.

The **Patient** is the main person during the surgical procedure, but has no active role. When entering OT, the time out procedure is performed (sometimes with an active patient's role) and then the anaesthetist brings the patient under complete, regional or local anaesthesia. Afterwards, nurses and the assistant place her / him in the correct position, which differs for the various types of surgery. The patient is covered with sterile sheets except for the part that is operated on, which is cleaned thoroughly.

The **Surgeon** (also operator) leads and is responsible for the surgery. Usually the surgeon is specialized in a specific discipline.

The **Assistant (Resident / Intern)** is also a surgeon / resident. A resident is a graduated medical student who attends and assists during surgeries for a period of time (at least five years in the Netherlands), after which s/he becomes a surgeon. The resident learns his profession based on an apprenticeship model, e.g., by watching, assisting, and performing surgeries under the surgeon's supervision[178].
Sometimes an intern is present. S/he is a medical student, without a full license to practice medicine unsupervised.

The **Scrub nurse** hands over instruments to the surgeon within the sterile field. S/he has followed a special education and knows the instruments' functions and usage, and when these are needed. S/he also prepares the patient and OT before surgery.

The **Circulating nurse** is also a surgical nurse and has followed the same education as the scrub nurse or is still following it. The circulating nurse performs all actions in the non-sterile area. S/he hands over the materials and instruments to the scrub nurse.

The **Anaesthetist** is a specialist who is responsible for monitoring the patient and administering anaesthetics, drugs, fluids, and blood. S/he also monitors the heart rate, oxygen level, and temperature. Because the anaesthetist takes care of more patients at one time in some hospitals, s/he is not always present during the whole procedure. In her / his absence, the nurse anaesthetist takes care of the patient.

Procedure specific persons Depending on the procedure, several additional persons are present, such as perfusionist, radiology staff, pathology staff, researchers, and guests.

1.1.2. Minimally invasive surgery (MIS)

Minimally invasive surgery (MIS), also called minimal access, endoscopic or keyhole surgery, is performed trough small incisions in the skin or through the natural openings of the human body. When MIS is performed in the abdomen this is called laparoscopy. The first documented laparoscopic procedure, a laparoscopic cholecystectomy (gallbladder removal), was performed by Erich Mühe in Germany in 1985.[150] This breakthrough changed modern surgery rapidly and definitely and now laparoscopy is a popular technique. Nowadays, approximately 15% of procedures are performed by means of MIS. Laparoscopic cholecystectomy has become the golden standard for the surgical management of gallstone disease and is performed in more than 95% of cases.[56, 145, 157]

MIS has particularly become popular due to the advantages for the patient compared to open surgery, such as less exposure to surgical and cosmetic trauma, less pain after surgery, shorter recovery time, less adhesions and incisional hernia, better cosmetic results and less liability for contamination due to the small incisions.[56, 211, 258] However, MIS also has some disadvantages, such as a greater need for and dependence on technology, poor ergonomics, and higher operating complexity.[4, 52, 116, 157, 211, 218, 234, 258, 281, 286] This is partly caused by the OT layout and the fact that apparatus and equipment have not yet chanced accordingly.

1.2. Errors

Human performance is not without error. At best performance, the risk is As Low As Reasonable Possible (ALARP).[53] As a consequence, errors occur, also in OT.

An error is defined as *'the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim'.*[124, 134] Errors may or may not have consequences. When errors have consequences they are called *adverse events*, and without consequences they are called *near-misses* (close call) or no-harm events.[54] It is estimated that the latter types occur 300 to 400 times more than adverse events. Although initially near misses are not harmful for the patient, a series of accumulated errors can eventually cross a threshold and result in an adverse event.[54, 219]

Each year 76,000 patients suffer from unintended harm due to medical errors in Dutch hospitals.[58] Actually, the number of medical errors will be even higher, as errors are likely to be underreported.[202] It is expected that 30,000 of these errors, including 1735 deaths, could have been prevented.[58] Furthermore, it is estimated that at least half of all medical errors occur in OT, indicating that during the treatment of patients in OT 40,000 errors were made.[32, 54, 71, 134] This implies approximately 2.5% of the 1.6 million surgical procedures performed in OT in 2008.

Beside the health of the patient, the large number of errors that could have been prevented also contributes to a cost increase, due to longer hospitalization and possible re-operations. It is estimated that this results in a debit of 167 million Euros (1.1%) on the collective Dutch hospital budget.[32] In addition, there are costs involved for society, such as loss of wages of the patient and caretakers, additional treatment in an outpatient department and additional medication. Also medical claims due to medical liability lead to cost increase.[71] The increase in advanced high-tech technology in OT, which makes the OT a more technologically complex high-risk environment, and the increased complexity of the surgical procedures contribute to the medical errors rates.[265] Potential causes of errors are shown in

Table 1.2. Of course, errors have to be limited in order to improve patient safety. Therefore, both the (unpredictable) surgical environment and the human-product activities have to be controlled.[53, 265]

Table 1.2. Causes of errors

Provider (surgeon) - Inattention - Stress - Lack of experience or training of staff - Bad performance - Wrong diagnoses - Failed reaction on results of monitoring and testing **Ambient** - Noise (80-85dB instead of 45dB) - Prevailing external circumstances - Equipment failure - Stage of surgery - Complexity of surgery - Inadequate information technology for staff **Physical** - Unsuitable OT ergonomics - Sleep deprivation - Circadian rhythms	**Social** - Failure of communication, decision making and situational awareness skills - Inadequate teamwork - Mental stress (leads to fatigue) **Organization** - Lack of staff - Time pressure - Overwork **Legal / regulatory / cultural / reimbursement** - Poor Leadership - Unclear protocols, briefings and procedures - Non-transparent culture - Lack of quality assurance measures - Lack of evidence-based practice - Inadequate system for detection of poor performance **Technology (apparatus, instruments, material)** - Failure - Incomplete - Non-intuitive - Inadequate training

1.3. Objectives

This thesis main question is: *How to improve patient safety in the operating theatre during surgery?*

In order to improve patient safety, the number of errors has to be reduced. In this respect lessons learned from other comparable industries, such as aviation, can be adapted and implemented in surgery.[134] Chapter 2 provides an overview of solutions to reduce errors in surgery by means of a systems approach. By analogy with other high-risk industries the proposed solutions can be categorised into: transparency and gaining insight in the process leading to errors, culture, standardisation, and training.

A first step to surgical quality improvement is to study the processes concerning 'planning, acting and recording' surgical procedures (Part A). An objective recording system, comparable to the blackbox (flight data recorder) in aviation, could support this process. By getting insight into these processes, finally an objective recording systems could be designed to support record keeping of surgical procedures. For the studies conducted within this part the MIS procedure laparoscopic cholecystectomy (LC) was chosen. The advantage of MIS is that procedures are relatively easy to record as an image is already generated in order to perform the procedure. LC was chosen as this procedure is the most performed minimally invasive procedure and is the method of choice for gallbladder disease.

The key questions / topics of **Part A** are:

- Gain insight in the current method for reporting surgical procedures and how these operative notes are used.
- Study the disadvantages of current operative notes.
- Define initiatives to improve the quality of current operative notes.

A second group of conditions directly influencing patient safety is the improvement of communication and teamwork in OT. Other industries have shown that 75% of errors are caused by non-technical skills rather than technical skills. Therefore procedures supporting the process of communication and teamwork in OT have to be introduced. The key questions of **Part B** are:

- What is the perception of communication and teamwork by the operating theatre team members and what are considered weak points?
- How can the communication and teamwork be improved?

Because errors are often the result of a mismatch between the environment and persons, the environment has to be adapted to the teams working in OT (ergonomics). Improving ergonomics affects the operating team directly. In addition, it improves patient safety indirectly, as the working conditions for the operating team improve, leading to less ‘distractions’ and thus improved (safer) surgical care. Finally, the key questions of **Part C** are:

- What is the current state of application of ergonomics in the operating theatre?
- What are the main points of attention in order to improve ergonomics the operating theatre?

These research questions are all important as today’s OT’s are technologically complex high-risk environments. This application of technology makes it necessary for engineers to be involved in the medical field. However, at the moment technicians are not part of the operating team. Part of the originality of this work lies in bridging the medical and technical fields by incorporating different methodologies that originate from design approaches and include multidisciplinary teams (e.g., technicians and medical professionals). It shows the current status of technology used and why knowledge from different fields is not yet applied in OT.

1.4. Outline

Figure 1.1 presents the outline of this thesis. First, chapter 2 provides the background of the thesis by comparing the safety in OT to other complex high-risk industries by means of the systems approach. This chapter deepens the understanding of the relation between the conditions in surgical care presented in the parts thereafter.

Part A | Blackbox focuses on one of the conditions improving patient safety directly. Chapter 3 describes the uniformity of hospital’s laparoscopic cholecystectomy (LC) protocols. Chapter 4 provides an overview of the different methods for writing operative notes and its use. Then, in chapter 5 the compliance with operative note guidelines is studied. Chapter 6 describes the subjectivity of current conventional operative notes, and chapter 7 compares visual recordings of LC with conventional operative notes.

Part B | TOP*plus* focuses on a second group of conditions improving patient safety directly, namely the implementation of a Time Out Procedure *plus* Debriefing to reduce errors and near misses and to improve communication and teamwork in OT. This part first describes the differences in perception of communication and teamwork in OT between surgeons, anaesthetists and nurses (chapter 8). Then, chapter 9 describes the basic design of the TOP*plus* instrument by applying participatory design principles. Chapter 10 elaborates on adapting the Time Out Procedure and Debriefing to the local context of the hospital.

Part C | Ergonomics in the Operating Theatre focuses on conditions improving patient safety indirectly by improving the working conditions of the operating team. Chapter 11 provides an overview of ergonomics for both open and minimally invasive surgery in OT, followed by Chapter 12 on the application of ergonomic guidelines during minimally invasive surgery. Finally, chapter 13 describes the product evaluation of surgical lights as part of the environmental ergonomics.

Finally, chapter 14 provides the conclusion, general discussion and recommendations.

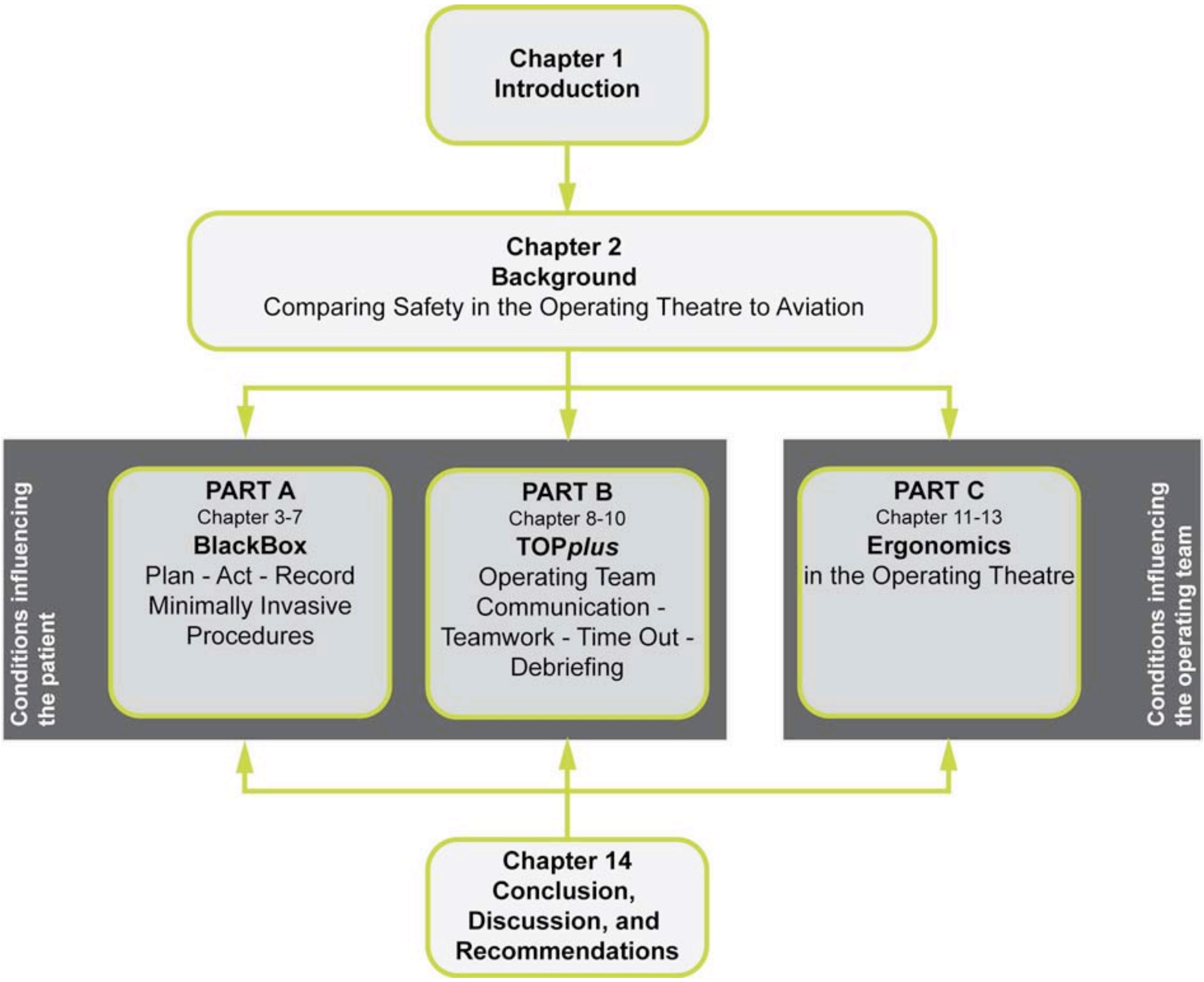


Figure 1.1. Outline thesis

Chapter 2. Safety in the Operating Theatre compared to Aviation

Abstract

Lessons learned from other high-risk industries could contribute to improve patient safety in the operating room (OR). This review describes current methods and solutions, within a systems approach, used in other high-risk fields to reduce errors, and it is evaluated whether these solutions could be expected to be relevant in the OR. PubMed and Scopus databases were systematically searched for relevant articles written in the English language published between 1998 and 2009. In total 19 articles were included in this review, all within the medical domain and mainly focusing on the comparison between surgery and aviation. In order to improve safety in the OR, multiple non-conflicting interventions have to be implemented. To see whether the solutions from other industries are useful, practical, and actually increase safety, further development and research is needed: defining training objectives, needs and means, further development of surgical simulators, optimal applicable reporting and recording systems, and implementation of error proof procedures (checks, briefings and debriefings).

Submitted as: Wauben LSGL, Lange JF, Goossens RHM. Adopting a Systems Approach to Improve Safety in the Operating Room.

2.1. Introduction

With the extensive developments in surgery and related disciplines over the last decennia, the procedures and the surgical environment have become more complex.[172, 192, 226, 249, 254, 266] This surgical complexity is determined by many factors, such as the patients and their condition, the complexity of the procedure, the surgeon's expertise, the equipment design and use, communication, workload, and the urgency and uncertainty of decisions.[146, 175, 177, 192, 242, 249] With this increasing complexity, there is a high incidence of errors being made, which are costly from a human, economic, and social viewpoint.[134, 137, 242] Furthermore, society has become ever more critical on non-transparency with regard to adverse events in healthcare.

Several studies have shown that 30-50% of errors can be prevented.[134, 172, 192] Recent insight in other high-risk industries has shown that besides lacking technical expertise (technical skills), non-technical skills (human factors) also cause errors.[70, 134, 175, 242] The currently dominant persons approach in healthcare focuses on improvement of individual technical skills and decreasing human variability, by means of disciplinary actions, retraining and further education.[242] However, adoption of a systems approach recognizes that humans are fallible and that factors within the system and direct working environment can lead to errors, which are to be expected and evitable.[2, 70, 106, 134, 137, 146, 242, 249, 254] Adopting a systems approach could also improve the process of learning from errors, support identification of possible (unlikely) sources leading to these errors, and reducing the occurrence of preventable patient safety incidents.[2, 16, 134, 242, 254, 266]

Building defenses by altering attitudes and modifying behavioral norms, improving quality of equipment or technology, training of professionals (both technical and non-technical skills training), and implementing protocols and safety reporting systems are some examples expected to reduce errors.[2, 70, 106, 120, 137, 192, 226, 242, 249, 254, 266]

The objective of this study was to review current methods and solutions used in other high-risk fields, within a systems approach, to reduce errors, and evaluate if these solutions could be expected to be relevant in the operating room (OR).

2.2. Methods

2.2.1. Data sources

A literature review was conducted using the PubMed and Scopus databases as primary sources. The search was restricted to articles written in the English language published between January 1998 and November 2009. The search terms used were a combination of a) "system(s) approach" AND b) "surgery" or "surgical procedure" or "operating room" or "operating theatre" or "healthcare" AND c) "aviation" or "oil-" or "nuclear-" or "high-risk-" or "process-" or "petrochemical industry" or "offshore". An additional second search session was carried out including the search terms: "system(s) approach" AND "patient safety" AND "surgery", or "surgical procedure" or "operating room" or "operating theatre".

2.2.2. Inclusion / exclusion criteria

For this review the articles should include at least one of the following subjects: a) elements within the systems approach which influence safety in high-risk industries, b) similarities and differences between surgery and other high-risk industries, and c) solutions adopted from other high-risk industries to improve safety in the OR.

Other inclusion criteria for articles were: 1) subject of interest was the OR and the team members working in this environment, and 2) the article had to be published in a peer-reviewed journal. Furthermore, all types of study designs were included, except editorial letters, books, interviews, and comments.

Studies focusing on medication safety and other healthcare environments (e.g., emergency room, ward, intensive care unit) were excluded from this review.

2.3. Results

The first search session resulted in 20 publications and the second session resulted in eight additional publications. All abstracts were read and nine articles were excluded for the following reasons: not focusing on the OR (n=4), focused on medication safety (n=3), personal vision (n=1), and one full-text article [285] was not available either online or through the Erasmus University Medical Center or Delft University of Technology libraries. In total, 19 articles remained, which were included in this review. These publications included seven reviews and 12 original research articles. All publications were within the medical domain and focused mainly on the comparison between surgery and aviation.

2.3.1. Error

In order to prevent errors first a definition of error has to be established, which also has to be familiarized by medical professionals.[137] The most common definition of an error is defined as follows: *'failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim'.*[134] Two types of error can be distinguished: active and latent errors (Table 2.1).[134]

Table 2.1. Types of error, error contributors and consequences for patients? (Adapted from La Pietra et al. 2005)[54, 134, 137]

Error contributors						
Active error - Human			**Latent error - Structure / process**			
Failure			Technical		Organisational	
Patient	Practitioner	External	External	Facilities	External	Management
Patient factors	Skill- / Rule- / Knowledge-based					Organisational culture Protocols / processes Transfer of knowledge

Consequence for patient?		
Yes	**No**	
Adverse event caused by medical management of the actor [54]	No harm event error is not recognized and the deed is done but the expected adverse event does not occur [54]	Near miss error is realized just in the nick of time and abortive action is instituted to cut short its translation [54]

At the sharp end are active errors, which are inflicted by humans (frontline operator). Latent errors are found in the structure and process. Both types of error could lead to near misses, no harm events or adverse events, the latter having negative consequences for the patient.[54, 134] Besides the classification in Table 2.1 additional systems can be used for the classification of errors; e.g., according to the setting (inpatient, outpatient), the kind of procedure involved (medication, surgery, etc.), or the probability of occurring (high, low).[137]

2.3.2. Similarities and differences between surgery and other high-risk industries

In order to prevent errors much can be learnt from other high-risk industries. For a surgical setting most comparisons were made with aviation. Table 2.2a-c show the similarities and differences between surgery and aviation, which were categorized into four groups.

Table 2.2a. Principles used in aviation: similarities and differences

	Comparable problems / conditions within surgery & aviation	**Differences between surgery & aviation**
1. Culture & environment	Doctors and Pilots: - Common interpersonal problems [2] - Similarities in professional culture [2] - Highly trained professionals [120] - Interdisciplinary teams where the performance of one sub team may be influenced by or influence other teams [2, 106, 172, 192] - Making rapid decisions in uncertain situations [120, 192] - Perform highly skilled actions [2, 120, 192] - Work in a highly complex, technological environment [137, 192, 242] - Enact intentional non-malevolent violations [10] Hospitals and Aviation: - Are profit-motivated organizations ▫ But interventions such as team training with interdisciplinary teams cost time and resources, and education has to be continued [106] ▫ It takes time before economical performance and reduction of lost lives is demonstrated [106, 266]	In Surgery: - Surgeons more often deny the effect of personal stress on their performance (82%) than anesthesiologists or pilots (53%) [2] - Surgeons more often deny the effect of fatigue on critical aspects of performance (70%) than anesthesiologists (47%) or pilots (26%) [2] - Difficult to recognize failure during surgery or postoperative period (error-false-hypothesis or deadly mindset) [120] - Culture of covering up mistakes [2] - Culture of working under substantial pressure [2] - Status within the team is important [2] - No safeguard (e.g., often no co-pilot in surgery) [106] - Actions and decisions often depend on subjective interpretation of the surgeon [120] - Discrepant perceptions of teamwork within the OR team [2] - Heterogeneous group of people [106, 226] - Dynamic composition of teams [106, 226, 249] - Situation is more variable than in commercial aviation [172] ▫ Patients have different pathology and anatomy [146, 172, 282] ▫ Environment is not standardized (but often this is accepted) [146] ▫ Sometimes following a specific action is not possible or dangerous [120] ▫ Some routines are not proven to prevent injury; depends on surgeon's experience, can happen before this routine is performed [120]

<u>Culture & environment (n=13 articles)</u>

Although the cockpit of an airplane and the OR are comparable, they are not similar. Main differences exist in patient's variance and in the existing culture, mainly in acknowledging human error and human fallibility.[2, 10, 106, 120, 137, 146, 172, 192, 226, 242, 249, 266, 282] Furthermore, violations (actions that is contrary to a rule) of safety procedures and norms could increase the risk of error or accident.[10] Currently, there is limited amount of research in high-risk industries on intentional non-malevolent violation (rule is broken on purpose but is not intended to harm the system). This is probably because these types of violation are socially undesirable and underreported or hidden (as they do not always result in a bad outcome). However, reasons for violation are manifold and sometimes these violations are even necessary. Alper and Karsh (2009) described the violation's situation and influencing factors in different industries.[10] Table 2.3 presents an overview of the factors found in healthcare and aviation associated with intentional non-malevolent violations.

Table 2.3. Situations and influencing factors of intentional non-malevolent violations in healthcare and aviation (based on Alper and Karsh 2009 [10])

Individual	
Individual characteristics	+ Previous accident* = Medical class* # Age experience; Total flight hours* - Attitude towards compliance; Habit to comply; Perceived behavioural intention to comply
Work system / Unit factors	
Competing goals	+ Time pressure; To save time; Conflicting demands - Perceived risk # Workload; Work pressure
Design to support worker needs	+ Design makes necessary
Organisational factors	
Information / education / training	- Worker level of knowledge
Problems with rules	+ Difficult to comply
Safety climate	+ Expectation by doctor; Poor management - Subjective norm to comply
External environment n/a	

+ Positive association (as factor increases, violations increase)
- Negative association (as factor increases, violations decrease)
= Non-significant association (no evidence found of an association between factor and violations)
Conflicting results (evidence about association between factor and violations not consistent)
* Aviation

<u>Reporting errors (n=5)</u>

Errors are inevitable and usually derive from an imperfect system, not from carelessness of the actor. A first step in order to prevent future errors and adverse events, which endangers the patient's safety, is to understand the full cause of errors. Aviation adopted a pro-active method for standardizing reporting errors and learning from these errors.[70] In surgery, safety reporting systems are only recently implemented and used.[16, 70, 254] The learning and training effect is limited up till now.[16, 70, 254]

<u>Standardization (n=1)</u>

Besides standardization used for error reporting and training, results of this review showed that in aviation, within a systems approach, standardization was mainly found in using procedural checklists.[266]

Table 2.2b. Principles used in aviation: similarities and difference

	Comparable problems / conditions within surgery & aviation	Differences between surgery & aviation
2. Reporting errors	In Surgery and Aviation: - Systems for collecting, codifying, aggregating and analyzing safety information without fear of blame and shame and provision of anonymity: [70] ▫ Aviation Safety Reporting Program [70] ▫ Veterans Affair's Patient Safety Reporting System [70]	In Surgery: - Healthcare organizations are not a learning organization, they lack capacity for gathering the right data, processing this into usable information, and transforming this information into knowledge, to improve safety [16, 70] - Underreporting of incidents (caused by fear of blame, time pressure, resource constraints, perception that reporting is unnecessary, lack of clear definition) [16, 254] - Non-standardized error reporting (not usable for benchmarking) [254] - Error reporting systems are recent In Aviation: - Important safety information derived from the analyses by safety analyst is communicated to other airlines and private pilots and used for training [70, 242] - High priority for safety [242] - Research and management strategies to recognize and recover form errors [242] - Error reporting provides data for training [106]
3.Standardization		In Aviation: - Use of checklist is standard practice (normal, non-normal, and emergency checklist) [266] - Specification for checklist design are provided (layout, letter fonts, physical construction format) [266]

<u>Team skills and training (n=6)</u>

A similarity between surgery and aviation is that 70-75% or errors are caused by human error, i.e. by lacking non-technical skills.[2, 175] Differences are that aviation started raising awareness for human error and started multidisciplinary team training (Crew Resource Management: CRM) 25 year ago.[2, 175, 192, 226] These training modules are certified, standardized, and use simulation to train staff.[282]

Current medical training is still random, mainly focused on technical proficiency, directed at the individual student or resident, is often performed on the actual patient, and skills have to be acquired by watching colleagues.[177] Non-technical skills are not taught in the medical curriculum yet, but have to be acquired over time.[2, 175, 177]

In contrast to aviation, in surgery it is still believed that individual surgeons cause surgical complications due to for instance errors in judgment, technique, and inattention to detail, instead of these errors being (partly) caused by the system.[87]

Table 2.2c. Principles used in aviation: similarities and difference

	Comparable problems / conditions within surgery & aviation	Differences between surgery & aviation
4. Team skills and training	In Surgery and Aviation: - 70% of errors in aviation are caused by human errors (lacking non-technical skills) [2, 175] - 75% of preventable errors in anesthesia and surgical trainees are caused by human error (e.g., lack of vigilance and failure to check, impaired decision making, absence of situation awareness, and failure in interpersonal communication) [2, 175]	In Aviation: - Teaching non-technical skills by means of Crew Resource Management (CRM; multidisciplinary team training) as part of education / training for 25 years [2, 175, 192, 226] - 20 years of using simulation for technical and non-technical skills training [192] - Training modules in aviation: ▫ Are defined by regulatory authorities (Federal Aviation Administration) [282] ▫ Means are certified [282] ▫ Extensive research led to many training tools; e.g., simulator training (basic and high tech training) [282] ▫ Includes non-technical skills training (CRM) consisting of seminars, lectures, and simulation training to understand limitation of human performance and develop a culture of safety [2] In Surgery: - Training is: [177] ▫ Random ▫ Focused mainly on technical proficiency (e.g., operation time, motion analysis) ▫ Often performed on the actual patient ▫ Skills have to be acquired by watching colleagues

2.3.3. *Solutions to prevent errors in surgery*

The Institute of Medicine (IOM) report described that "Much can be learned from the analysis of errors" [134], which is in accordance with the view of clinicians who are willing and able to learn critical appraisal of care.[192] The first steps are adopting a systems approach and moving towards an open and non-punitive environment where human limitations are recognized and questioned. Furthermore, patient safety has to be the priority for the organization by providing resources.[242] Solutions from a systems approach perspective can be categorized into four groups (see Tables 2.4a-c).

<u>Transparency and Gaining insight in the process leading to errors (n=9 articles)</u>

In order to determine errors responsible for adverse events, near misses, and no harm events, a classification system is needed.[16, 87] Patient safety reporting systems should use combinations of methods, such as performance monitoring, HFMEA, or RCA to gain information of underlining contributors to errors.[137, 146, 192, 242, 254] These reporting systems have to provide fast and effective feedback, consisting of corrective actions and addressing specific vulnerabilities in the care system, to raise awareness of safety issues.[16, 70] Starting a dialogue with the staff working in the OR that uses local systems is important, as they must support the implementation of risk management systems. This is not done on a structural basis yet.[16] Adopting a proactive approach by sharing, training and learning from operational experience could lead to error prevention.[16, 70, 87, 242, 254] Figure 2.1 provides an overview of the feedback loop for safety incidents in a healthcare setting. Intentional malevolent violations have to be studied as well, as they are an indication that rules do not meet the standards of the workers.[10] More understanding for these kinds of violation is needed so working environments can be designed that eliminate or reduce violations, or make sure that these violations happen safely.[10] Finally, technology, such as video and audio recording in the OR, improves the possibilities of objective assessment of skills.[120]

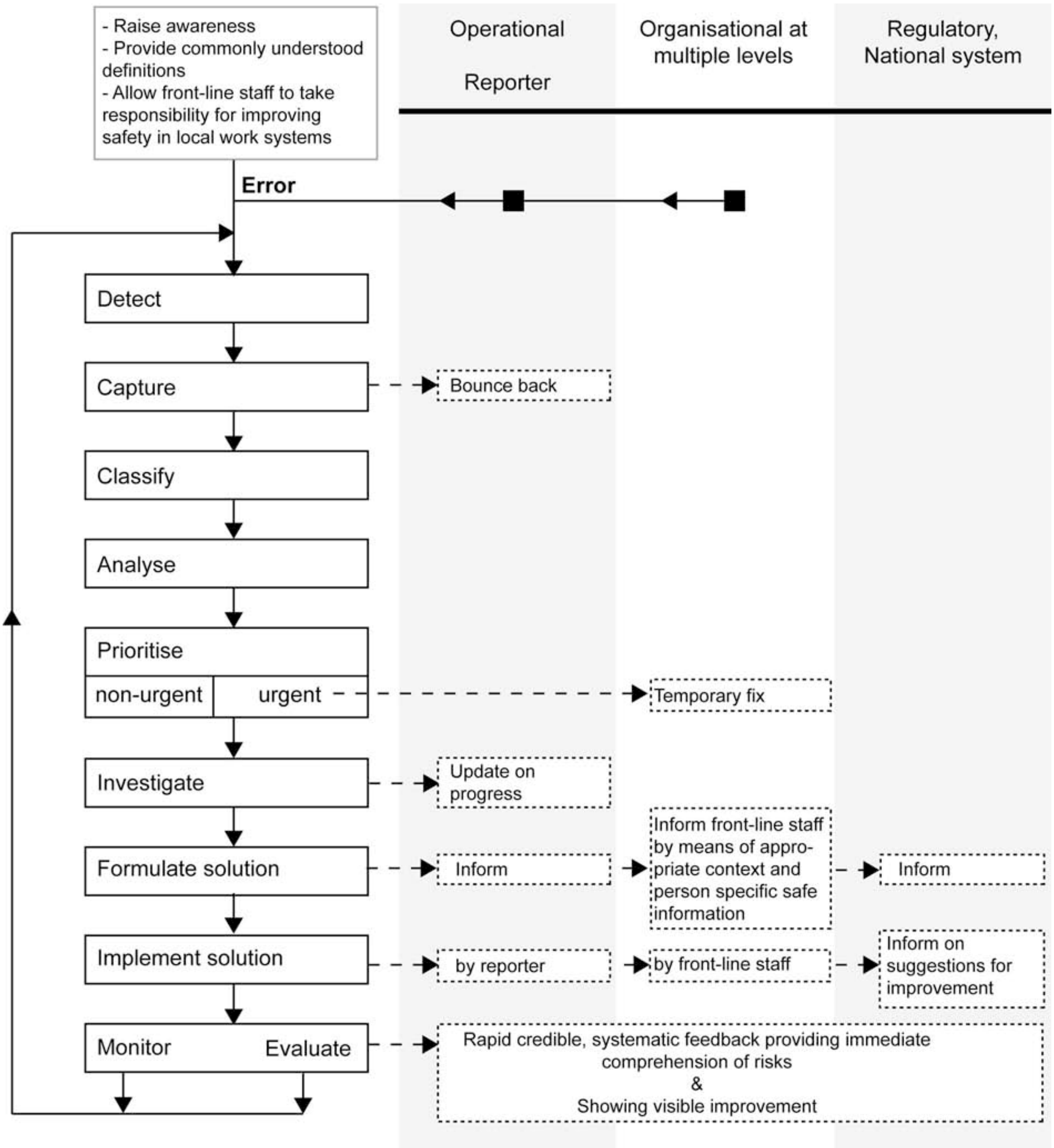


Figure 2.1. Feedback loop for safety errors in healthcare (Adapted from Benn et al 2009 [16])

Table 2.4a. Solutions to improve safety in surgery

Principles	Solutions
1. Transparency and Gaining insight in the process leading to errors	- (Electronic) classification system for reporting medical error(s) during operations to determine errors responsible for surgical complications (e.g., added to the weekly complication reporting system [87]) [16, 137] - Patient Safety Reporting System: focuses on performance improvement and safety, and should lead to corrective remedial measures and increased awareness of current operational risks [16, 70] Conditions are: ▫ Provide feedback information and recommendations based on the outcomes to all parties involved [16, 70] Some examples of how this can be done are: meetings, bulletins, campaigns, newsletters, safety walk rounds, staffing adjustment or supervision, improving policies, education, manuals, etc [16, 87] ▫ Share, train and learn from operational experience, leading to a proactive approach of error prevention [16, 87, 242] ▫ Provide action feedback [16] ▫ Not to be used for punitive purposes [16, 70] - Collecting and summarizing data followed by analyzing and planning remedy of problem, using combinations of: [87, 137, 146, 192] ▫ Retrospective chart review ▫ Performance monitoring ▫ Anonymous non-punitive incident and near misses reporting ▫ Event audits ▫ Analysis of complaints and litigation ▫ (H)FMEA ((Healthcare) Failure Mode and Effect Analysis): indentifying and assessing potential process failures before they occur-proactive risk management [137] ▫ RCA (Root Cause Analysis): examining underlining contributors to an adverse event or condition [137, 242] - LOTICS (Leiden Operating Theatre and Intensive Care Safety): identify system failures in the OR in order to serve for benchmarking, monitoring effectiveness of changes, and monitoring changes in patient safety [254] - Video recordings for debriefing purposes to allow recognition of near misses or free lessons [120]
2. Culture	- Train basic Human Factors principles [120] ▫ No avoidance and denial of the fallibility of human performance [2] ▫ Admitting errors are made [16, 137] ▫ No blame and shame for the actor of error [16, 242] - Encourage reporting errors [242] - Do not operate in an environment or use equipment that the user cannot totally control [146]

Culture (n=5)

In order for the proposed interventions to work, the culture has to change. This can be done by training and education of health professionals on the basis of human factors principles.[2, 16, 120, 137, 242] Furthermore reporting errors has to be encouraged and staff should not operate in an environment or use equipment that they cannot totally control.[146, 242]

Standardization (n=10)

Besides standardization of definitions and the interventions described above, a standardized defense strategy to prevent human errors has to be implemented.[16, 137] This defense system has to provide a memory aid to enhance task performance, facilitate team coordination, and support quality control.[16, 242] Additionally, checklists can be created to maintain a safety culture in the OR.[266] Different checklist designs can be used for systematically checking important patient and procedural factors, involving all team members, and checking e.g., the presence of equipment ('call-do-response' or 'do-verify' method).[120, 146, 266]

Furthermore, valid and reliable assessment systems are needed to assess the influence of both technical and non-technical skills on clinical outcomes.[172, 226] Currently, several assessment systems are used in surgery (e.g., OCHRA, NOTECHS, ANTS, OTAS).[172, 192, 226, 249]

Table 2.4b. Solutions to improve safety in surgery

Principles	Solutions
3. Standardization	- Standard terminology and classifications for e.g., error / adverse event (better support to obtain valid and reliable data, better support to assess the impact of a specific organizational intervention) [16, 137] - Standard reporting systems in terms of feedback mechanisms and degree of which organizations provide feedback to reporters and broad communities as a whole [16, 242] - Checklists to reduce reliance on memory (paper / electronic / computer based): normal, non-normal and emergency for: [242, 266] ▫ Key points in the operation, cross-checking with the whole team (e.g., CVS) [120, 146, 266] ▫ Pre-operative briefings (improving safety attitude and double-checking important patient and procedure related items) [266] ▫ Anesthesia equipment [192, 266] ▫ Laparoscopic instruments [192, 266] - Valid and reliable assessment systems on clinically relevant outcomes: [172, 226] ▫ Assessment of postoperative complications ▫ Cancellations of cases ▫ Delays in lists ▫ Returns to OR ▫ Recalls of surgeons / anesthesiologists to recovery ▫ Clinical incidents - Valid and reliable assessment systems for measuring both technical and non-technical skills on clinically relevant outcomes: [172, 226] - Technical performance: ▫ Observation Clinical Human Reliability Assessment (OCHRA) [172] ▫ Retrospective chart review [192] ▫ Imperial College Surgical Assessment Device (ICSAD); structured observation of skills and motion analyses [249] - Non-technical performance: [172, 192, 226, 249] ▫ Surgical Non Technical performance (NOTECHS) ▫ Anesthetists Non-Technical Skills assessments (ANTS) ▫ Situation Awareness Rating Technique (SART) ▫ Situation Awareness Global Assessment Technique (SAGAT) ▫ Observational Teamwork Assessment for Surgery (OTAS) ▫ Judgment Analysis

Training (n=10)

Training is needed to bridge the gap between senior and junior residents and surgeons.[192] Besides training individual technical skills (e.g., navigation principles, dexterity, hand-eye coordination), non-technical skills and focusing on cognitive competence and behavior, have to be trained as well.[2, 106, 120, 146, 172, 175, 177, 226, 242, 249] Training non-technical skills is important as performing surgery is "75% decision making and only 25% dexterity"[2]. Non-technical skills training is expected to improve operational performance and also provide "*the foundation for policy, procedures, and practices that cross division within the healthcare setting to allow communication, accountability and the creation and maintenance of interdisciplinary* *teams”.*[106] Team training depends on mentoring, culture, personality, and exposure to positive role models. However, team training has shown limited construct validity, also in aviation / anesthesia.[175, 177] Furthermore, acceptance of non-technical skills training in healthcare might be slow, as this was also the case for CRM training in aviation, where acceptance was slow but steady.

Technical and non-technical skills can be trained by means of simulation. This has some advantages, such as: inflicting no harm to the patient,[2, 175, 177, 282] teaching trainees the skills to control crisis situations (e.g., bleeding),[2, 177, 282] understanding the nature of mistakes and learn from them,[2] teaching consequences of unsafe or inappropriate actions,[2, 177] providing objective feedback on technical and non-technical performance during “real lifelike” procedures,[2, 175, 177] and identifying trainees competences, or that trainees need further training to meet professional standards.[2, 177]

Table 2.4c. Solutions to improve safety in surgery

Principles	Solutions
4. Training **a) Technical skills training**	- <u>Individual technical skills</u> [2, 146, 177, 192, 249] - <u>Navigation principles</u> to prevent spatial disorientation in laparoscopy (leading to misidentification of anatomy and not recognizing injury postoperatively) [120] ▫ For laparoscopic cholecystectomy: start from a fixed point, know where you are at all times, ‘the clearing bearing (e.g., CVS)’ [120] - <u>Simulation of both common and rare crises scenarios</u> ▫ Common scenarios require basic training of mainly skill- and rule based behavior [282] Crises scenarios require advanced training of all behaviors, including knowledge based behavior [282]
b) Non-technical skills training	- <u>CRM / Team training / Cognitive competence training</u> Training aspects: [2, 106, 146, 172, 175, 226, 242, 249] ▫ Situation awareness and vigilance (by controlling external distractions, anticipation of future events, appropriate use of all members of the team) [172] ▫ Leadership and management ▫ Teamwork and cooperation ▫ Problem solving and decision making ▫ Communication processes - Attitudes: ▫ Assertiveness / inviting input / horizontal authority [120, 242] ▫ Recognizing effect of self fatigue, time pressure and personal worries [120] ▫ Cross-checks [120] ▫ Implement a curriculum designed by task analysis, e.g., the Advanced Qualification Program (AQP) that uses the resources human, hardware and information [106]
c) METHOD for training technical AND non-technical skills → Simulation	- <u>Interdisciplinary simulations</u> in an operational environment, such as the simulated OR [2, 175] Training of: [106] ▫ Common and rare crises scenarios [2, 177] ▫ Individual technical skills [2, 175, 177] ▫ Team skills [2, 175, 177]

2.4. Discussion

This overview showed that improving patient safety in surgery has gained increased awareness over last five years. However, much has to be done in surgery to reach the same safety levels as other high-risk industries. Besides the solutions described above, healthcare organizations have to stress the importance of shared or organizational learning from process failure, in order to become a learning organization.[16, 70, 181] A learning organization is *"one that is successful at acquiring, cultivating, and applying knowledge that can be used to help it continually adapt to change"* [70]. [249]

In order to improve safety, multiple non-conflicting interventions have to be implemented and committed front-line staff members are needed.[16, 137, 266] However, these interventions and actions need to be proportional to their impact on outcome and the cost of preventing them in the short term but also in the long term, as it takes time before economical performance and reduction of lost lives is demonstrated.[106, 137, 266] Preferably, the design and implementation of solutions should involve the end user.[266]

The solutions described in Table 2.4 need further development, such as: 1) defining training objectives, needs and means for surgical training,[282] 2) further development of high fidelity surgical simulators comparable to those used in anesthesia for knowledge based trainings (which requires gaining knowledge of the behavior of soft tissue organs and getting insight in other important properties),[175, 181, 282] 3) optimal applicable reporting systems, including multiple modes of feedback i.e. information and action feedback,[16] and 4) recording systems in the OR to get insight in the causes of errors (for research purposes these systems already exist: clinical data recorder).[2, 175, 181]

This literature review focused on interventions and solutions adopted from other high-risk industries within a systems approach. Although "systems approach" is a familiar term in the healthcare research domain, the authors found that this term has limited adoption in surgical literature itself as relatively few articles were found. Although "systems approach" has been used for many years, and was reported in the IOM report "To Err is Human", the results of this review showed that most articles including this term were published in the last five years. This probably explains why only one article studying the use of checklists was found [266] in contrast to the many checklists used in the OR today to e.g., support briefings and debriefings, checking the presence and functioning of equipment and instruments, and improve team interaction.[35, 64, 111, 120, 146, 264, 266, 289]

Team interaction and safety can be also be improved by using collaborative cross-checks.[67, 181, 197] Cross-checks (or double-checks) are performed by at least two people who first collect and evaluate the available facts independently, assess and then discuss and decide on further steps.[67, 181, 197] Diamond and Mole (2005) reported that cross-checking reduces perceptual errors and led to no biliary injury during laparoscopic cholecystectomy.[67]

Further research is needed to prove the effectiveness of safety reporting systems, training, and checklists to see whether these systems from other industries are useful and practical, and actually increase safety in the OR.[16, 70, 175, 177, 226, 242, 266]

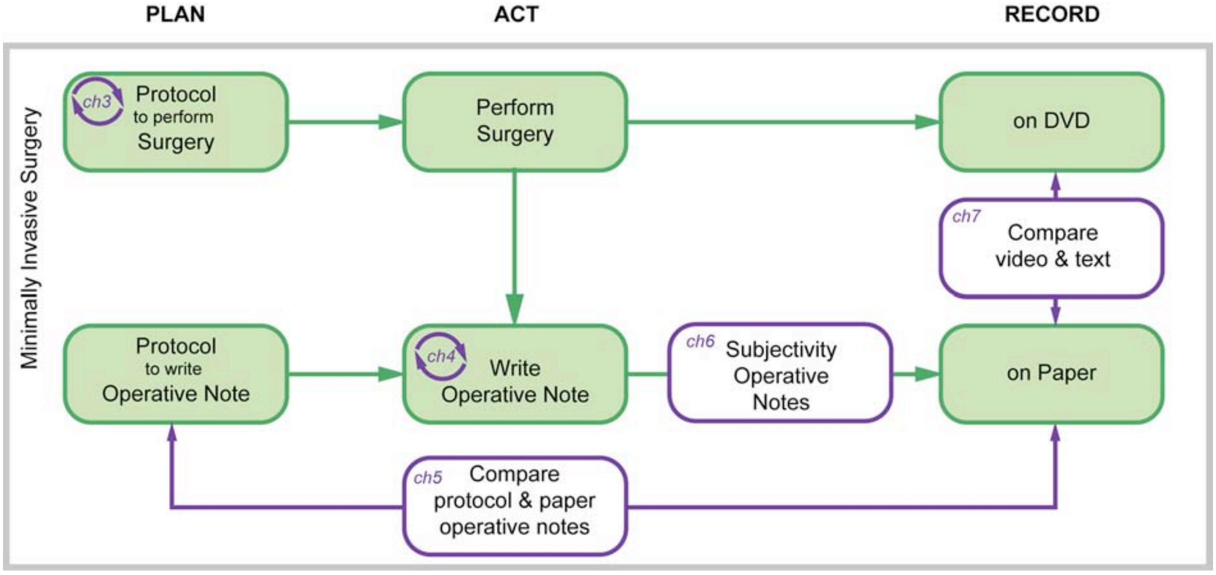
Finally, in order to improve patient safety the gap between research findings, guideline development and their implementation in the OR has to be bridged.[192]

2.5. Conclusion

High-risk industries, particularly aviation, have a protracted affair of improving safety. In order to improve safety in the OR, multiple non-conflicting interventions adopted from other high-risk industries have to be implemented focusing on e.g., 1) transparency and gaining insight in the process leading to errors, 2) the OR culture, 3) standardization, 4) training of technical and non-technical skills. To see whether these solutions are useful, practical, and actually increase safety, further development and research is needed: defining training objectives, needs and means, further development of high fidelity surgical simulators, optimal applicable reporting and recording systems, and implementation of error proof procedures (checks, briefings and debriefings).

PART A

BlackBox | Plan, Act and Record Minimally Invasive Procedures



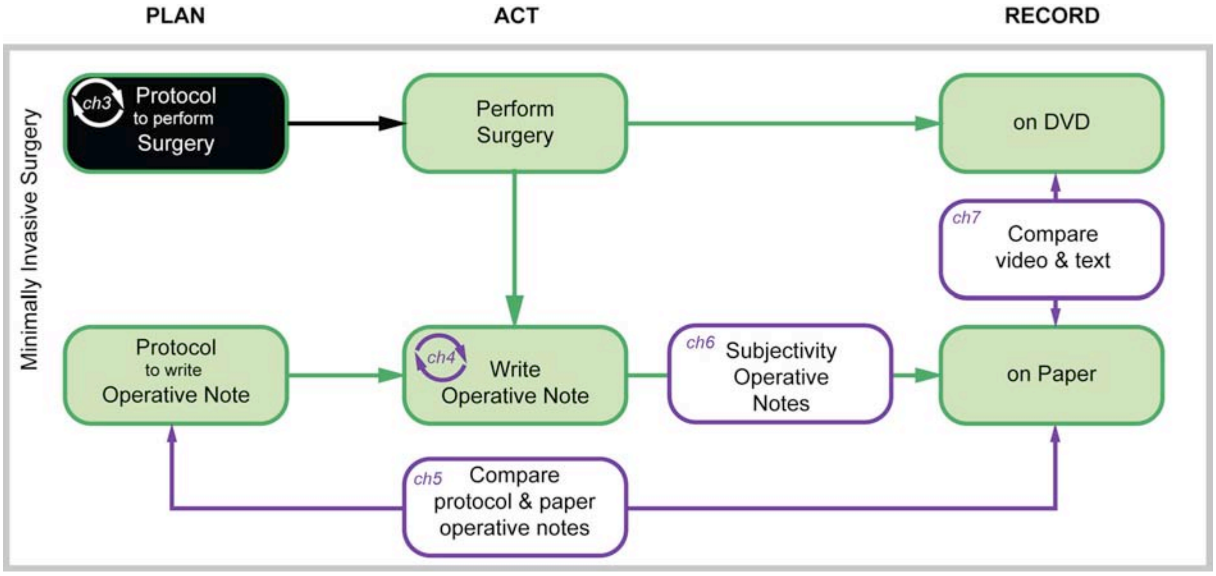
Introduction

The previous chapter showed that one of the factors to improve patient safety is to learn from errors and near misses. A precondition for this learning is recording the performed actions objectively.

Both open and minimally invasive surgical procedures are described in protocols (plan). During surgery these protocols are applied (act). At present, after the surgical procedure all actions are described by means of paper operative notes (record). This method has some disadvantages; it is a subjective testimony written from the memory of the surgeon, and the timeframe between surgery and the actual writing is often unsure.

One of the most performed minimally invasive procedures is the laparoscopic cholecystectomy (LC). This part focuses on this procedure, starting with studying the uniformity of hospital's LC protocols in chapter 3. Chapter 4 elaborates on the different methods for writing operative notes, its use and relevance. Then, chapter 5 compares the paper operative notes to national guidelines for writing operative notes, followed by chapter 6 which described the subjectivity of current conventional written operative notes. Finally, chapter 7 compares the video recordings of LC with the conventional operative notes.

Chapter 3. Protocol Uniformity



Abstract

Background: Iatrogenic bile duct injury remains a current complication of laparoscopic cholecystectomy. One uniform and standardized protocol, based on the ‘‘critical view of safety’’ concept of Strasberg, should reduce the incidence of this complication. Furthermore, owing to the rapid development of minimally invasive surgery, technicians are becoming more frequently involved. To improve communication between the operating team and technicians, standardized actions should also be defined. The aim of this study was to compare existing protocols for laparoscopic cholecystectomy from various Dutch hospitals.

Methods: Fifteen Dutch hospitals were contacted for evaluation of their protocols for laparoscopic cholecystectomy. All evaluated protocols were divided into six steps and were compared accordingly.

Results: In total, 13 hospitals responded - 5 academic hospitals, 5 teaching hospitals, 3 community hospitals - of which 10 protocols were usable for comparison. Concerning the trocar positions, only minor differences were found. The concept of ‘‘critical view of safety’’ was represented in just one protocol. Furthermore, the order of clipping and cutting the cystic artery and duct differed. Descriptions of instruments and apparatus were also inconsistent.

Conclusions: Present protocols differ too much to define a universal procedure among surgeons in the Netherlands. The authors propose one (inter)national standardized protocol, including standardized actions. This uniform standardized protocol has to be officially released and recommended by national scientific associations (e.g., the Dutch Society of Surgery) or international societies (e.g., European Association for Endoscopic Surgery and Society of American Gastrointestinal and Endoscopic Surgeons). The aim is to improve patient safety and professional communication, which are necessary for new developments.

Published as: Wauben LSGL, Goossens RHM, van Eijk DJ, Lange JF. (2008). Evaluation of Protocol Uniformity concerning Laparoscopic Cholecystectomy in the Netherlands. *World Journal of Surgery* 32:613-620.

3.1. Introduction

Laparoscopic cholecystectomy is the most performed and acknowledged minimally invasive operation in the Netherlands (15,000 laparoscopic cholecystectomy procedures in 2005).[60, 100, 126, 222] Still, a regular complication of this procedure remains iatrogenic biliary tract injury.[47, 100, 120, 235] The most common cause of serious injuries is misidentification of the anatomy in general and misidentification of the cystic duct in particular.[36, 100, 120, 136, 235, 236, 278] Consensus exists that complete dissection of Calot's triangle reduces the incidence of bile duct injury.[36, 120, 202, 236, 278] This is especially achieved by the technique of "critical view of safety" of Strasberg in which Calot's triangle is completely unfolded by mobilizing the gallbladder neck from the gallbladder bed of the liver before transecting the cystic artery and duct (Figure 3.1).

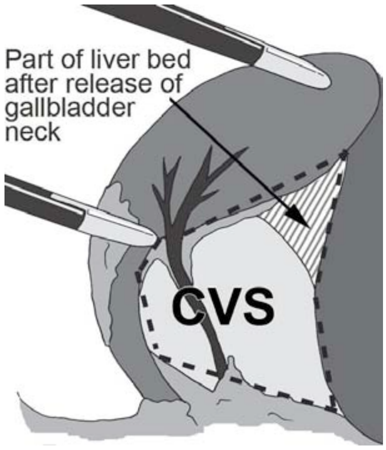


Figure 3.1. Critical view of safety (CVS) for laparoscopic cholecystectomy

Consequently, the availability of a uniform, standardized protocol such as those used in other technical high-risk fields (e.g., aviation, nuclear industry, oil industry) would be advantageous for patient safety.[134] A protocol is a formal set of guidelines usually consisting of actions to be performed, leading to a specific end result. An example are the protocols used in aviation (checklists) in which cross-checking the crucial steps is deployed to guarantee safety.[63]

Successful surgery and enhancing the safety of health care also depends on effective teamwork. Because of the growing complexity and continuing developments in surgical operations, the entire operating team (surgeons, nurses, anesthesiologists, assistants, residents) should be more actively involved during surgery.[113, 251] A uniform standardized protocol could contribute to the shared understanding of their roles, tasks, and objectives throughout the surgical process as well as enhancing surgical education and training.

Furthermore, owing to the fast growth of minimally invasive surgical techniques accompanied by the increased use of more complex apparatus and instruments, technicians are no longer a supplier of equipment but represent an important source of information.[4, 43, 265] Because technical principles from industry play a substantial role in improving medical treatment, a major point of interest is the implementation and integration of technical quality systems in health care.

The Dutch Society of Surgery demands that each surgical department of a Dutch training hospital has a protocol for operative procedures. The use of the protocol is obligatory and is globally checked by means of site visits by the Dutch Society of Surgery every 1-5 years. Although no specific requirements are provided by the Society, in this study a protocol is defined as the steps to perform a successful operation (operation method), whether to include the necessary apparatus and instruments.

The aim of this study was to evaluate the existing protocols for laparoscopic cholecystectomy from various hospitals in the Netherlands by comparing the described steps (actions).

3.2. Materials and Methods

3.2.1. Participants

In January 2006, a total of 15 surgical departments of Dutch hospitals were selected from the (2006) Dutch database of Wauben et al., with a special focus on laparoscopic surgery.[276] In total, 6 (of 8) academic hospitals, 6 (of 53) teaching hospitals, and 3 (of 33) community hospitals were contacted. By means of a letter, the contacted surgeons were requested to send the most recent protocol for laparoscopic cholecystectomy; or in case no protocol was available, participants were requested to inform the authors of its absence.

3.2.2. Technical information

The protocols were divided into six steps based on the ‘‘Best Practice for Laparoscopic Cholecystectomy 2006,’’ which was drawn up by order of the Dutch Society of Surgery. The steps are (A) introduction of trocars; (B) exploration of the abdomen; (C) opening of the peritoneal envelope; (D) mobilization of the infundibulum and ‘‘critical view of safety’’; (E) clipping and cutting the cystic artery and duct; and (F) performing retrograde cholecystectomy and terminating the procedure. The protocols for laparoscopic cholecystectomy of the various hospitals were compared in which the chronologic action order was maintained. Initially, instructions, warnings, remarks, and the use of specific instruments were not included in the comparison.

3.3. Results

A total of 13 hospitals responded to the request: 5 academic hospitals (A1-A5), 5 teaching hospitals (T1-T5), and 3 community hospitals (C1-C3) (Table 3.1). Various documents were received: best practice, protocols (n = 4), instructions (n = 3) and operative reports (n = 2). In this study, ‘‘instruction’’ meant a document in which the gallbladder and biliary tract were described including deviations, surgical abnormalities, and surgical procedures, including laparoscopic cholecystectomy. The term ‘‘operative report’’ included a document used to compile the report after the procedure has been performed. The pre-described text section was then interpreted as the protocol. This article refers to all received documents as ‘‘protocol.’’

Table 3.1. Response and properties of the protocols for laparoscopic cholecystectomy

Protocol	Hospital	Type	Author mentioned	Edition / update	Reference	Lay-out
A1	Academic	Best practice	Yes	December 2005	Yes	Text in paragraphs
A2		Protocol	Yes	November 12, 2003	–	Step by step
A3		Instruction	–	–	–	Step by step
A4		Instruction	–	–	–	Step by step
A5		Instruction different procedure	n/a	n/a	n/a	n/a
T1	Teaching	Protocol	–	–	–	One text
T2		Operative report	–	–	–	One text
T3		Instruction	–	April 2003	–	Step by step
T4		Protocol	–	December 2005	–	Step by step
T5		No protocol	n/a	n/a	n/a	n/a
C1	Community	Operative report	–	–	–	One text
C2		Protocol	Yes	June 3, 2003	–	Step by step
C3		No protocol	n/a	n/a	n/a	n/a

n/a: not available

Three responses could not be used because hospitals T5 and C3 did not have a protocol and hospital A5 sent a protocol concerning a different procedure (Table 3.1). From the 10 remaining protocols, only A1 (''Best Practice'') included references, and only three protocols stated the author. Furthermore, two protocols were of a recent date (< 1 year old), and three were between 2.5 and 3.0 years old. Finally, the layout of the protocols differed: A1 described the actions in a single text subdivided into paragraphs; T1-2 and C1 described the actions in a single text; and the remaining protocols described the actions step by step. The results below are discussed according to the six steps.

Figure 3.2 shows the trocar positions (*step A*). The position of the *optical trocar* for C2 and A2 differed. They were placed above the umbilicus and in the umbilicus, respectively. T1 described the use of the Hasson trocar but did not describe a specific location. Except for A4 (no position indication), the positions of the *epigastric trocars* did not differ. Deviant position C2 was described by means of a graph. Three groups could be distinguished for the position of the *working trocars*. First, subcostally at the level of the axillary line (A3, T3, C1) and right at umbilical level (T4 and C2). Second, subcostally right (A2, T2, T4) and finally at the midclavicular line (A2-3, T2-3, C1). Protocols A1, A4 and T1 did not describe a specific position for the working trocars. C2 used, as opposed to all other protocols, only one working trocar, indicating a total of three instead of four trocars.

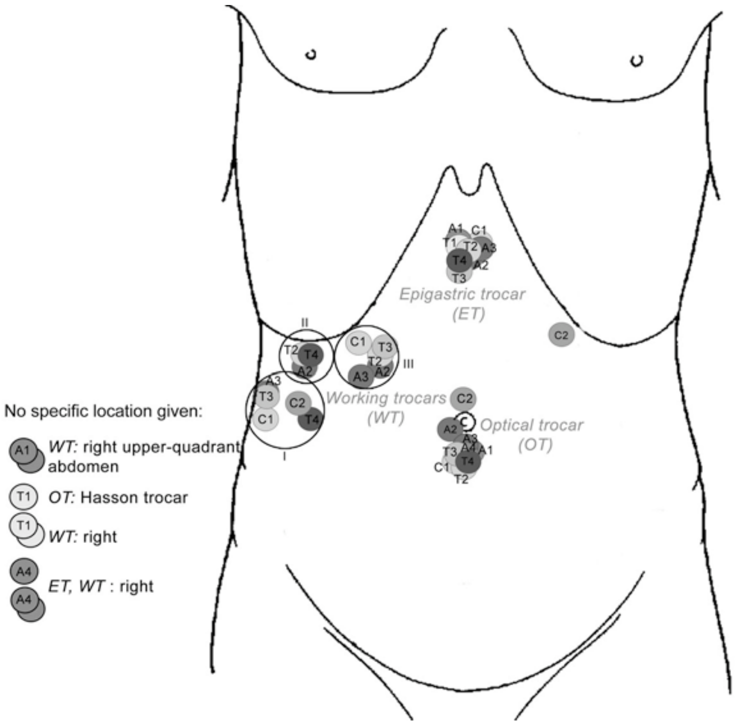


Figure 3.2. Trocar positions

Table 3.2 gives a brief overview of the steps in the protocols. In *step B* (exploration of the abdomen) only protocols A1, A2, and T1 explicitly described the inspection of the abdomen and gallbladder. Protocol A1 also described the identification of Rouvière's sulcus.

Table 3.2. Steps from the protocols for laparoscopic cholecystectomy

Steps	**A 1**	**A 2**	**A 3**	**A 4**	**T 1**	**T 2**	**T 3**	**T 4**	**C 1**	**C 2**	**Identical steps** (no.)
(A) Introduction of trocars											
1. Optical trocar	x	x	x	x		x	x	x	x	x	9
2. Inspect abdomen / GB			x	x		x		x	x		5
3. Incisions for trocars								x			1
4. Epigastric trocar	x	x		x	x	x	x	x			7
5. Working trocar (first)	x	x	x	x	x	x	x	x	x	x	10
6. Working trocar (second)			x	x			x				3
7. Epigastric trocar			x						x	x	3
8. Introduce instruments									x		1
(B) Exploration of abdomen											
9. Inspect abdomen / GB	x	x			x						3
10. Identify Rouvière's sulcus	x										1
(C) Opening the peritoneal envelope											
11. Grab fundus / top GB	x	x		x	x	x	x	x	x	x	9
12. Adjust / position GB			x	x		x					3
13. Apply traction cranially	x	x					x				3
14. Grab infundibulum	x				x						2
15. Tighten caudoventrally	x										1
16. Identify Hartmann's pouch		x					x				2
17. Apply traction laterally and somewhat caudally		x									1
18. Open peritoneum	x				x		x	x			4

Table 3.2. Steps from the protocols for laparoscopic cholecystectomy (continued)

Steps	**A 1**	**A 2**	**A 3**	**A 4**	**T 1**	**T 2**	**T 3**	**T 4**	**C 1**	**C 2**	**Identical steps** (no.)
19. Open peritoneum right side / in ligamentum hepatoduodenale, dissect tissue around arteria and ductus	x			x	x			x			4
(D) Mobilize the infundibulum and CVS											
20. Dissect ΔCalot		x	x		x		x		x		5
21. Establish CVS by mobilizing infundibulum GB approx. one-third GB length from GB bed of the liver	x										1
22. Dissect ductus	x	x	x	x		x	x		x	x	8
23. Dissect arteria	x	x	x	x	x				x	x	7
24. Dissect bottom edge GB and dissect ΔCalot				x	x						2
25. Exclude abberant right ductus hepaticus		x									1
(E) Clip and cut cystic artery and duct											
26. Clip arteria	x		x					x			3
27. Cut arteria	x		x					x			3
28. Check CVS and Rouvière's sulcus	x										1
29. Dissect ductus								x			1
30. Dissect ΔCalot								x			1
31. Clip ductus	x	x	x	x	x	x	x	x	x	x	10
32. Cut ductus	x	x	x	x	x	x	x	x	x	x	10
33. Dissect arteria							x				1
34. Clip arteria		x				x	x		x	x	5
35. Cut arteria		x				x			x	x	4
(F) Retrograde cholecystectomy and terminating the procedure											
36. Pull GB bed by means of tightened GB and last check GB bed	x										1
37. Dissect GB	x	x	x	x	x	x	x	x	x	x	10
38. Park GB on liver						x					1
39. Check hemostasis		x		x	x		x	x		x	6
40. Detach GB					x		x				2
41. Relocate scope	x				x	x			x		4
42. Remove GB	x	x	x	x	x	x	x	x	x	x	10
43. Check hemostasis			x						x		2
44. Lavage abdomen				x							1
45. Remove trocars				x	x	x	x				4
46. Start desufflation						x	x		x	x	4
47. Remove trocar(s)						x				x	2

GB: gallbladder; arteria: cystic artery; ductus: ductus cysticus; ΔCalot: Calot's triangle;
CVS: critical view of safety

In *step C* (opening the peritoneal envelope), grabbing the fundus (top) of the gallbladder is described by all protocols, except A3. However, protocols A4, T4, and C2 did not give an exact description of the actions (''adjust by positioning gallbladder,'' ''retract gallbladder,'' and ''grab gallbladder,'' respectively). Opening the peritoneum was described by protocols A1, A4, T1, and T3-4.

In *step D* (mobilizing the infundibulum and ''critical view of safety''), protocol A1 used the term ''critical view of safety'' of Strasberg.[235, 236] Seven protocols used the term Calot's triangle (A2-4, T1, T3-4, C1) but did not describe complete dissection of Calot's triangle; the other protocols did not mention these terms. The identification and dissection of the duct and artery was described by most protocols (duct: A1-4, T2-3, C1-2; artery: A1-4, T1, C1-2).

The main difference in *step E* (clipping and cutting the cystic artery and duct) was the order for clipping these structures. Protocols A1, A3, and T4 clipped and cut the cystic artery first and then the cystic duct. A2, T2-3, and C1-2 described clipping and cutting the cystic duct first. Protocols A4 and T1 did not emphatically described clipping and cutting the cystic artery. The level of detail for clipping the duct also differed. Protocol A3 only described clipping the duct, protocol T2 included the number of clips, and five protocols also described the location of these clips (A1-2, T1, C1-2). Furthermore, the location description showed a difference in terminology used: "2x central," "2x distal, 1x toward gallbladder," "2x choledochus side, 1x gallbladder side," "2x central, 1x peripheral," and "2x proximal, 1x distal." The level of detail also differed for clipping the artery. A1-3 only described clipping the artery; protocols T2 and T4 included the number of clips; and three protocols also described the location of these clips (T3, C1-2). Again, different terminology was used for the location description: "2x arteria hepatica side, 1x gallbladder side," "2x central, 1x peripheral," and "2x proximal, 1x distal."

Finally, in *step F* (retrograde cholecystectomy and terminating procedure) all protocols described dissecting the gallbladder. Here, different terminology was also used; A1, A3-4, T2, T4, and C2 described dissecting the gallbladder from the liver bed. T1 and C1 described subserous dissection of the gallbladder from the liver bed, and A2 noted antegrade removal and T3 retrograde removal of the gall- bladder. Before disconnecting the gallbladder, seven protocols (A1-2, A4, T1, T3-4, C2) described checking the gallbladder bed and hemostasis. A3 and C1 described the check after disconnecting the gallbladder. All protocols described the removal of the gallbladder. A3, T2, and T4 described removal under vision; and protocols A1-2, T1-4, and C1 indicated removal via the umbilical trocar opening. Protocols A4 and T1-3 only described removal of the trocars under vision, whereas T2 and T3 also described the desufflation. Conversely, C2 described the desufflation first and removal of the trocars next. T2 removed three trocars first, desufflated via the last remaining 10mm trocar, and removed this trocar afterward. None of the protocols described a checkup for bleeding at the trocar sites after their removal.

3.4. Discussion

Many differences exist in the studied Dutch surgical protocols for laparoscopic cholecystectomy. Currently, no standard for the surgical protocol is available in the Netherlands. Two hospitals, T5 and C3, did not even have a protocol, although it is compulsory for teaching hospital T5.

The protocols differ too much to be transferable, which if tried would lead to a lack of clarity. One of the differences concerns the definition of a protocol. Several documents are known and used as a protocol, which explains receiving both operative reports as well as instructions in this study. Although the influence of the lack of a uniform standardized protocol for laparoscopic cholecystectomy has not been determined scientifically, in the sense of a greater incidence of poor outcome, this lack of standardization in general and its influence has been proven in high-risk industries. Already in health care, several associations use protocols and guidelines for clinical decision making, for facilitating relevant training of the operating team, and as support for maintaining professional standards in daily practice.[134, 293, 294, 296] One of the merits of standardizing the operative process in general and individual protocols in particular is improved communication among members of the operating team and between physicians and technicians by avoiding confusion with regard to the procedure's technical details (tasks and direction). Furthermore, ''man-machine'' interaction (communication between members of the operating team and the instruments and apparatus) can also be improved by using these protocols. Standardization also forms the basis for further use of the information and communication technology necessary for digitizing patient data, such as the use of the electronic medical record and the digital operative report. In addition, one standardized protocol, in combination with increasing surgical experience, can lead to a lower conversion rate during laparoscopic cholecystectomy.[99]

This study gives a good representation of the current status of protocols used in academic hospitals (four of eight academic hospitals responded). These protocols mostly described the actions step by step. One advantage of a protocol is the detailed definition of actions, step by step, serving as a checklist comparable to those used in aviation. Also, without checking each action, the protocol diminishes the possibility of skipping important actions such as control of port-site bleeding after trocar removal.[63, 120, 134]

The content of the protocols also differed. Although not emphasized in this study, it was noted that most protocols described the required instruments and equipment (A1, A3-4, T1-4, C2). By including equipment in the standardized protocol, a thorough preoperative setup can be established, thereby reducing the total operating time (no waiting for missing equipment).[265] Warnings, instructions, and additional explanations during critical stages in the operation, such as instructions for adequate dissection of Calot's triangle, ''critical view of safety,'' and instruction to prevent gallbladder perforations (resulting in bile leakage and stone spillage, possibly leading to complications) were not included in all protocols (A3, T2, C1-2).[100, 126, 235, 236] Including these items contributes to the completeness of the standardized protocol.

With regard to unambiguous language, it was concluded that different terminology was used and that the steps differed in their level of detail. This is mainly the case for clipping and cutting both the cystic duct and artery and the introduction of trocars, for which the location and introduction angles are of importance to prevent injury to organs and to create optimal working conditions.[25, 40, 89] However, scant literature is available that emphasizes the problems associated with poorly placed trocars.[89] Adequate trocar placement should provide direct access to target organs, optimal vision, decreased mental fatigue, and cognition of pathology and anatomy.[89] The position and size of the trocars varies among institutions and surgeons. For most standard techniques, the optical trocar is placed in the peri-umbilical region and the epigastric trocar in the epigastric region. These positions correspond to the results found. However, different locations for the working trocars can be found in the literature. In 2004, Ferzli and Fingerhut described placing these trocars in the right upper quadrant with one trocar parallel to the common bile duct, whereas Websurg (accessed April 2007) describes placing the working trocars left laterally to the umbilicus and in the right iliac fossa.[89, 297] Protocol C2 used the positions indicated by Websurg, and all other protocols used the standard four-trocar technique indicated by Ferzli et al.[89]

The use of intraoperative cholangiography (IOC) to prevent common bile duct injury during laparoscopic cholecystectomy and routine versus selective IOC are still matters of debate.[11, 120, 136, 169, 187, 236, 292] Injuries can occur despite the use of IOC, so it is not a precondition for safe performance.[236, 278, 290] Although our study did not focus on this aspect of laparoscopic cholecystectomy, it should be stated that none of the protocols described routine IOC. However, five protocols mentioned and described the use of selective IOC (A2-4, T3, C2). Both selective and routine IOC requires special expertise; and as yet surgeons in the Netherlands are not being trained for this technique.

Until now, the effect of introducing and using protocols regarding the safety of the procedure and the related bile duct injury is difficult to determine: first because of the absence of an implementation date (only five of ten protocols mentioned the edition date) and second because complication rates are not yet openly available in the Netherlands. With the introduction of a uniform protocol, the relation between the use of such a protocol and complication rates (e.g., bile duct injury) could be studied systematically.

International societies such as the European Association of Endoscopic Surgery (EAES) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) also provide guidelines for laparoscopic cholecystectomy.[136, 185] Both societies' guidelines describe dissection in Calot's triangle using the ''critical view'' technique: The cystic duct and cystic artery must be identified clearly prior to clipping and cutting.

Although this study focused on the actions from trocar introduction to removal, preoperative and postoperative management (including establishing the pneumoperitoneum) should also be included in the future standardized protocol.

The authors propose that a uniform standardized protocol based on the ''critical view of safety'' principle (including complete dissection of Calot's triangle) be used that communicates through unambiguous steps and language. Standardization is no longer a matter to be left to personal preference. Implementation of a uniform standardized protocol can best be accomplished by the endorsement of an acknowledged association, such as a national scientific association or international society (e.g., the EAES and SAGES). Each time these associations distribute guidelines, a standardized protocol (including actions described step by step) should be added that can be used directly and without interpretation in the operating theatre. A future standardized protocol should also include patient data and indicate which data are to be recorded at what time.[43] Such an organized protocol can improve postoperative reporting and make it less time-consuming.

After having studied Dutch surgical protocols for laparoscopic cholecystectomy in this study and the protocols used in other fields of industry (e.g., aviation), the first version of a new protocol was drawn up by the Taskforce for Endoscopic Surgery of the Dutch Society of Surgery (Figure 3.3).[75] Since November 2006, this protocol is the certified and officially collated protocol for laparoscopic cholecystectomy in the Netherlands. It recommends image recording (analogue or digital) of the ''critical view of safety'' prior to cutting the duct and artery.[202] Image recordings are of interest for postoperative reporting and for understanding and treating possible complications. Furthermore, the recordings can contribute to the education of the operating team members. Finally, the Dutch Health Care Inspectorate recently announced that it would adopt this advice for their quality standard for laparoscopic cholecystectomy.

Step 1 Preparation of the operation (not included)

Step 2 Trocar positions
Optical trocar
Access: caudally to the umbilicus. In case of obesity with a caudally situated umbilicus: optical trocar access cranially to the umbilicus.

Epigastric trocar
Two fingers caudally to the xyphoid process, at the right to the teres and falciform ligaments.

Two working trocars
At the level of the right upper quadrant of the abdomen.

Step 3 Abdominal exploration
Examine the condition of the gallbladder (adhesions, acute and/or chronic inflammation) and the liver (steatosis, cirrosis). Identification of Rouvière's sulcus is helpful.

Step 4 Opening of peritoneal envelope
Retraction of gallbladder
To open the peritoneal envelope the gallbladder must be adequately retracted. Pull the gallbladder's fundus cranially over the liver. After placing a clamp on the infundibulum (neck, Hartmann's pouch), retract caudo-ventrally.

Location for opening of peritoneal envelope
Both on the left and right side of the gallbladder the peritoneum directly on the neck of the gallbladder must be opened. Then the gallbladder's peritoneum is stripped off carefully.

Step 5 Mobilisation of the neck and Critical View of Safety (CVS)
Mobilise the neck of the gallbladder up to approximately 1/3 of the gallbladder length from the gallbladder-bed of the liver. The supposed cystic duct and cystic artery are cleared circumferentially. Only after these two steps, in which two 'windows' are established ('two window technique') CVS is established. Not before this maneuver the cystic duct and the cystic artery are to be clipped.

Imaging and CVS
It is recommended to record CVS prior to transection of the cystic artery and cystic duct.

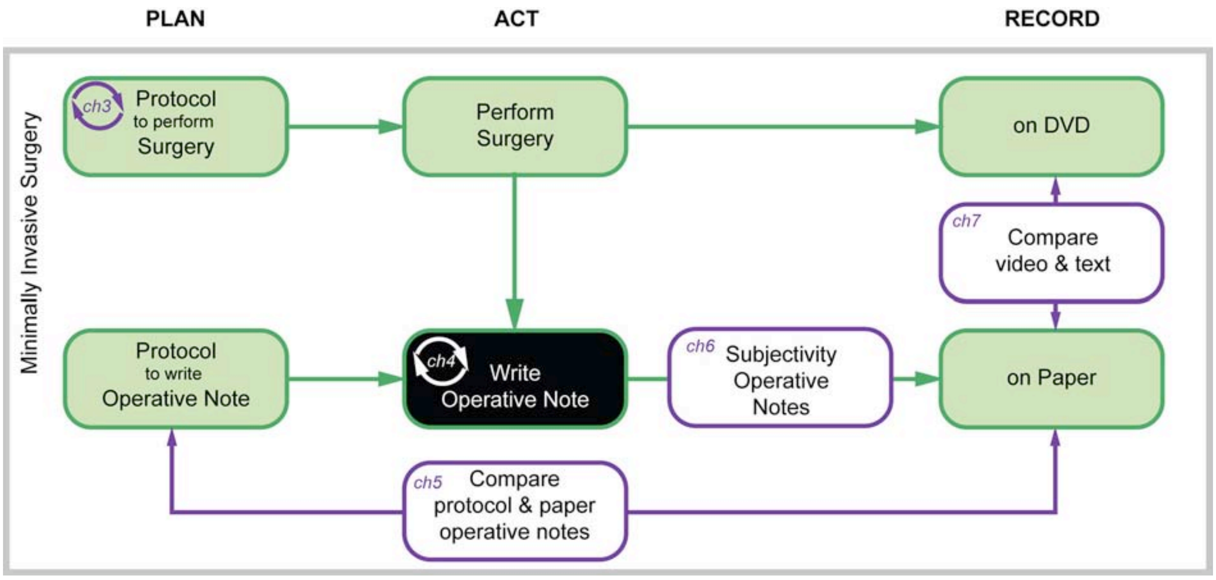
Step 6 Cutting of cystic artery and duct
Cystic artery
The cystic artery (diameter<1mm) is preferably clipped and cut prior to clipping and cutting of the cystic duct. This measure also simplifies the view on Calot's triangle (increase of Calot's triangle up to 20%) If the cystic duct is clipped and cut prior to clipping and cutting of the cystic artery, the artery can get torn by traction on the gallbladder.

Cystic duct
The cystic duct is clipped (two central clips) and cut after double check of CVS and Rouvière's sulcus. With regard to the central stump a large rim (≥1mm), peripherally to the clips, should be respected to limit the possibility of sliding off the clips.

Step 7 Retrograde cholecystectomy and termination of procedure
Prior to disconnecting the gallbladder a final check of haemostasis with regard to the gallbladder-bed must be made. Preferably remove the gallbladder, after replacing the laparoscope to the subxyphoidal port, through the optical trocar port site. The fascia of the two port sites with a diameter ≥10 mm must be closed to prevent hernias.

Figure 3.3. Summary of the steps of the Dutch protocol: ''Best Practice: The Technique of Laparoscopic Cholecystectomy (CVS)" by the Taskforce for Endoscopic Surgery of the Dutch Society of Surgery (English translation)

Chapter 4. Operative Notes - Methods, Use and Relevance



Abstract

Background: Operative notes form an essential element in safe patient care and follow up. This literature review provides an inventory of current methods for writing operative notes, and reviews their use and relevance.

Data sources: A literature review was carried out using PubMed and Scopus databases. The search was restricted to articles written in the English language published between January 1998 and October 2009. The search terms used were a combination of: ‘operative’, ‘operation’, ‘surgical’ and ‘note’, ‘report’, ‘record’, ‘dictation’. In total, 45 reports (32 via search and 13 via references) were selected and included in this review.

Conclusions: Although most operative notes are still being dictated, a trend towards templates and database-based notes is seen. Occasionally images and / or video are added. Although notes are used for e.g., research, education / training, medicolegal, and billing purposes, they are unsuitable to serve all functions. Solutions to improve operative notes are: 1) introducing formal training, constant feedback and critical appraisal, 2) introducing black-box based principles using photo, video and audio recording.

Submitted as: Wauben LSGL, Goossens RHM, Lange JF. Operative Notes: a Review of its Methods, Use and Relevance.

4.1. Introduction

Effective communication is indispensable for all disciplines within a hospital setting, as ineffective communication impairs the quality of patient care, endangers risk management, and has a negative effect on the care process.[45, 195, 215] Operative notes form part of this communication and are standard practice for all surgical disciplines. Their content includes recording specific anatomical and pathological findings, operative techniques, and complications. Operative notes form an essential element in safe patient care and follow up, but they are also useful for research, education, medicolegal, and billing purposes.[27, 39, 45, 143, 158, 167, 180, 194]

In order to assure surgical quality, operative notes should be clear, timely written, include complete data, and use consistent terminology.[15, 51, 68, 78, 138, 164, 195, 206, 214] However, in contrast with the extensive developments in surgery and related disciplines over the last centuries, the operative note has remained much the same: it was initiated as a handwritten registration and today it is often still a subjective, non-standardized or regulated testimony, dictated to a transcription service or secretary.[27, 49, 109, 138, 158] Although surgical associations and organizations dictate explicit standards concerning the timeframe and content of the operative notes, these are not always upheld causing incompleteness and inaccuracy.[76, 238, 241] The timeframe between surgery and dictation is unclear and the quality of the resulting operative notes is variable and poor.[14, 27, 45, 49, 51, 80, 94, 138, 143, 194, 195, 214]

The aim of this literature review was to provide an inventory of current methods for writing operative notes, and review their use and relevance.

4.2. Methods

4.2.1. Data sources

A literature review was carried out using PubMed and Scopus databases as primary sources. The search was restricted to articles written in the English language published between January 1998 and October 2009. The search terms used were a combination of the following words: *'operative'*, or *'operation'*, or *'surgical'* and *'note'*, or *'report'*, or *'record'*, or '*dictation'* (e.g., 'operative note').

4.2.2. Inclusion / exclusion criteria

For this review the articles should include at least the following subjects: a) studies focussing on surgical disciplines (e.g., general surgery, gynaecology, cardiosurgery), b) studies focussing on methods for generating operative notes, c) studies focussing on the use of operative notes, and d) the article had to be published in a peer-reviewed journal. Furthermore, all types of study designs were included, except editorial letters, books, interviews, and comments.

Studies focussing on the entire medical record, admission notes, discharge notes or notes used by other disciplines (e.g., radiology, gastroenterology) were excluded from this review.

4.2.3. Data extraction

Each full-text article was retrieved and reviewed. Additionally, apparently relevant articles identified in the reference lists were hand-searched and retrieved as well. Relevant articles were categorized based on the different methods for writing operative notes: narrative based, (electronic) template based, database management system based, and image / video based. In addition, they were classified based on their use: research, education / training, medicolegal, and billing.

4.3. Results

4.3.1. Selection of articles

In total, 45 reports (32 via search and 13 via references) were selected and included in this review. The reports included 44 original research articles [3, 12, 14, 15, 27, 39, 45, 48, 49, 51, 55, 68, 78, 80, 82, 88, 94, 109, 112, 118, 119, 125, 127, 130, 138, 143, 152, 158, 164, 167, 188, 189, 194, 195, 198, 202, 206, 212, 214, 215, 221, 231, 274] and one review.[66]

4.3.2. Methods for writing operative notes

<u>Narrative operative notes (n=22)</u> [3, 12, 14, 15, 49, 51, 68, 78, 82, 94, 109, 138, 143, 164, 180, 188, 189, 195, 198, 214, 215, 231]

Most operative notes are still narrative reports, often being dictated or handwritten.[27, 180] Advantages of this method are its familiarity, ease of use, flexibility, and customizability.[49] Disadvantages of dictated operative notes are amongst others: inadequate and underreporting of information on the surgery performed, on the indications for surgery, and postoperative instructions.[14, 68, 78, 82, 94, 109, 143, 180, 189, 214] Furthermore, handwritten (narrative) notes are often illegible.[14, 15, 51, 68, 143, 164, 180] Finally, the educational value of narrative operative notes for assessment of the quality of surgery and the improvement of surgical techniques is limited.[78, 82, 94, 109, 214]

Dictated notes have to be transcribed, verified and corrected for errors by the surgeon. This method is subjective, time-consuming, costly, and sometimes data are accidentally excluded during transcription.[49, 138, 198] Studies have shown that 55% of operative notes were not dictated within 24 hours of the procedure, and 67% of the late dictations (dictated by residents) led to incomplete operative notes.[94, 189, 214]

<u>(Electronic) template based operative notes (n=17)</u> [3, 12, 15, 49, 51, 66, 68, 78, 109, 125, 138, 152, 188, 195, 198, 215, 231]

Recently, other methods for creating operative notes, such as (web-based) structured (electronic) note templates, have been introduced. Several studies have shown that the use of these templates improved record keeping (e.g., efficiency, comprehensiveness, completeness, accuracy, effectiveness), uniformity, ease of use, administration time and costs, and physicians' satisfaction.[3, 15, 49, 51, 66, 68, 78, 138, 152, 188, 194, 198, 215, 231] These templates allow the surgeon to write the operative notes themselves, often using choice lists in the form of dropdown menus or typing.[125, 152] Unpredictable events can be noted in an additional text box.[78, 152] The completeness is guaranteed by not allowing completion until all items answered, thus serving as an aide-memoir.[78, 138, 152]

Parikh et al.[195] showed that a dictation template increased documentation of intra-operative measures by 31%. Harvey et al.[109] showed similar results: operative and peri-operative details were reported more often when using a standardized dictation template (95-100% versus 14-100% for non-standardized notes). The notes included more actions, as routines were also recorded, and reminders were integrated to prevent forgetting important steps.

Cowan et al.[49] showed that errors of omission and documentation of incorrect information were reduced by 75% when using electronic templates compared to the use of oral dictation templates. Finally, the compliance with national standards for operative note documentation was increased.[12, 51, 109, 138]

Template based operative notes also improved their availability, as the notes can be reviewed, approved, and added to the patient's electronic medical record immediately, enabling caretakers in any hospital locations to access the information more quickly.[49, 51, 66, 78, 138, 152]

Potential disadvantages of electronic templates are the requirements for efficient information and technology infrastructure (investment), additional staff training, staff resistance to new technologies (disruption of current practice patterns), and initially a longer completion time than when dictating.[3, 49, 109, 138, 152]

<u>Database management system based operative notes (n=2)</u> [55, 274]

Operative notes can also be written using computer databases.[55, 164] This method proved to have similar advantages to the template (when compared to narrative notes)[55, 143] Additional advantages are that data can be used more easily for (evaluative) research purposes, clinical audits, and operation logs for trainees.[55, 143]

A challenge for operative databases is the compliance with data entry. Warsi et al.[274] described a lack of this compliance, resulting in a total omission rate of 22% for three (cancer) surgery databases. The type of data recording influenced the omission rate. Other disadvantages of operative databases are similar to those for electronic template-based operative notes.[49, 143, 164, 274]

<u>Image and video based operative notes (n=8)</u> [88, 112, 118, 119, 130, 202, 206, 212]

Some surgical disciplines are adding pre-, intra-, and postoperative digital images to their (template based) operative notes.[119, 202] Plaisier et al.[202] showed that imaging techniques were complementary to the notes when recording the 'critical view of safety' during laparoscopic cholecystectomy. Other studies have shown that images provide: 1) extra information concerning anatomical and pathological changes and surgical outcome, 2) give better insights into potential problems, 3) enable earlier detection of complications, and 4) ease the planning and discussion with respect to follow-up surgery or treatment with the patient.[112, 119, 158, 212] Furthermore, this additional information is particularly useful in the patient's postoperative care by clinical staff.[112, 212]

Another method for recording surgical procedures for operative note purposes is by using video- and audio recordings.[130, 158, 206] An example for generating such operative notes was proposed by Rafiq et al.[206] i.e. the Surgical Care Information Management System. This software system captures audio and video during the procedure and it uses a predetermined pick list to generate the operative note postoperatively.

Potential concerns with respect to video- and audio recordings are: acceptance of the implementation of (information) technology, liability, initial investment, editing time, file storage, training of staff, and an adequate infrastructure.[88, 119, 212]

4.3.3. *Use of operative notes*

Operative notes are often used for other purposes than patient follow-up, postoperative management, and quality assurance. The following section describes the range of applications of operative notes.

Research

At the moment, conventional operative notes cannot yet be used as an adequate instrument for data collection for clinical research studies or audits.[221] Operative notes lack sufficient and reliable data on a number of aspects of surgical procedures, e.g., occurrence of complications, actual performance of a procedure, and medication prescribed.[221] However, reminder systems, the use of operative databases, template-based forms, and / or video recordings, better support obtaining a full range of data.[51, 164, 194, 206, 221]

Education / Training

Besides feedback and critical appraisal to staff, operative notes are considered to be an important instrument for learning and training processes for both junior and senior physicians.[127, 152, 194] In order for physicians to review their personal results objectively, the notes have to be complete and accurate.[78, 152] Video recordings of surgical procedures can contribute to teaching technical techniques and skills.[118, 130, 158, 206]

Little literature is available about teaching the core-skill of writing operative notes.[27, 80, 167] Several studies have shown that although 91-95% of trainees and trainers find the teaching of operative note writing important, only 8-31% of physicians have received formal education on how to write operative notes (e.g., lectures, seminars, courses, or as part of curriculum). Others received training by means of instruction from senior trainees or by reading notes written by colleagues.[27, 80, 167] Currently, only 10-18% of institutions offer operative note writing as part of their residency program.[167] Nevertheless, 60% of program directors were in favour of addressing education in operative note writing.[167]

Medicolegal

As operative notes often form a critical piece of evidence in medicolegal cases, an adequate representation of the procedures performed is necessary.[15, 39, 49, 68, 143, 164, 194] However, Lefter el al.[143] showed that 45% of the operative notes proved to be non-defensible in a potential complaint in court, as important information was missing. In these cases additional expert opinions are required, introducing an element of doubt.[143] However, Bateman et al.[15] and Din et al.[68] showed that the use of an aide-memoir improved the quality of the operative notes.

Billing

Reimbursement for services provided depends on operative notes and quality indicators (e.g., 75-90% of surgeon's revenue in U.S.A.).[45, 94, 195] Studies have shown that incomplete and inaccurate operative notes led to reduced or delayed reimbursement, loss of revenue, and even to healthcare fraud.[94, 189]

As more hospitals are using pay-for-performance formats, the operative note as billing documentation has become more important.[195] Flynn and Allen[94] concluded that although the information needed for billing purposes is fairly simple and straightforward, the use of operative notes as a billing document should be reassessed. Surgeons must provide the information necessary to expedite reimbursement (preferably within 24 hours after surgery), and residents must be better taught and instructed for this purpose.[94, 189] However, the use of electronic operative note templates facilitated billing,[66] improved charge lag time,[198] and increased gross billing. When using operative databases the coding for billing can be performed automatically.[164]

4.4. Discussion

Operative notes serve many purposes, all of which require capturing specific data. As the need for exact communication of operative data is increasing in order to improve both patient outcomes and physician performance, it is logical to develop the operative note further into a realistic, objective, and detailed registration of facts, instead of impressions.[78, 82, 94, 214]

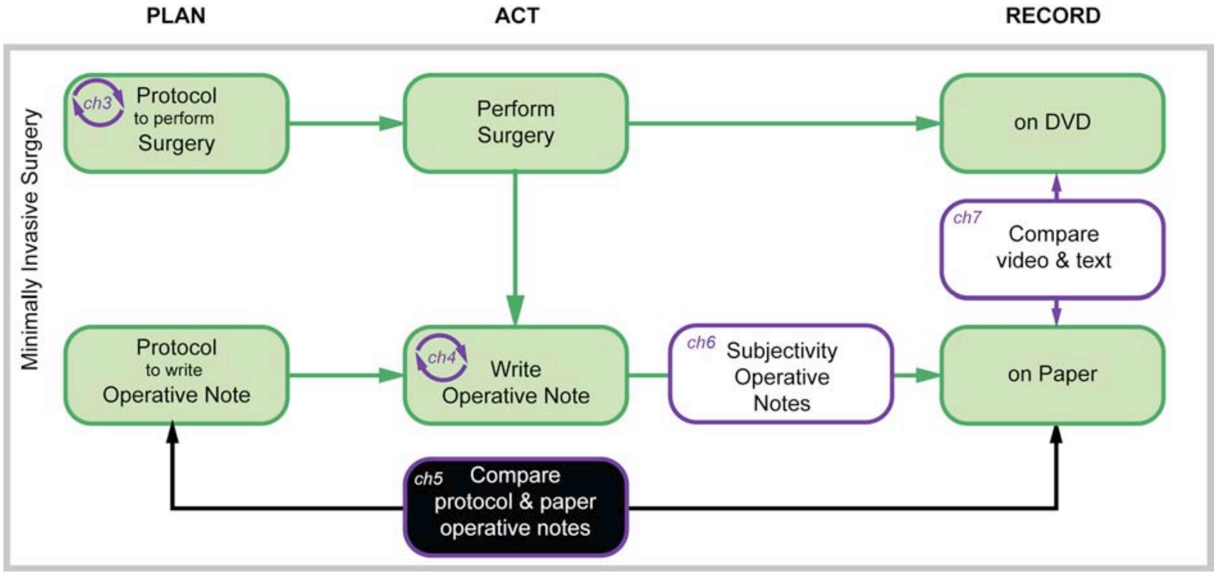
This review shows that, at present, there is a lack of uniform structured standards for operative notes. Many studies have shown that this often leads to inadequate and incomplete information on surgical procedures. Although not fully validated yet, the trend towards the use of (electronic) templates and operating databases seems to result in improvements in operative note writing and quality.

An important first measure to improving the quality of operative notes is represented by the introduction of formal training for residents on how to write operative notes, as this is not part of the curricula that were studied yet.[27, 39, 127, 167, 174] Surgeons should be trained to write their operative notes according to the (inter)national guidelines for operative notes.[75, 76, 238, 240, 241] In addition, constant feedback and critical appraisal for both residents and surgeons has to be given (e.g., audit).

Secondly, the authors believe that proven principles from other comparable fields, such as the black-box-concept of aviation, should be seriously considered as a central element of future operative notes. The main advantage of objective, interpretable, accurate, black-box supported operative notes is clear: elimination of 'human factor' dependent interpretation as a factor in translating intra-operative image-related reality to textual operative notes, and to conclusions for the patient's benefit.[139, 190, 298] Research shows that the technology and functionality are already available (e.g., voice recognition, standardized software, secure storage, and access of digital images and illustration modes). Other disciplines, such as gastroenterology, radiology and emergency care, are adding images and video to their notes as well.[103, 130, 152, 206] Although some concerns on privacy and legal aspects exist, this technology could be used for generating a new format for objective operative notes.[27, 112, 212] Combining standardized templates with mandatory fields and video recordings of operative procedures (into video-included-notes) could improve the quality of operative notes. Rafiq et al.[206] mentioned a method for structuring intra- and postoperative data for note writing: a synchronized timeline. Intra-operatively the surgeon can make comments by means of voice control, add time markers or capture still images by means of voice control, which all will be linked to the video timeline. Postoperatively the markers can be linked to the text by means of e.g., drag-and-drop. In addition, information on the patient's condition during the procedure (e.g., anaesthetic report) can be added to the timeline as well.

Video-include-notes support evidence of good practice and establish an open attitude to patient safety.[118, 130] Furthermore, it was mentioned that they provide a better guarantee for: 1) improved analysis of short and long term complications, 2) better educational opportunities, 3) more profound research, 4) less flow of paper, 5) better availability of the notes, 6) reduction of billing inaccuracy, and finally, 7) coherent legal and assurance related deliberation.[15, 103, 112, 118, 206, 221] Conversely, as video recordings in the operating theatre are a recent development, the effect on patient care has not yet been systematically researched. However, medical experts already agreed on its advantages; the recordings being used for presentation of new techniques, patient information, research purposes, peer review before participating in clinical trials, surgical quality assurance, and commercial and teaching purposes. Furthermore, objective information can be utilised to determine and evaluate errors in surgical care, therefore assuring surgical quality.[88, 130, 158, 206]

Chapter 5. Compliance with Operative Note Writing



Abstract

Background: Laparoscopic cholecystectomy (LC) is the most performed minimally invasive surgical procedure and has a relatively high complication rate. As complications are often revealed postoperatively, clear, accurate, and timely written operative notes are important in order to recall the procedure and start follow-up treatment as soon as possible. In addition, the surgeon's operative notes are important to assure surgical quality and communication with other healthcare providers. The aim of the present study was to assess compliance with the Dutch guidelines for writing operative notes for LC.

Methods: Nine hospitals were asked to send 20 successive LC operative notes. All notes were compared to the Dutch guideline by two reviewers and double-checked by a third reviewer. Statistical analyses on the ''not described'' items were performed.

Results: All hospitals participated. Most notes complied with the Dutch guideline (52-69%); 19-30% of items did not comply. Negative scores for all hospitals were found, mainly for lacking a description of the patient's posture (average 69%), bandage (94%), blood loss (98%), name of the scrub nurse (87%), postoperative conclusion (65%), and postoperative instructions (78%). Furthermore, notes from one community hospital and two teaching hospitals complied significantly less with the guidelines.

Conclusions: Operative notes do not always fully comply with the standards set forth in the guidelines published in the Netherlands. This could influence adjuvant treatment and future patient treatment, and it may make operative notes less suitable background for other purposes. Therefore operative note writing should be taught as part of surgical training, definitions should be provided, and procedure-specific guidelines should be established to improve the quality of the operative notes and their use to improve patient safety.

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5.1. Introduction

Laparoscopic cholecystectomy (LC) is the most performed minimally invasive surgical procedure performed by both junior and senior physicians (approximately 15,000-19,000 are performed annually in the Netherlands)[60, 147, 230] It is the method of choice for gallbladder removal, and in the Netherlands the Dutch Society of Surgery has adopted a guideline for performing the procedure [75] (for the English translation see Figure 3 in Wauben et al. 2008 [275]). However, the complication rate (e.g., trocar injury, injury to the common bile duct, vascular injury) is still relatively high in comparison to open cholecystectomy: the rates for bile duct injury range from 0.3 to 0.5%.[60, 133, 147, 216, 230, 300] As these complications are often revealed postoperatively, accurate operative notes are important in order to recall the procedure and start follow-up treatment (e.g., surgical intervention such as relaparotomy, percutaneous drainage, or nonsurgical intervention, such as placing a stent or the performance of percutaneous transhepatic dilatation) as soon as possible.[3, 60, 127, 147, 215, 216, 268]

Operative notes written by the surgeon are used for systematic documentation of every operation and are an essential element in safe patient care and follow-up.[3, 68, 80, 109, 127, 215, 268] In addition, they are useful for research, education, medicolegal cases, and quality assurance.[3, 27, 45, 68, 80, 109, 127, 143, 167, 180, 214-216, 268] Although all of these issues require registration of particular items, general requirements have to be met: operative notes have to be clear, accurate, and written in a timely fashion.[45, 268]

To assure surgical quality and communication with other healthcare providers (e.g., nursing staff, general practitioner, surgeon performing follow-up consultation), associations and organizations have dictated explicit standards (guidelines) concerning the time frame and content of operative notes.[77, 239, 241] All such guidelines have similar standards (Table 5.1), but previous research has shown that these standards are not always upheld. The time frame between surgery and operative note writing (dictation) is often unclear, and the quality of the operative notes is variable and poor.[27, 45, 80, 109, 143, 214]

The aim of the present study was to assess compliance with the Dutch guideline for writing operative notes concerning laparoscopic cholecystectomy.

5.2. Materials and Methods

5.2.1. Data collection

Nine hospitals (i.e. two academic hospitals, six teaching hospitals, and one non-teaching hospital) were contacted to participate in the study. To be included, each hospital had to collect and send 20 successive LC operative notes. The names of the hospitals, patients, and staff could be obscured for privacy reasons, but it was important to be able to see whether names had been filled out.

5.2.2. Data analysis

All operative notes were blinded to the reviewers for the different hospitals. All notes were compared by two reviewers to the different items of the guideline of the Dutch Society of Surgery (edition 2002) [77] and rated item by item as “described (1),” “not described (0),” or “not applicable.”

To reach interrater agreement, two operative notes were fully analyzed by two different reviewers (with no medical background) and compared and discussed with a third reviewer (L.W.). No systematic differences between the three reviewers were observed. However, it was decided in consultation with a surgical expert (J.L.) to rate the items ‘‘antibiotic prophylaxis,’’ ‘‘complication(s),’’ ‘‘specific medication,’’ ‘‘drains, etc,’’ and ‘‘histology’’ as ‘‘not applicable’’ because these were not mandatory according to the LC guidelines.[75] The two reviewers then reviewed all notes independently, and then came together to discuss any uncertainties. All ratings were double-checked by the third reviewer.

Statistical analyses were performed on the ‘‘not described’’ ratings of the operative notes using SPSS 16.0 for Mac. The Kruskal-Wallis test was then performed, followed by exploratory Mann-Whitney U-tests. The Bonferroni adjustment for multiple comparisons was applied.

Table 5.1. Content and timeframe described in the guidelines for operative note writing [77, 239, 241]

Item	DSS - 2002	RCS - 2008	JC - 2008
Procedure date	x	x	
Procedure time		x	
Consultant name		x	
Name patient	x		
Gender patient	x		
Date of birth patient	x		
PID number patient	x		
Operator	x	x	x
Assistant(s)	x	x	x
Anesthetist	x	x	x
Scrub nurse	x	x	x
Indication for surgery	x	x	
Type of anesthesia	x		
Antibiotic prophylaxis	x		
Patient posture	x		
Incision	x	x	
Confirmation expected pathology	x	x	
Unexpected events / complications	x	x	
Extra procedure(s)		x	
Procedure performed:			x
Remove gallbladder	x	x	
Hemostasis	x		
Closure	x		
Type of sutures / staplers	x	x	
Bandage	x		
Specific medication	x		
Drains / catheters / probes	x		
Histology	x		
Blood loss	x		x
Postoperative conclusion / summary	x		x
Postoperative instructions / treatment	x	x	

DSS = Dutch Society of Surgery, RCS = Royal College of Surgeons England, JC = Joint Commission

5.3. Results

All nine hospitals participated in the study: two academic hospitals (A1, A2), six teaching hospitals (T1-T6), and one non-teaching hospital (C1). Teaching hospital T6 did not send the complete operative notes: patient and staff information (steps 1-3, Table 5.2) were deleted for privacy reasons. Hospital T5 only sent eleven operative notes.

5.3.1. Compliance with reporting content per hospital

Figure 5.1 shows that most hospitals' notes comply with the Dutch guideline (52-69%); only 19-30% of the items in the notes did not comply. Table 5.2 provides the percentages (per hospital) at which the notes described specific items or at which items were not applicable.

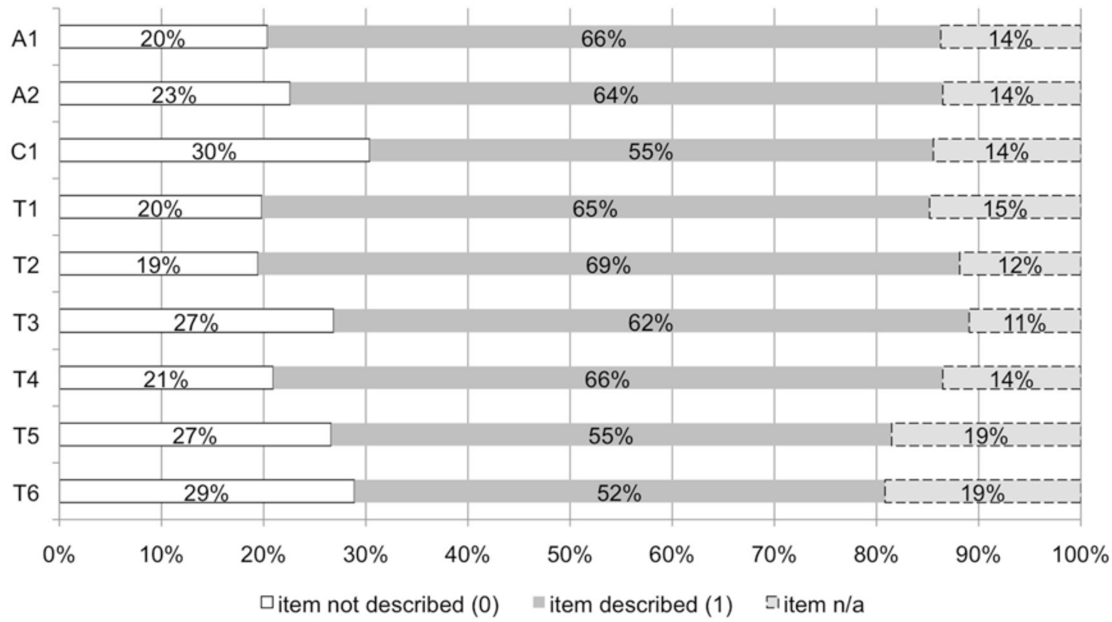


Figure 5.1. Compliance with Dutch guideline for writing operative notes per hospital: percentages of items "described," "not described," or "not applicable."

Table 5.2 shows that items related to patient information were described in most notes, except for the description of the patient gender in the notes of hospitals T3 and T5. The procedure date was described in all notes.

Provision of the names of the operator, assistant(s) and anesthetist complied with the guidelines in most cases (on average in 100, 84, and 92% of cases, respectively). However, the name of the scrub nurse was given only in most notes of hospital T3.

The indication for surgery was described in all operative notes. Also, all hospitals (except C1) described the type of anesthesia in most notes. Antibiotic prophylaxis was often not applicable (average 79%). The patient's posture was described in 50% of notes of hospitals A1 and T2. Notes from the remaining hospitals included fewer descriptions of patient posture (10-45% of cases). Hospital C1 did not describe patient posture at all. Item 5.4 "incision" was described in most operative notes (average 95%).

In seven hospitals most notes (55-95%) confirmed the expected general pathology. However, the notes from hospitals T4 and T6 described the expected general pathology in only 30 and 50% of cases, respectively. On average, complications and unexpected events (e.g., bleeding, iatrogenic gallbladder perforation) occurred in 44% of cases and were documented in all hospitals' notes, including the additional procedures performed to treat the complication.

Table 5.2. Percentages of items on the Dutch guideline described or not applicable (n/a), by hospital

	Items	A1	A2	C1	T1	T2	T3	T4	T5	T6	Total average per item	Total average per category*
1.1a	**Name patient**	100	100	100	100	100	100	100	100	md	100	94
1.1b	**Gender patient**	100	100	100	100	100	0	100	0	md	75	
1.2	**Date of birth patient**	100	100	100	100	100	100	100	100	md	100	
1.3	**PID number**	100	100	100	100	100	100	100	100	md	100	
2.	**Procedure date**	100	100	100	100	100	100	100	100	md	100	100
3.1	**Operator**	100	100	100	100	100	100	100	100	md	100	72
3.2	**Assistant(s)**	85	100	25	85	100	80	100	100	md	84	
3.3	**Anesthetist**	100	95	85	100	55	100	100	100	md	92	
3.4	**Scrub nurse**	0	0	5	0	0	80	0	18	md	13	
4	**Indication for surgery**	100	100	100	100	100	100	100	100	100	100	100
5.1	**Type of anesthesia**	100	100	35	80	100	85	100	91	65	84	68
5.2	**Antibiotic prophylaxis**	25 / *75 n/a*	*95 n/a*	10 / *70 n/a*	*100 n/a*	*95 n/a*	25 / *15 n/a*	25 / *75 n/a*	*100 n/a*	10 / *90 n/a*	11 / *79 n/a*	
5.3	**Patient posture**	50	15	0	40	50	30	10	45	40	31	
5.4	**Incision**	85	100	100	90	100	85	100	91	100	95	
5.5a	**Confirmation expected pathology**	70	80	95	95	85	60	30	55	50	69	
5.5b	**Unexpected events / complications**	60 / *40 n/a*	45 / *55 n/a*	25 / *75 n/a*	55 / *45 n/a*	40 / *60 n/a*	55 / *45 n/a*	65 / *35 n/a*	*100 n/a*	50 / *50 n/a*	44 / *56 n/a*	
5.6	**Remove gallbladder**	100	100	100	100	100	100	100	100	100	100	
5.7	**Hemostasis**	75	75	100	95	90	65	100	73	55	81	
5.8	**Closure**	100	100	100	100	100	100	100	100	90	99	
5.9	**Type of sutures / staplers**	100	100	45	95	100	85	85	100	90	89	
5.10	**Bandage**	5	30	0	0	10	10	0	0	0	6	
6.1	**Specific medication**	20 / *80 n/a*	20 / *80 n/a*	25 / *75 n/a*	20 / *80 n/a*	60 / *40 n/a*	5 / *95 n/a*	*100 n/a*	*100 n/a*	40 / *60 n/a*	21 / *79 n/a*	x
6.2	**Drains / catheters / probes**	10 / *90 n/a*	*100 n/a*	30 / *70 n/a*	15 / *85 n/a*	15 / *85 n/a*	25 / *75 n/a*	10 / *90 n/a*	*100 n/a*	10 / *90 n/a*	16 / *87 n/a*	
6.3	**Histology**	15 / *85 n/a*	65 / *35 n/a*	*100 n/a*	10 / *90 n/a*	60 / *40 n/a*	35 / *65 n/a*	35 / *65 n/a*	*100 n/a*	45 / *55 n/a*	29 / *71 n/a*	
6.4	**Blood loss**	5	0	0	0	0	0	0	9	5	2	2
7.1	**Postoperative conclusion / summary**	65	0	10	10	90	50	10	0	80	35	32
7.2	**Postoperative instructions / treatment**	10	0	0	75	0	5	100	0	5	22	

md=missing data, n/a = not applicable

* items n/a excluded

Removal of the gallbladder was described in all operative notes. On average 81% of notes described ‘‘checking for hemostasis’’ as part of the procedure. Step 5.8 ‘‘closure’’ was described in all hospitals notes, except for two notes (10%) from hospital T6. ‘‘Types of suture’’ was described in most notes (85-100% of cases), except for the notes of hospital C1, which described the type of suture in only 45% of cases. ‘‘Type of bandage’’ was described in very few notes (average 6%).

Step 6.1 ‘‘administering specific medication’’ and step 6.2 ‘‘placing of drains or removing catheters’’ were often noted as not applicable (average 79 and 87%, respectively). Sending the retrieved gallbladder for histology was described in 10-65% of cases. In the remaining cases this step was rated ‘‘not applicable.’’ The amount of blood loss was described in one note each from hospitals A1, T5, and T6.

None of the hospitals’ notes described both the postoperative conclusion and the postoperative instructions. Notes from hospitals A1, T2, T3, and T6 mostly included postoperative conclusions (50-90%), whereas the notes from hospitals T1 and T4 stated the postoperative instructions (75 and 100%, respectively). The notes from hospitals A2 and T5 included neither of these items.

5.3.2. Differences between hospitals for “not described” items

The average percentages of items ‘‘not described’’ per operative note were compared by hospital (Figure 5.2). Hospital T6 was excluded from this comparison because of the large amount of missing data.

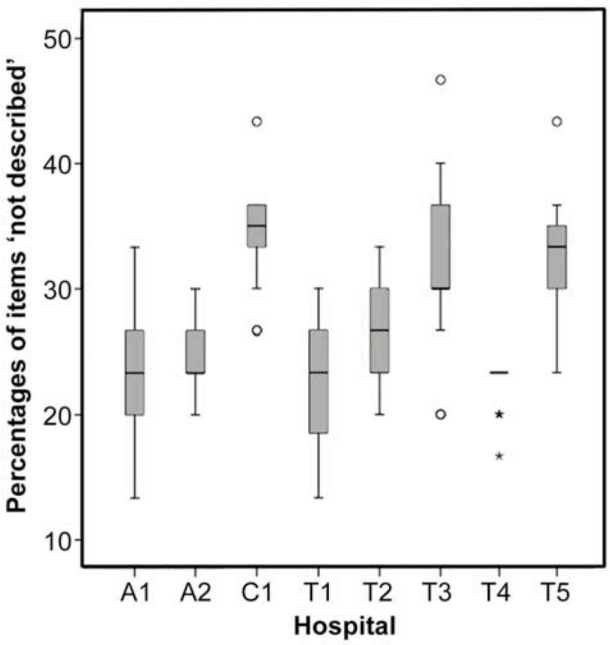


Figure 5.2. Boxplot summaries for percentages of items “not described” per hospital (median, interquartile range, (o) outliers, and (*) extreme cases)

Figure 5.2 shows that hospitals C1, T3, and T5 have the highest mean scores in items ‘‘not described’’ in their operative notes. Mann Whitney U-tests (with the Bonferroni correction; significance P<0.0018) showed significant differences between hospital C1 and all other hospitals except hospitals T3 and T5 (Table 5.3). No significant differences were observed between hospitals T3 and T5. Hospitals T3 and T5 show significant differences between hospitals A1, A2, T1, and T4. Furthermore, no significant differences were observed between hospitals A1, A2, and T1. Hospital T2 only showed significant differences with hospitals C1 and T4.

Table 5.3. Significant differences between hospitals for the ''not described'' items from the Dutch guideline (Mann-Whitney U-test: P values have been adjusted for multiple comparisons using the Bonferroni method)

	P value							
	A1	A2	C1	T1	T2	T3	T4	T5
A1	-	ns	<0.001	ns	ns	<0.001	ns	<0.001
A2	ns	-	<0.001	ns	ns	<0.001	ns	<0.001
C1	<0.001	<0.001	-	<0.001	<0.001	ns	<0.001	ns
T1	ns	ns	<0.001	-	ns	<0.001	ns	<0.001
T2	ns	ns	<0.001	ns	-	ns	<0.001	ns
T3	<0.001	<0.001	ns	<0.001	ns	-	<0.001	ns
T4	ns	ns	<0.001	ns	<0.001	<0.001	-	<0.001
T5	<0.001	<0.001	ns	<0.001	ns	ns	<0.001	-

ns= not significant

5.4. Discussion

Accurate and complete operative notes are considered a critical element of quality assurance in surgery. However, operative notes are often incomplete, impeding the patient's postoperative management. Standards and guidelines aim to improve operative note writing. Although a guideline is not a law, it still has to be observed as good practice. If a surgeon deviates from the guideline, a reason has to be provided.

Although the present study shows an average overall compliance of 62%, in 24% of all LCs recorded in the participating hospitals, the operative notes did not comply with the Dutch guideline (in 14% of cases items were designated ''not applicable''). Negative scores for all hospitals were mainly attributable to the lack of a description of patient posture (average 69%), type of bandage (94%), amount of blood loss (98%), name of scrub nurse (87%), postoperative conclusions (65%), and postoperative instructions (78%). Furthermore, the notes from hospitals C1, T3, and T5 complied significantly less with the guidelines when compared to most other hospitals' operative notes. For example, hospitals T3 and T5 did not describe the patient's gender.

Although some items to be included in the operative notes may seem to be logical and consistent components of all procedures, describing these items in every operative note minimizes the chance of overlooking them when they influence outcome (e.g., patient posture in relation to postoperative neuromuscular complications). Furthermore, as operative notes are often used for research purposes, audits, and medicolegal / risk management, including all the items detailed in the guideline is important.[80, 127, 215]

Although the Dutch guideline requires describing both postoperative conclusion and postoperative instructions (in contrast to other guidelines that require only one of these items), none of the hospitals in the present series included both items. Furthermore, the notes from hospitals A2, C1, and T5 included neither. Reasons for not describing both items probably lie in their unclear definition. The lack of postoperative instructions in the notes from the present study is relatively high (78% of cases) when compared to other studies (entailing different surgical procedures), which show average rates of 0-42% [3, 68, 109, 127, 143, 214, 215, 231]

Although the direct effect of failure to adhere to the guideline and of incomplete and inaccurate operative notes has not yet been studied, describing items 1-4 in Table 5.2 is vital for quality assurance. In addition, including the subsequent items (5-7) in the operative note has a direct effect on the patient's postoperative management; therefore, not describing these items increases the safety risk. One of the complications of LC with a high socioeconomic impact is bile duct injury (BDI).[60, 147, 216] De Reuver et al. showed that BDI was mostly (61%) diagnosed before patient discharge (usually within the first postoperative 24h [147]).[60] However, in 34% of cases BDI was diagnosed after discharge, with a mean time interval between LC and BDI diagnosis of 4 weeks. Other studies have shown similar results: the majority of BDIs were not recognized during initial surgery.[147, 216] Managing the complications caused by BDI (and other complications as well - e.g., bile leakage, stone spill) requires early recognition in order to reduce patient morbidity and improve the treatment outcome.[60, 216, 230, 300] Other complications, such as abdominal abscess, fistula formation, cystic duct stump leakage, dislocation of clips, bile duct stricture, and trocar site bleeding, might arise months or years after operation.[133, 147, 230, 300] When assessing the surgery retrospectively, the surgeon then has to rely on the operative notes, and this presents problems if the notes are not accurate and complete.[300]

The current guideline for operative note writing is applicable to all types of surgical procedures, and so they include only general requirements for describing the intraoperative findings and actions. Although the present study shows that most intraoperative findings and procedures are described according to the guideline, it is recommended that more procedure-specific guidelines be developed. Ideally, the operative notes would consist of a general section and a procedure-specific section to allow a step-by-step operative description.[180]

In the case of operative notes describing LC, the procedure-specific section should be linked to the procedural guideline provided by such (international) societies as the European Association of Endoscopic Surgery and the Society of American Gastrointestinal and Endoscopic Surgeons.[136, 185] The Dutch LC procedure guideline describes six key steps: (1) introduction of trocars under vision, (2) condition of gallbladder, (3) establishing critical view of safety (CVS), (4) placing of clips, (5) hemostasis of liver bed, and (6) removal of trocars under vision.[75] Steps 2 and 5 are already included in the general operative note's guideline. Adding the description of steps 1, 3, 4, and 6 provides a better basis for postoperative care, as all of these steps may lead to complications.[133, 230, 300]

The present study showed that complications were described in 44% of cases and, although not required by the Dutch guideline, actions to treat these complications were described in all these notes. However, it can only be assumed that in the remaining procedures no complications occurred. Therefore, if items are not applicable for a specific procedure (e.g., gallbladder perforation, assistance of scrub nurse, drains, specific medication, complications), these should be mentioned as well, proving that the notes are complete and that no items were forgotten.[215]

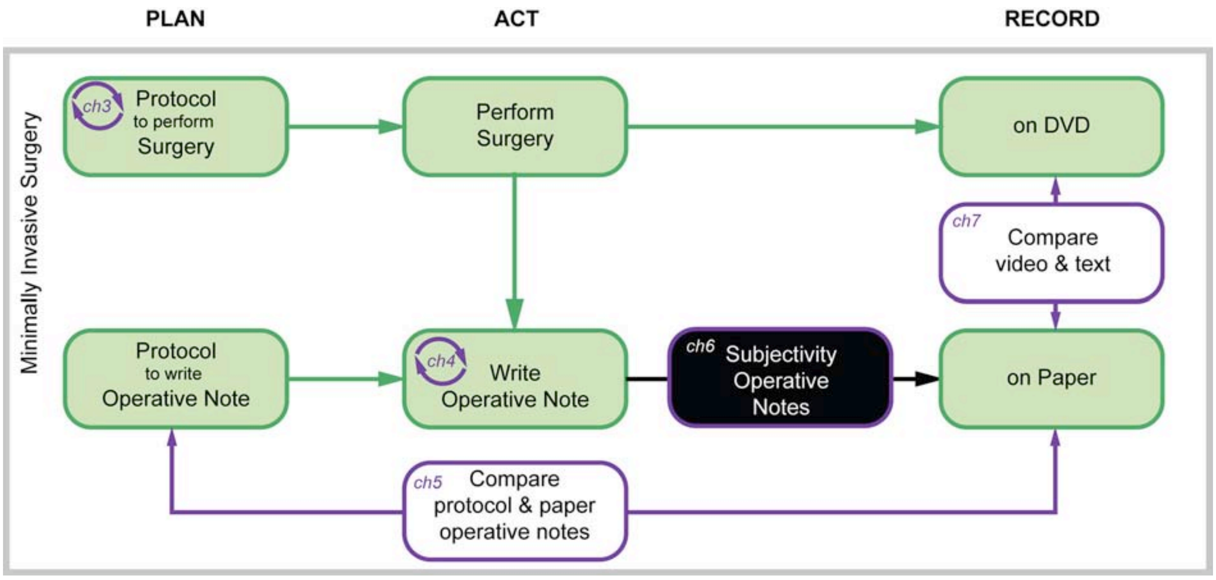
Here we have considered the content of the operative notes, but the time frame for writing the notes and making them available is important as well (this study did not include this aspect). The Dutch guideline recommends that the operative notes are ‘‘dictated, made available, and added to the medical record as soon as possible’’.[77] Other countries' guidelines require the notes to be ‘‘dictated immediately after an operative or high-risk procedure, or if this is not possible, an operative process note should be added’’.[239, 241] The Joint Commission defines *immediately* as: ‘‘upon completion of surgery, before the patient is transferred to the next level of care’’.[239] Adding a specific time frame for writing the operative notes to the Dutch guideline (e.g., within 24h of the procedure) is advisable.

Although authorship of the operative notes is not studied here, it is expected that in teaching and academic hospitals most LCs are performed by residents, who then also write the operative note. A lack of formal education on operative note writing might account for the large gaps in reporting noted in the present study (24% of items in the guideline were not described). At present only 10-18% of institutions globally offer operative note writing as part of their residency program,[27, 80, 109, 127, 167, 174] and most senior physicians have never received such training. Rogers et al. showed that residents were more likely to include accurate information about the suture used for closure, the dressing used, or the postoperative instructions than the specialists.[214]

The present study did not focus on studying whether the data provided represented actual events that occurred during the operation (e.g., prophylactic administration of antibiotics). We believe that the results can be interpreted as a minimum level of deviation from the Dutch guideline. In addition, we have designed a follow-up study to establish whether the physician's position, surgeon or resident, influences the completeness and accuracy of the operative notes. For the future, the direct effects of failure to adhere to the guidelines need to be studied as well.

To improve the quality of the operative notes and the use of that information to improve patient safety, operative note writing should be taught to physicians in training as well as senior staff who never received such training; definitions should be provided, and procedure-specific guidelines should be introduced.[80, 127, 167] Implementation of processing the operative notes as a final, cross-checked part of the operation itself might improve reliability. Although not yet fully validated, there is a trend toward the application of information technology and services for operative notes. Systems like video registration of procedures, electronic aide-memoirs, surgical templates, and electronic reminders, will improve the accuracy and completeness of the operative notes.[3, 27, 45, 68, 109, 127, 143, 167, 180, 214, 215, 231]

Chapter 6. Subjectivity of Operative Notes



Abstract

Objective: To study: 1) current routine of operative note writing for laparoscopic cholecystectomy (LC), and 2) differences between notes on the same operations written by surgeons and residents.

Summary Background Data: In order to guaranty safe patient care, operative notes need to be complete and accurate.

Methods: Participants were sent a DVD with three LC's and asked to 'write' the corresponding operative notes, and fill out a questionnaire. Dictation tapes were typed out literally, and all notes were analysed per procedure ('item described' or 'item not described'). Fisher's exact tests were performed using SPSS 16.0 for Mac.

Results: Thirteen sets of typewritten notes and ten dictation tapes were received. The questionnaire's results showed that 16/23 notes were dictated. Eight respondents found the current system for generating operative notes inadequate. Current routine of operative note writing showed that on average 21/45 general items analysed were included in more than half of all notes. Although some significant differences were observed for mentioning specific general items per procedure, no overall systematical relationship could be observed. On average the residents significantly more often described: 'condition / inspect abdomen (LC1: P=0.015)', 'open peritoneal envelope (LC2: P=0.029)', 'location of clips on artery (LC2: P=0.039)' and 'Critical View of Safety' checked (LC3: P=0.021)'. Besides mentioning 'gallbladder perforation' (20/21 notes) other deviations and complications were underreported.

Conclusions: Information concerning complications or deviations in the procedure were underreported. This impedes direct postoperative patient care and also inhibits possibilities for training, education, research and medico legal cases. Future notes should be more standardized and must include objective information on important steps performed.

Submitted as: Wauben LSGL, Goossens RHM, Lange JF. Subjectivity of Operative Notes. An Evaluation in Laparoscopic Cholecystectomy.

6.1. Introduction

Laparoscopic cholecystectomy (LC) is the most performed minimally invasive surgical procedure representing the method of choice for gallbladder removal.[146, 300] However, the complication rates are still relatively high in comparison to open cholecystectomy.[61, 146] The complication rates for bile duct injury range from 0.5-0.8%, and although the reported complication rates for iatrogenic gallbladder perforation are low (0.08-0.3%), perforation often occurs (in 13-14% of cases).[61, 146, 300] Though complications should be mentioned in the operative notes, these and other items are not always reported, which makes the notes less accurate and complete.[14, 45, 80] This impedes postoperative treatment, quality assurance, and could even lead to medical malpractice matters.[45, 78, 80, 143, 151, 212] Operative notes can also be used for quantitative and qualitative research in order to understand the cause of encountered complications.[51, 78, 195, 212, 221] Additionally, they are considered to be an important source for medico legal cases, training, and learning process in surgery for both junior and senior physicians.[51, 61, 78, 80, 143, 212]

At present, the operative note is often still a subjective, non-standardized or regulated testimony, dictated to a transcription service or secretary.[206] In order to improve operative note quality upcoming methods for writing operative notes are (electronic) template-based notes or database management systems for generating operative notes.[51, 78, 143, 152, 195] Another method for generating operative notes is using video registration.[206] Although currently no operative notes are created solely based on video recordings, sometimes images or video are added to the notes.[152, 212] They provide additional information concerning anatomical and pathological changes and surgical outcome, give better insights in potential problems, enable earlier detection of complications, and ease the planning and discussion with respect to follow-up surgery or treatment with the patient.[212]

For this study it was chosen to study LC, as this high volume and standardised procedure is relatively easy to record and is performed by both surgeons and residents. Furthermore, there is an official guideline of the Dutch Society of Surgery describing this procedure (for English translation of the guideline see Wauben et al.[275])[75]

The aim of this study was twofold: 1) to study the current routine of operative note writing for laparoscopic cholecystectomy, and 2) to study the differences between operative notes of the same operations written by surgeons and residents.

6.2. Methods

6.2.1. Data collection

For this study three LC's recorded on DVD were selected, which were first analysed, based on the Dutch guideline for LC,[74] by a senior resident, an experienced laparoscopic surgeon (JL), and a researcher (LW).

All procedures entailed open installation of pneumoperitoneum with the Hasson technique. However, the recordings started when first entering the abdomen with the endoscope and ended when removing the last trocars. LC 1 was performed by a senior resident and entailed: normal anatomy, introduction of trocars under vision, critical view of safety (CVS) by Strasberg[235] was *not* checked, adequate placing of clips, *no* adequate checking of haemostasis of the gallbladder bed (i.e. checked actively by pulling up the liver, or by pushing up the liver edge by means of an instrument), and removal of trocars under vision. Additionally, minor bleeding was observed. A junior resident performed LC 2, which was taken over by the supervising surgeon and entailed: normal anatomy (but with enlarged left liver lobe), introduction of trocars under vision, CVS checked, adequate placing of clips, *no* adequate checking of haemostasis, and *not* removing the trocars under vision. Additionally, bleeding and iatrogenic gallbladder perforation occurred. During LC 3, performed by a surgeon with normal anatomy, all steps of the guideline were followed.

In total 62 surgeons and residents of both teaching as well as non-teaching hospitals were contacted by E-mail. They were asked to participate in the study and requested to invite one of their junior and senior residents to participate as well. All participants were sent a DVD with the three LC's, recorded in standard quality. All respondents were asked to write or dictate (depending on their current practice) the operative note after watching the video on their computer, as if they had performed the procedures themselves. Software used for watching the video was dependent on the subject's computer. The DVD could be watched at double speed.

In addition, the respondents were asked to fill out a questionnaire, see Table 6.1.

Table 6.1. Questionnaire

Question	Answer
Function?	O Surgeon O Resident
Type of hospital?	O Teaching O Non-teaching
Number of procedures performed independently?	O <50 O 50-100 O 100-500 O 500-1000 O >1000
Number of procedures performed under supervision? (to be answered by resident)	
Number of operative notes written independently (both open and laparoscopic)?	
How do you generate your operative notes?	O I dictate the operative note, and I O check / O not check, the transcribed operative note. O I copy a comparable operative note and adapt this. O I use a template O without / O with required fields.
Do you perceive the current method for generating operative notes as adequate?	O Yes O No: What is the problem? and What would you like to change?
Remarks	

6.2.2. Data analysis

Dictation tapes were typed out literally and all operative notes were analysed per procedure. Personal comments or judgement concerning the technical skills of the surgeon were excluded. After establishing a basic format for all items, each item was rated 'described' or 'not described'. In case an item was described in one operative note only, this item was deleted from the format.

Additionally, statistical analyses were performed using SPSS 16.0 for Mac. Fisher's exact tests for nominal variables were used to compare 1) all items described by all respondents compared between procedures, and 2) all items described by surgeons or residents per procedure.

6.3. Results

In total 10 surgeons and 13 residents, of 19 teaching and three non-teaching hospitals, responded with various levels of experience (see Table 6.2). In total 13 sets of typewritten notes and 10 dictation tapes were received. One tape could not be transcribed, as this type was not readable.

Table 6.2. Respondents, number of LC's performed and number of operative notes written

<table>
<tr><th colspan="2">Function</th><th colspan="2">Hospital type</th><th colspan="2">LC performed independently</th><th colspan="2">LC performed under supervision</th><th colspan="2">Number of operative notes written</th></tr>
<tr><td></td><td>n</td><td></td><td>n</td><td></td><td>n</td><td></td><td>n</td><td></td><td>n</td></tr>
<tr><td>Resident</td><td>13</td><td>Teaching</td><td>19</td><td><50</td><td>9</td><td><50</td><td>7</td><td><50</td><td>5</td></tr>
<tr><td>Surgeon</td><td>10</td><td>Non-teaching</td><td>3</td><td>50-100</td><td>2</td><td>50-100</td><td>5</td><td>50-100</td><td>4</td></tr>
<tr><td colspan="2" rowspan="5"></td><td>Missing</td><td>1</td><td>100-500</td><td>4</td><td>100-500</td><td>1</td><td>100-500</td><td>5</td></tr>
<tr><td colspan="2" rowspan="4"></td><td>500-1000</td><td>2</td><td>500-1000</td><td>0</td><td>500-1000</td><td>0</td></tr>
<tr><td>>1000</td><td>4</td><td>>1000</td><td>0</td><td>>1000</td><td>8</td></tr>
<tr><td>Missing</td><td>5</td><td>Missing</td><td>1</td><td>Missing</td><td>1</td></tr>
<tr><td></td><td></td><td>n/a</td><td>9</td><td></td><td></td></tr>
</table>

6.3.1. *Questionnaire*

The results of the questionnaire showed that in the teaching hospitals most operative notes were dictated (n=16, Table 6.3). Six of the dictated notes were checked after transcription, five were not checked, and one was sometimes checked. In the three non-teaching hospitals, two surgeons routinely copy a comparable operative note and adapt this to the actual LC. In total, 13 respondents found their current system for generating operative notes adequate, and eight found this inadequate. Recommendations provided for a new system included adding a template or using an electronic checklist per procedure to improve completeness.

Table 6.3. Results of questionnaire on operative note writing

<table>
<tr><th>Hospital type</th><th colspan="2">Method for writing operative notes?</th><th colspan="2">Current system adequate?</th><th>Recommendations</th></tr>
<tr><td rowspan="12">Teaching</td><td colspan="2">6x dictate & checked</td><td colspan="2">11x Yes</td><td rowspan="12">- Electronic checklist per procedure (SUR)
- Standard list with required fields is preferable, could prevent incompleteness (SUR)
- Checklist including standard steps (e.g., adhesions yes / no, triangle of Calot; critical view of safety; deviating anatomy) (RES)
- Template including crucial steps would be better concerning not forgetting specific steps and dictating (2x RES)</td></tr>
<tr><td>3x RES</td><td>3x SUR</td><td>7x RES</td><td>4x SUR</td></tr>
<tr><td colspan="2">1x dictate & sometimes checked</td><td colspan="2">7x No</td></tr>
<tr><td>1x RES</td><td></td><td>5x RES</td><td>2x SUR</td></tr>
<tr><td colspan="2">5x dictate & not checked</td><td colspan="2" rowspan="2">1x Missing</td></tr>
<tr><td>4x RES</td><td>1x SUR</td></tr>
<tr><td colspan="2">4x dictate & missing if checked</td><td colspan="2" rowspan="6"></td></tr>
<tr><td>3x RES</td><td>1x SUR</td></tr>
<tr><td colspan="2">1x copy & adapt</td></tr>
<tr><td></td><td>1x SUR</td></tr>
<tr><td colspan="2">2x template & required field</td></tr>
<tr><td>2x RES</td><td></td></tr>
<tr><td rowspan="2">Non teaching</td><td colspan="2">2x copy and adapt</td><td colspan="2" rowspan="2">1x Yes
1x No
1x Missing</td><td rowspan="2"></td></tr>
<tr><td colspan="2">1x missing</td></tr>
<tr><td rowspan="2">Unknown</td><td colspan="2">1x template & no required field</td><td colspan="2" rowspan="2">1x Yes (SUR)</td><td rowspan="2"></td></tr>
<tr><td></td><td>1x SUR</td></tr>
<tr><td>Total</td><td colspan="2"></td><td colspan="2">13x Yes
8x No
2x Missing</td><td></td></tr>
</table>

RES = resident, SUR = surgeon

6.3.2. *Current routine of operative note writing: total average*

Table 6.4 shows that on average 21 out of the 45 general items analysed were included in more than half of the operative notes for LC generated by both residents and surgeons.

Introducing the three trocars was described in all LC notes. However, introduction of the epigastric trocar and two working trocars *under vision* was described on average in 42% and 46% of all notes respectively (Table 6.4, column 'total average'). Location of the trocars was described in 76-80% of all notes, and trocar size in 55-61% of notes.

'Condition and inspection of the abdomen' was described on average in 68% of all notes. Only few respondents described inspection of the gallbladder and 'identification of Rouvière sulcus' (30% and 17% of notes respectively).

'Tighten the gallbladder' was described in most notes (92%), whereas 'tighten Hartmann's pouch' was described in few notes (29%).

Opening the peritoneal envelope around the structures of Calot's triangle was described on average in 62% of all notes, and 31% of notes also included the method for opening the peritoneal envelope. Dissection of the hilar area and its method was described in only 29% and 16% of all notes, respectively.

In total, 37% of all notes described the identification and dissection of Calot's triangle. Fifty-one percent of notes described 'identify cystic artery' and 54% described 'identify cystic duct', respectively. Furthermore, CVS was described on average in 62% of all cases.

Clipping and cutting the cystic artery and duct were described in most operative notes (95-100%). However, the location and number of clips was reported infrequently (location: 29-31%, number of clips: 43-50%).

Dissection of the gallbladder was described in all notes and the method and instrument(s) used, were described in most operative notes (average 69% and 64%, respectively).

'Checking for adequate haemostasis' was described in 54% of all notes. Lavaging the abdomen was performed mainly in LC 2: this was described in almost all notes.

Removal of the gallbladder was described in all notes. Location for removal was described in 76% of all notes, under vision in 8% of notes, and the use of an endobag in 68% of all notes.

Removing the trocars and mentioning whether this was performed under vision was described on average in 74% and 63% of all notes, respectively.

Finally, checking the trocar sites for bleeding was described in 16% of all notes.

6.3.3. Differences between procedures

Fisher exact tests showed significant differences for describing general items between procedures by all respondents.

Comparison between LC 1 & LC 2

Lavaging the abdomen was performed mainly during LC 2, and therefore written down only in the corresponding notes. Removing the gallbladder with or without an endobag was described significantly more often in the notes of LC 2 ($P<0.001$). However, the notes of LC 1 described significantly more often 'remove trocars' ($P=0.017$) and added 'under vision' for this removal ($P<0.001$).

Table 6.4. Percentages of general items described: total average, average per procedure by residents (RES), surgeons (SUR), and total average per function

Item no.	Item	Total average %	LC1		LC2		LC3		Total average per function	
			% described by RES (total n=12)	% described by SUR (total n=10)	% described by RES (total n=12)	% described by SUR (total n=9)	% described by RES (total n=12)	% described by SUR (total n=9)	% described by RES	% described by SUR
1.	Introduce trocar 1 (epigastric)	100	100	100	100	100	100	100	100	100
2.	& under vision	42	50	50	42	56	33	22	42	43
3.	& location	80	92	70	92	67	92	67	92	68
4.	& size	55	75	40	50	33	67	67	64	47
5.	Introduce trocar 2 (working)	100	100	100	100	100	100	100	100	100
6.	& under vision	46	33	60	58	67	25	33	39	53
7.	& location	76	92	70	75	67	83	67	83	68
8.	& size	61	75	40	75	33	75	67	75	47
9.	Introduce trocar 3 (working)	100	100	100	100	100	100	100	100	100
10.	& under vision	46	33	60	58	67	25	33	39	53
11.	& location	76	92	70	75	67	83	67	83	68
12.	& size	61	75	40	75	33	75	67	75	47
13.	Condition / inspect abdomen	68	92	40	75	78	58	67	75	62
			*P = 0.015							
14.	Inspect gallbladder	30	42	40	50	11	17	22	36	24
15.	Identify Rouvière's sulcus	17	0	20	25	33	0	22	8	25
16.	Tighten gallbladder	92	75	90	100	100	100	89	92	93
17.	Tighten Hartmann's pouch	29	42	20	33	11	33	33	36	21
18.	Open peritoneal envelope	62	75	40	92	44	75	44	81	43
					*P = 0.029					
19.	& method (e.g., diathermy)	31	33	30	58	33	33	0	41	21
20.	Dissect hilar area	29	42	40	25	22	33	11	33	24
21.	& method (e.g., diathermy)	16	33	30	0	22	0	11	11	21
22.	Identify & dissect ∆Calot	37	33	40	33	33	25	56	30	43
23.	Identify cystic artery	51	58	50	25	56	58	56	47	54
24.	Identify cystic duct	54	58	50	33	78	58	44	50	57
25.	CVS reached	62	67	40	75	33	100	56	81	43
							*P = 0.021			
26.	Clip cystic artery	98	100	100	100	89	100	100	100	96
27.	& location	29	33	30	42	0	33	33	36	21
					*P = 0.039					
28.	& number of	43	42	50	50	22	50	44	47	39
29.	Cut cystic artery	95	92	90	100	100	100	89	97	93
30.	Clip cystic duct	100	100	100	100	100	100	100	100	100
31.	& location	31	25	20	50	22	33	33	36	25
32.	& number of	50	42	60	50	44	50	56	47	53
33.	Cut cystic duct	96	83	90	100	100	100	100	94	97
34.	Dissect gallbladder	100	100	100	100	100	100	100	100	100
35.	& method (e.g., diathermy)	69	75	60	42	56	83	100	67	72
36.	& instrument	64	50	70	83	56	67	56	67	61
37.	Check haemostasis	54	50	30	42	33	100	67	64	43
38.	Lavage abdomen	35	8	0	92	100	8	0	36	33

Table 6.4. Percentages of general items described: total average, average per procedure by residents (RES), surgeons (SUR), and total average per function (continued)

Item no.	Item	Total average %	LC1		LC2		LC3		Total average per function	
			% described by RES (total n=12)	% described by SUR (total n=10)	% described by RES (total n=12)	% described by SUR (total n=9)	% described by RES (total n=12)	% described by SUR (total n=9)	% described by RES	% described by SUR
39.	Remove gallbladder	100	100	100	100	100	100	100	100	100
40.	& which location	76	75	100	58	78	58	89	64	89
41.	& under vision	8	17	0	8	11	0	11	8	7
42.	& e.g., endobag	68	17	10	100	100	100	78	72	63
43.	Remove trocars	74	92	80	58	44	92	78	81	67
44.	& under vision	63	92	80	25	22	83	78	67	60
45.	Check trocar sites	16	17	40	0	11	17	11	11	21
	Range of number of items described		22 to 32	17 to 33	20 to 34	18 to 35	21 to 36	16 to 32		

* Fisher's exact test (exact significance 1 sided) for the comparison of describing items by surgeons and residents

Comparison between LC 1 & LC 3

The method for dissecting the hilar area was described significantly more often in the notes of LC 1 (P=0.027). However, the notes of LC 3 significantly more often described 'checking haemostasis' (P=0.003) and removing the gallbladder with or without an endobag (P<0.001).

Comparison between LC2 & LC3

Introducing the working trocars *under vision* was described significantly more often in the notes of LC 2 (P=0.031). Furthermore, the method for opening the peritoneal envelope was also described significantly more often in LC 2 (P=0.050). However, the notes of LC 3 significantly more often described 'method for dissecting the gallbladder' (P=0.003), 'checking haemostasis' (P=0.002), 'remove trocars' (P=0.022), and added 'under vision' for this removal (P<0.001).

6.3.4. Differences between operative notes written by surgeons and residents

Table 6.4 also presents the percentages of items described by residents (RES) and surgeons (SUR) per procedure and the total average for all procedures. For LC1, the residents included 22-32 items and the surgeons included 17-33 items of the total of 45 general items. For LC2, the residents included 20-34 items and the surgeons included 18-35 items. For LC3 the residents included 21-36 items and the surgeons included 16-32 items. In 17% of general items (Table 6.4), surgeons and residents mentioned a specific item equally. In 56% the residents' notes included more items, and in 27% the surgeons' notes included more items.

Fisher's exact tests showed significant differences between items described by the residents or surgeons. Item 'condition and inspection of the abdomen' for LC1 was significantly more often described in the residents' notes (P=0.015).

The notes of LC2 showed significant differences for describing 'open the peritoneal envelope' (P=0.029) and for describing the location of the clips on the cystic artery (P=0.039). In both cases the residents included the description more often.

Finally, the residents described ‘CVS checked’ significantly more often in the notes for LC3 (P = 0.021).

6.3.5. Procedure specific items and complications

In LC1 extra structures were encountered, which were described in all notes (Table 6.5). Furthermore, although no gallbladder perforation occurred, six respondents described that ‘no perforation’ and ‘no bile spill’ occurred.

Table 6.5. Number of residents (RES) and surgeons (SUR) describing procedure specific items and complications

		LC1		LC2		LC3	
Item no.	**Item**	**No. of RES (total n=12)**	**No. of SUR (total n=10)**	**No. of RES (total n=12)**	**No. of SUR total (n=9)**	**No. of RES (total n=12)**	**No. of SUR (total n=9)**
A	Deviations (e.g., extra structures)	12	10	4	1		
B	Identify common bile duct					4	4
C	Dissect common bile duct			2	-		
D	Loss pneumoperitoneum			2	-		
	& extra procedure			2	-		
E	Bleeding in hilar area			12	9		
	Extra procedure:						
	& diathermy			7	3		
	& tamponnade			4	3		
	& lavage			4	1		
	& suction			7	1		
				*P = 0.037			
F	Bleeding artery			5	1	4	1
	Extra procedure:					4	1
	& diathermy			3	-	3	1
	& lavage			1	-		
	& suction			1	-		
G	Bleeding in liver bed			5	1		
	& diathermy			4	-		
	& lavage			2	1		
	& suction			1	1		
H	Gallbladder perforation?	4	2	12	8	-	2
	(no) bile spillage	4	2	11	5	3	1
I	Diathermic damage liver bed			2	5		

* Fisher’s exact test (exact significance 1 sided) for the comparison of describing items by surgeons and residents

In LC2, five respondents described encountering ‘extra structure(s)’. Furthermore, two residents described dissection of the common bile duct. During LC2 several ‘complications’ occurred:

1. Loss of pneumoperitoneum, which was described by two residents only.
2. Bleeding in the hilar area was described in all notes. Residents reported the extra procedure performed (i.e. diathermy, tamponnade, lavage) to control the bleeding slightly more often. A significant difference was observed between residents and surgeons for describing ‘suction’ (P=0.037 by Fisher's exact test).

3. ‘Arterial bleeding’ was described by six respondents. Three residents described the extra procedure performed to control this bleeding, and one resident described lavaging and suctioning the abdomen.
4. ‘Bleeding from the gallbladder bed’ was described by six respondents. Four residents described that this was solved by means of coagulation.
5. ‘Gallbladder perforation’ was described by almost all respondents (lacking one surgeon). Eleven residents versus five surgeons also included ‘bile spill’. However, one resident and one surgeon described that no perforation had occurred.
6. Seven respondents described diathermic damage to the liver bed.

In the notes of LC 3, eight respondents described identifying the common bile duct. Furthermore, four residents and one surgeon described the arterial bleeding and the extra procedure performed. Although no gallbladder perforation had occurred, two surgeons described that ‘no perforation occurred’ and three residents and one surgeon described that ‘no bile was spilled’.

6.4. Discussion

Operative notes are part of the communication within the hospital setting. Effective communication is indispensable for all disciplines, as ineffective communication impairs the quality of patient care, endangers risk management, and has a negative effect on the care process.[45, 80, 143, 167, 195, 212] However, nowadays, conventional operative notes lack sufficient and reliable data (e.g., occurrence of complications, actual performance of a procedure, routine and uncommon items), which also limits its use for other purposes, such as clinical research studies, medico legal cases, audits, training, and learning.[78, 143, 152, 189, 195, 206, 212, 221]

This study showed that on average 21 of the 45 general items analysed, were included in more than half of the respondents’ operative notes for LC. The remaining items were often not included in the notes. This shows the subjectivity of operative note keeping, which was first described in this study. Incompleteness and inaccuracy are partly caused by the practice of operative note writing.[45, 195] Besides the surgeon’s individual responsibility, it has been suggested to adopt a systems approach in order to improve the conditions for record keeping.[45, 141, 209] Five respondents indicated the use of a checklist to establish more complete notes. Literature shows that when using checklists or reminder systems, the notes will include more relevant items.[78, 152, 195, 221]

Guidelines for performing LC are available.[136, 185, 275] Combining these existing procedure’s guidelines with the general guidelines for operative note writing, literature, and the current routine for operative note writing shown in this study, results in a checklist of 11 main items that should realize complete operative notes (Table 6.6).[77, 136, 185, 239, 241, 275, 300] This study showed that most of these items are already included in the majority of notes of surgeons and residents. Items which were reported in less than 50% of all notes are the introduction under vision (step 1), inspection of the gallbladder (step 2), dissection of the hilar area and the method used (step 3), and the location and number of clips used (step 5). Significant differences were observed for mentioning specific general items per procedure. Although LC3 significantly included more items of checks 6-9 compared to LC1 and LC2 (which included more items of checks 1-3), no overall systematical relationship could be observed. Including all items is important to create complete operative notes in order to provide information for other healthcare providers, and also to provide data for research, audit and training purposes.[78, 195, 221] Especially including item 11 ‘complication’ generates important data that effects the patient’s postoperative treatment and early diagnosis of future complications.[141, 206, 209, 300] Besides improving care of the specific patient by means of faster and more adequate follow-up treatment, it might help patients in general. This could also promote gaining insight into ‘no harm events’ or ‘near misses’, so these can be prevented from emerging into an actual future ‘adverse event’.[141, 153, 206, 209] Although gallbladder perforation was reported by almost all respondents, other complications were underreported in this study, which is in accordance with literature.[78, 221] Furthermore, reporting whether e.g., ‘no perforation or spillage’ occurred, or CVS was checked, improves the notes as this shows that they are complete and no items were forgotten.[300]

Table 6.6. Checklist for operative notes for laparoscopic cholecystectomy

Check no.	Check items:
1.	Introduction of optical, epigastric and working trocars under vision
	Location of trocars
2.	Confirmation expected pathology of the abdomen and gallbladder
3.	Open peritoneal envelope
	Grab / tighten gallbladder
	Dissect hilar area (& method?)
	Open peritoneum (& method?)
4.	CVS reached?
5.	Clip and cut cystic artery and duct
	Clip cystic artery (& location & number)
	Cut cystic artery
	Clip cystic duct (& location & number)
	Cut cystic duct
6.	Dissect gallbladder
	Method ?
7.	Check haemostasis
8.	Remove gallbladder
	Location
	Bag used?
9.	Remove trocars under vision
10.	Deviation(s)
11.	Complication(s)?
	Cause
	Method used for restoring

The study showed that in 56% the residents’ notes included more items, and in 27% the surgeons’ notes included more items. On average the residents included two to three general items extra compared to the surgeons. Items ‘condition / inspect abdomen’, ‘open peritoneal envelope’, ‘CVS checked’, and ‘location of the clips on the artery’ were described significantly more often by the residents. Edhemovic et al. and Baigrie et al. showed a similar trend, where residents wrote more complete reports than the consultants for rectal surgery, in contrast to Novitsky et al. who showed that residents’ operative notes were less accurate and complete (leading to reduced or delayed reimbursement).[14, 78, 189] Furthermore, besides formal training of operative notes writing (as part of their residency program) adequate constant feedback and critical appraisal on all physicians’ operative notes has to be provided.[78, 80, 167, 189]

Implementation of new information technology and services for operative notes could support the process of operative notes writing.[51, 78, 104, 152, 206, 212] An example is generating operative notes by including video. These ‘video-included operative notes’ have the advantage that they represent an objective registration of all actions and are independent of the surgeon’s memory.[104, 146] Especially minimally invasive procedures, such as LC, are suitable for recording, as a video image is already generated.[104, 146, 206] An advantage of ‘video-included operative notes’ is that they can also be used for quantitative and qualitative research (e.g., gain insight into causes of complications)[104, 141, 146, 206, 209] This makes it possible for physicians (but also other team members) to review their own performance and provide comments on their mental processes.[90, 104, 141, 146, 153, 206] Furthermore, it could support training of procedures.[146, 206] The value of video for training purposes has already been proven for trauma resuscitations.[90, 153]

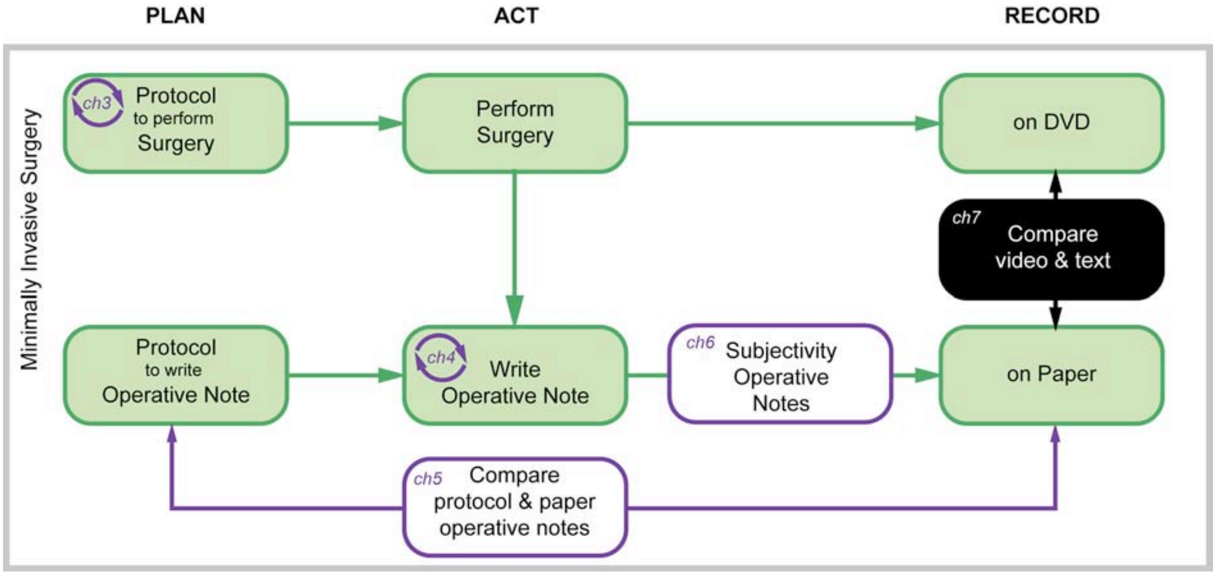
The notes from this study were immediately written after watching the procedure on DVD. However, the results also showed that most of the notes are still being dictated, which is often done in a separate room after the procedure. The timeframe between surgery and actual dictation also influences the accuracy of the notes, as the surgeon then has to rely on his memory (which is fallible).[45, 141] Formulating and adopting an explicit standard for the timeframe, such as ‘written upon completion of surgery, before the patient is transferred to the next level of care’[239], is expected to increase accuracy and completeness.[45, 141, 239, 241]

In conclusion, we found that most surgeons and residents already report most important general items. However, some items were clearly underreported. Especially information concerning complications or deviations in the procedure were underreported, impeding direct postoperative patient care and also inhibiting the possibilities for training, education and research. Therefore, future notes should be more standardized and include objective information on important steps performed during the procedure.

6.5. Acknowledgement

The authors would like to thank all surgeons and residents of each hospital for participating in the study. Additionally, the authors would like to thank the contact persons: Dr. N. Bouvy, Dr. E.C.J. Consten, Dr. P. Heres, Dr. P.W. Plaisier, Dr. D. Swank, Dr. A.A.W. van Geloven, Dr. B. Vierhout, and Dr. W. Vrijland.

Chapter 7. Video Recordings versus Written Operative Notes



Abstract

Objective: To compare video recordings, taken during laparoscopic cholecystectomy (LC), with operative notes, and to establish its additional value.

Summary background data: Operative notes form an essential element in safe patient care and follow-up, requiring them to be clear, accurate, and timely written.

Methods: Starting in August 2007, nine Dutch teaching and non-teaching hospitals were invited to record 20 successive LC each and collect their corresponding operative notes. Participants (surgeons and residents) being recorded were randomly selected. The main outcome measures were the overall differences and correspondence between video recordings and operative notes: 1) based on the Dutch LC guideline, 2) for iatrogenic gallbladder perforation.

Results: Seven hospitals participated and 125 recordings and notes were fully analysed. Cumulative scores showed mainly differences for a) introduction trocars under vision: in 69% of cases observed - in 46% described, b) gallbladder's status: 97% observed – 66% described, c) critical view of safety: 79% observed – 59% described, and d) removal trocars under vision: 73% observed – 64% described. Individual comparison showed that in 33-93% of cases recordings and notes were similar. In 2-39% steps were observed, but not described, and in 1-18%, steps were described, but could not be observed. Iatrogenic gallbladder perforation occurred in 37%, of which 87% was described.

Conclusions: Today's operative notes in the Netherlands do not fully correspond to the actual events observed in the recordings. Video recordings of LC significantly support the quality of operative notes and therefore improve their use with regard to postoperative treatment, quality assurance, evidence in medico legal cases, and teaching.

Submitted as: Wauben LSGL, van Grevenstein WMU, Goossens RHM, Lange JF. Added Value of Video Recordings over Operative Notes.

7.1. Introduction

Operative notes are standard practice for all surgical disciplines and are used for systematical documentation of every operation. They form an essential element in safe patient care and follow-up. In order to assure surgical quality, operative notes should be clear, accurate, and timely written.[78, 195, 268] Furthermore, operative notes are also useful for research, education, medico legal cases, and quality assurance.[27, 51, 80, 119, 143, 164, 167, 268]

In contrast with the extensive developments in surgery and related disciplines over the last centuries, the operative note has remained much the same: it is often a subjective, non-standardized or regulated testimony, dictated to a transcription service or secretary.[27, 49, 138] Most often operative notes are immediately dictated or written after the operation, but delays, unrealistically appealing to the surgeon's memory, are no exception.[49, 51, 80, 138, 143, 195, 268] Although written / dictated operative notes are familiar to the surgeon, are flexible and easily adaptable, recent studies have shown that disadvantages exist. Amongst others, they entail inadequate, incomplete data on the surgery performed and the indication for surgery, they miss postoperative instructions, and there is uncertainty of the timeframe between surgery and documentation.[49, 51, 78, 143, 189, 195]

Other (upcoming) methods for writing operative notes are (electronic) template based notes or database management systems for generating operative notes.[49, 51, 78, 138, 143, 164, 195] Several studies have shown that these methods improve record keeping.[49, 51, 78, 138, 143, 195] However, potential disadvantages are the requirements for efficient information and technology infrastructure, a longer completion time compared to dictating, and the registration of unpredictable events is still subjective and left to the surgeon.[49, 138, 143, 164]

Another method for generating operative notes is using video registration. Currently, no operative notes are created solely based on video recordings. Images portray more information than the written word and studies have shown that they provide additional information concerning anatomical and pathological changes and surgical outcome, give better insights into potential problems, enable earlier detection of complications, and ease the planning and discussion with respect to follow-up surgery or treatment with the patient.[112, 119, 202] However, potential concerns are the acceptance of information technology, liability, privacy, initial costs, and file storage.[119]

Current technology might improve and support the process of operative note writing. This study focuses on establishing the added value of video recordings over operative notes. It was chosen to study laparoscopic cholecystectomy (LC), as this procedure is relatively easy to record. Furthermore, there is an official guideline of the Dutch Society of Surgery describing this procedure in which image registration by photo of the critical view of safety[235] (CVS) is recommended (for English translation of the guideline see Wauben et al.[275]).[74]

The aim of this study was to compare the video recordings of the endoscope, taken during LC, with the operative notes.

7.2. Methods

7.2.1. Data collection

Starting in August 2007, nine Dutch teaching and non-teaching hospitals were invited to participate in the study. Each hospital had to record the images of the endoscope during 20 successive LCs on DVD in at least standard quality. Therefore, participants (surgeons and residents) being recorded, were randomly selected. The image had to be recorded starting at first entering the abdomen until disconnection of the endoscope. The operative notes were collected as well.

7.2.2. Data analysis

All data were made anonymous before analyzing. All DVD's were copied to a hard disk and the operative notes were re-typed, deleting all patient data, staff's and institution's names. Each recording and corresponding operative note was given an ID-number.

First the recordings were viewed (on Mac / PC) and analysed by a researcher (LW) and a surgeon (WvG), based on the (stepwise) LC guideline of the Dutch Society of Surgery.[74] In case of no consensus a second surgeon was contacted (JL). The six steps had to be rated whether they were 'performed according to the guideline', 'not performed' or 'performed in an acceptable way'. Additional comments could be added to all steps. In addition, iatrogenic gallbladder perforations were recorded as well. Secondly, the operative notes were analysed in a similar way.

Finally, the cumulative ratings of the recordings were compared with the cumulative ratings of the notes. Additionally, each individual recording was compared to its corresponding note.

7.3. Results

Seven out of nine contacted hospitals participated. One hospital failed to collect the data before the inclusion date (May 1st, 2009) and one hospital wanted to wait until the new operating theatre was fully functional (later than inclusion date). As the recordings were anonymous, no distinction could be made between hospitals or between senior surgeons and residents.

In total 139 DVDs and operative notes were received. Five DVD's could not be analysed, as they could not be viewed on the Mac / PC. Conversions were entailed in eight recordings. Reasons for conversion were unclear anatomy (n=7), and one bile duct injury caused by a diathermic cutting hook. One recording could not be compared to the operative note, as this was not dictated at the moment of receiving the hospital's data (three months after the procedure). In total 125 DVDs and operative notes were fully analysed.

Table 7.1 describes the overall cumulative scores of the comparison between recordings (REC) and operative notes (NOTE) per step.

Step 1: Introducing trocars under vision

Table 7.1 step 'intro trocars' shows the average number of procedures in which the three trocars (i.e. epigastric and two working trocars) were introduced. Most recordings (69%) showed introducing the trocars under vision. In four cases (3%) this was not observed, and in 28% of cases data were missing, as the procedure was not recorded from the start by mistake.

In contrast to the recordings, 54% of the notes did not describe introducing the trocars under vision. However, in 46% of cases this was described.

Step 2: Condition of gallbladder

Almost all recordings showed the status of the gallbladder (97%).

Most notes (66%) described the status of the gallbladder as well. However, 34% of notes lacked this description.

Table 7.1. Comparison between recordings (REC) and operative notes (NOTE): overall cumulative scores (n= and % of total 125 analysed procedures)

		executed / described		not executed / not described		acceptable		missing data	
		n	%	n	%	n	%	n	%
Intro trocars (average)	**REC**	86	69	4	3	-	-	35	28
	NOTE	58	46	67	54	-	-	-	-
Condition gallbladder	**REC**	121	97	-	-	-	-	4	3
	NOTE	83	66	42	34	-	-	-	-
CVS	**REC**	99	79	24	19	2	2	-	-
	NOTE	74	59	51	41	-	-	-	-
Clips	**REC**	117	94	3	2	5	4	-	-
	NOTE	116	93	5	4	4	3	-	-
Haemostasis	**REC**	91	73	27	22	6	5	1	1
	NOTE	89	71	35	28	1	1	-	-
Remove trocars (average)	**REC**	91	73	23	18	2	2	9	7
	NOTE	80	64	44	35	-	-	1	1

Step 3: Critical view of safety (CVS)

CVS was defined as presented in Figure 7.1 and had to be established before clipping the structures.

Recordings showed that CVS was established in most cases (79%). In 24 cases (19%) CVS was not reached adequately, and in two cases CVS was rated ‘acceptable’.

The notes showed fewer descriptions of CVS. In only 59% of cases CVS was described literally and in 41% of cases (n=51) CVS was not described. In these 51 cases, the majority described ‘dissect cystic duct and cystic artery’ (n=25) and ‘Calot’s triangle’ (n=12). In four cases ‘CVS was not reached’ was described due to a different surgical approach or bleeding. Nevertheless, the recordings showed that in 36 of these 51 cases CVS was reached.

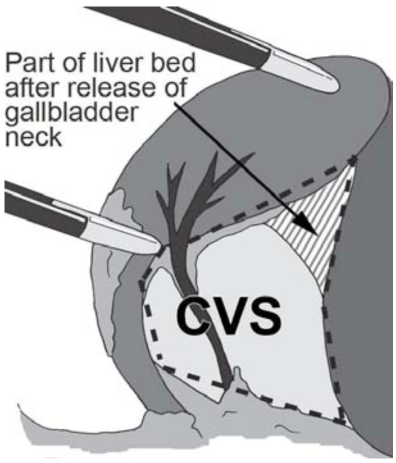


Figure 7.1. Definition of Critical view of safety (CVS) for laparoscopic cholecystectomy

Step 4: Adequate positioning of clips

The recordings showed that in 94% of cases the clips were positioned adequately (=clips encircling the whole structure). In three cases the structures were not clipped adequately: 1) clips were placed and replaced, leaving six clips on the cystic duct, and dropping one clip that was not retrieved, 2) partial resection of the gallbladder, no structures were clipped and cut, and 3) the clips did not encircle the entire cystic duct. Furthermore, in five cases placing the clips was rated acceptable (e.g., did not remove wrongly placed clips, did not place clips on gallbladder side).

The notes showed similar results: positioning the clips was described in 93% of cases, not described in five cases, and somewhat described in four cases (e.g., clipping both structures was described instead of just clipping only the cystic duct).

Step 5: Checking haemostasis of liver bed

In 73% of cases the liver bed was actively checked for haemostasis. In 22% of cases it could not be observed whether this was checked actively by pulling up the liver (lifting of gallbladder) or by pushing up the liver edge by means of an instrument (acceptable). In six cases it was rated acceptable.

Most notes (71%) described checking the liver bed, except in 28% of cases, where description of this performed step was absent. In one case the liver bed was checked after full dissection (acceptable).

Step 6: Removing trocars under vision

Table 7.1 step ‘remove trocars’ shows the average number of procedures in which the three trocars were removed. Most recordings (73%) showed removing the trocars under vision. In 18% of cases this could not be observed, and in two cases it was rated acceptable as the trocars were removed with unclear image.

Most notes (64%) described removing the trocars under vision. However, in 35% of cases the removal was not described.

Individual comparison

Each recording was compared to its corresponding operative note. Table 7.2 shows that for the different procedural steps the recordings and notes were similar in a range from 33-93% of cases, with an average score of 56%. The remaining data showed that the recordings proved advantageous in 2-39% of cases, as most steps could be observed, but were not described in the note. However, in 1-18% of cases steps were described, but could not be observed in the corresponding recording. Table 7.2 shows that in 85 cases steps were (acceptably) described, but not (acceptably) executed. The majority of these steps entailed removing the trocars under vision (7, 11 and 23 cases).

Table 7.2. Individual comparison between recording and corresponding operative note (n= and % of total 125 analysed procedures)

	(acceptably) described, but not (acceptably) observed		(acceptably) observed, but not described		REC-NOTE similar		Missing data	
	n	%	n	%	n	%	n	%
Introduce: 1st trocar	3	2	39	31	44	35	39	31
2nd trocar	1	1	49	39	41	33	34	27
3rd trocar	4	3	48	38	41	33	32	26
Condition gallbladder	-	-	40	32	81	65	4	3
CVS (as described in Figure 7.1)	11	9	36	29	78	62	-	-
Adequate placing of clips (encircling the whole structure)	6	5	3	2	116	93	-	-
Haemostasis liver bed (check before complete dissection from the liver bed)	19	15	21	17	84	67	1	1
Remove: 1st trocar	7	6	34	27	77	62	7	6
2nd trocar	11	9	33	26	72	58	9	7
3rd trocar	23	18	24	19	68	54	10	8
Total average	**9**	**7**	**33**	**26**	**70**	**56**	**14**	**11**

Iatrogenic gallbladder perforation

Table 7.3 shows that in 79 cases (63%) no iatrogenic gallbladder perforation occurred and in 46 cases (37%) a perforation occurred. Out of 31 perforations with spilled bile only, 29 cases (94%) were recorded and reported in the operative note. Conversely, two recordings showed perforations with spilled bile, which was not described in the corresponding note. Out of 15 perforations with spilled bile and stones, 11 cases (73%) were recorded and reported. Four recordings showed perforations with spillage that was not described in the corresponding note.

Table 7.3. Gallbladder perforation, spilled bile and spilled stone(s) (n=)

	Total	REC + NOTE	REC	What was seen
No perforation	79 (=63%)	-	-	
Gallbladder perforation(s) + Spilled bile	31 (=25%)	29	2	- (some) spilled bile (n=2)
Gallbladder perforation(s) + Spilled bile + Spilled stone(s)	15 (=12%)	11	4	- Spilled stones (just the perforation, not the spilled stones, was described) (n=2) - Spilled stones (n=1) - Gallbladder perforation during extraction of gallbladder with spilled stones and bile (n=1)

7.4. Discussion

This study compared reporting of LC procedures in the operative notes with video recordings. We found that the recordings are a valuable supplement to most currently operative notes in the Netherlands. This study proved that only in a small majority of LC (average 56%) the operative notes corresponded to the recordings on the six steps of the Dutch LC guideline. In up to 39% of cases the recordings proved advantageous, as they recorded more data than written in the notes. Furthermore, in some cases the notes described items, which could not be verified in the recordings. The largest contributor was 'removing trocars under vision', which mentioning is important as port-site bleeding (leading to abdominal hematomas) might occur.[208] Nevertheless, occasionally (average 11%) the recordings were incomplete as well. Especially the introduction of the trocars was often not recorded, as this is not part of the team's routine yet. This could be solved by automatically starting recording when the endoscope is attached and switched on.

Reasons for inaccuracy are partly caused by the practice of operative note writing. Besides the surgeon's individual responsibility, a system approach has been suggested to be adopted in order to improve the conditions for record keeping.[141, 209] Although in some Dutch hospitals the notes are written in the operating theatre (using electronic templates), mostly they are not written immediately after the operation. This study showed that in one case the operative note was still not written three months after the operation. This large delay requires reliance on memory. Studies on human behaviour in law have shown that testimony accuracy of eyewitnesses, although feeling confident, decreases over time, leaving 84% to be accurate.[132, 191] Fallibility of memory is often overlooked in health and safety literature: 'eyewitness testimony is not like a video-tape recorder; memory is fragile, malleable, and susceptible to forgetting, even in optimal conditions.'[132] Accuracy is influenced during encoding or acquisition of the memory, during storage and retrieval. During retrieval of information people often rely on scripts (knowledge about the sequence of events) when encountering a familiar event. This is more likely when items are related to the script or when the retention interval is longer.[132] This also accounts for writing operative notes. Sometimes they are written / dictated after several identical procedures or at the end of the day in a separate room, making the reliance on scripts higher.[138, 189] In contrast to other countries the Dutch guideline for operative note writing does not include a specific timeframe to write the notes: they only recommend that notes are 'dictated, made available, and added to the medical record as soon as possible'.[77] Other countries' guidelines require the notes to be 'dictated immediately after an operative or high risk procedure, or if this is not possible, an operative process note should be added'.[239, 241] Furthermore, The Joint Commission defines 'immediately' as: 'upon completion of surgery, before the patient is transferred to the next level of care'.[239] Although this study did not record the timeframe between procedure and note writing, the data showed that in up to 39% of cases the recordings and notes differed. Reliance on script is triggered even further when using pre-defined templates. Especially during uncomplicated LC with minor deviations the surgeon will 'copy-paste' this template, forgetting details, near misses or no harm events (that are especially useful for quality assurance and teaching / education purposes). These self-reporting notes lead to underreporting, therefore precluding both qualitative and quantitative analyses for prevention of future occurrence of a similar nature.[54, 121, 141, 206, 209] Furthermore, lacking information also impedes communication with other healthcare providers.[78, 94, 141, 206]

Another problem of operative note writing is that this is not officially part of the residency program. Studies have shown that currently only 10-18% of institutions with a residency program offer operative note writing as part of their program.[167, 174] Furthermore, only 8-31% of physicians have received formal education on how to write operative notes (e.g., lectures, seminars, courses or as part of curriculum).[27, 80, 167, 174] Others received training by means of instruction from senior trainees or by reading notes written by colleagues.[27, 80, 167] Since operative notes are considered to be an important instrument for learning and training processes for both junior and senior physicians, they have to be complete and accurate, so physicians can review their personal results objectively and improve their surgical techniques.[27, 78, 167]

Common bile duct injury (BDI) is the main complication encountered in LC.[59, 202, 220, 300] Although the Dutch Healthcare Inspectorate and the Dutch Society of Surgery advice to record CVS by photo, live video image of the whole procedure is advantageous in order to asses the achievement of CVS. Recording the whole procedure also allows studying in which circumstances the error occurred.[85, 202, 206] However, when using recordings it is advisable to add time-markers during surgery in order to improve re-viewing and adding comments on specific steps.

Another problem is iatrogenic perforation of the gallbladder with possible loss of (infected) bile and / or gallstones.[121, 220, 300] Although the complication rates described in literature are low (0.08-0.3%) this could lead to septic and biliary complications and fistulas.[220, 300] The 37% iatrogenic gallbladder perforation rate and 12% perforation with gallstone spillage from this study are both at the high-end of ranges found in literature (13-40% and 5-19%, respectively).[121, 300] This can be explained by the fact that spillage is often underreported.[121] This also holds for losing clips, which could lead to sepsis.[121] This study showed that in one case a clip was lost, but not described in the note. Nevertheless, lacking clear description of spillage or loss of clips in the operative notes could effect the patient's postoperative treatment and obstruct early diagnosis of later complications.[121, 220]

Future operative notes should be a combination of video recordings combined with the surgeon's written comments (also in case the recording system fails).[119, 206] These video-included-notes have some distinct advantages, such as recording all data objectively, making it possible to refresh the memory when notes cannot be written immediately after surgery, and making it more transparent to discuss the procedure postoperatively with the patient or (junior) physicians.[27, 112, 119, 206] Conversely, challenges are met within the field of storage capacity, investment, privacy, and liability. However, in a comparable setting Groenen et al. showed that although initial costs were relatively high (for electronic production of endoscopic reports including video) the financial benefit was positive within five years.[103] Additionally, they showed an improved availability of the reports, reduction of billing inaccuracy, and a reduction in manual stages leading to a lower risk of errors.

Although storage capacity is growing fast, present hospital servers have limited capacity to record each operation. For this study the average storage capacity required was 1.6 GB, depending on the format and duration of the procedure. For now procedures can be recorded on DVD or external hard disk. The DVD or a link directing to the recording can then be added to the (electronic) patient record.[85]

Operative notes often form a critical piece of evidence in medico legal cases.[49, 143, 164] However, often they are non-defensible in a potential complaint in court, as important information is missing.[143] Moreover, poor medical records could contribute to surgeons' liability.[54] Cases in which medical records are incomplete require additional expert opinions, which introduces an element of doubt.[143] De Reuver et al. (2008) showed that the reliability of expert witness testimonies (based on complete medical history) in BDI malpractice litigation cases was insubstantial as in only one out of ten cases full agreement was reached.[59] The experts' subjective judgment on negligence could have major implications for patients and colleagues.[54, 59] In this study two operative notes described that 'the common bile duct was clipped and cut', which was actually not the case. However, in case of a complaint this could lead to liability.

Although other elements, such as defect instruments, are important as well, this study focused only on the operative technique of LC as defined by the Dutch guideline and on iatrogenic gallbladder perforation. This was done in order to prove the added value of recordings first, as some surgeons feel reluctant to the recording of their procedures. Furthermore, this study included mainly surgeons willing to be recorded (anonymously). However, when contacting the contact persons in the participating hospitals none of them declined participation for that particular reason. Nevertheless, the participants knew the procedure was recorded are their notes would be compared to these recordings. This Hawthorne effect (better performance due to fact that the subjects are being studied) could have led to slightly deviant results.

Future research should study recording open surgical procedures as well, because currently only little research is available on this subject.[130, 206] However, this is also applicable during conversion of minimally invasive procedures. Furthermore, the incremental effect of patients who had their operations video recorded, in relation to complications and e.g., postoperative treatment, has to be studied as well.

In conclusion, video recordings of LCs significantly support the quality of operative notes and therefore improve their use with regard to postoperative treatment, quality assurance, information for patients, evidence in medicolegal cases and teaching.

7.5. Acknowledgement

The authors would like to thank the contact persons of each hospital for providing the recordings and operative notes: Dr. J.P.C.M. Oomen, Dr. R. Vree, Dr. P. Plaisier, Dr. N.D. Bouvy, Dr. H.A. Prins, Dr. E.G.J.M. Pierik, Dr. B.A. Van Wagensveld, and Dr. A. Doeksen.
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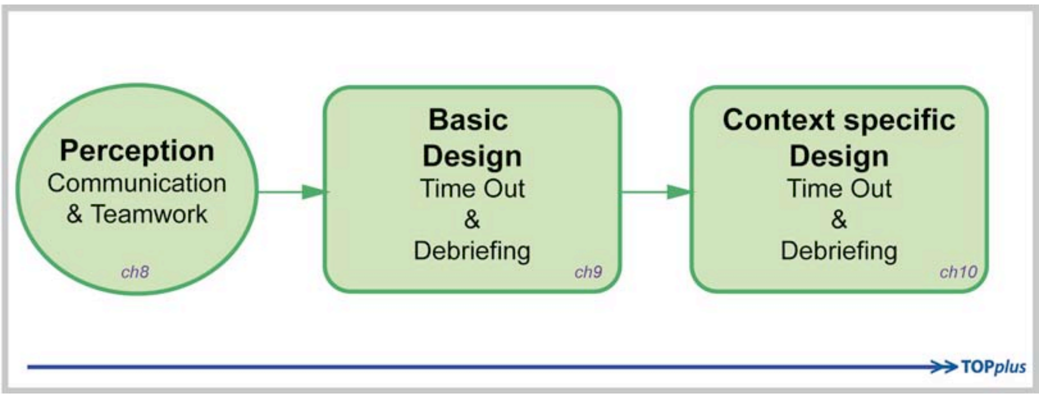
PART B

TOP*plus*



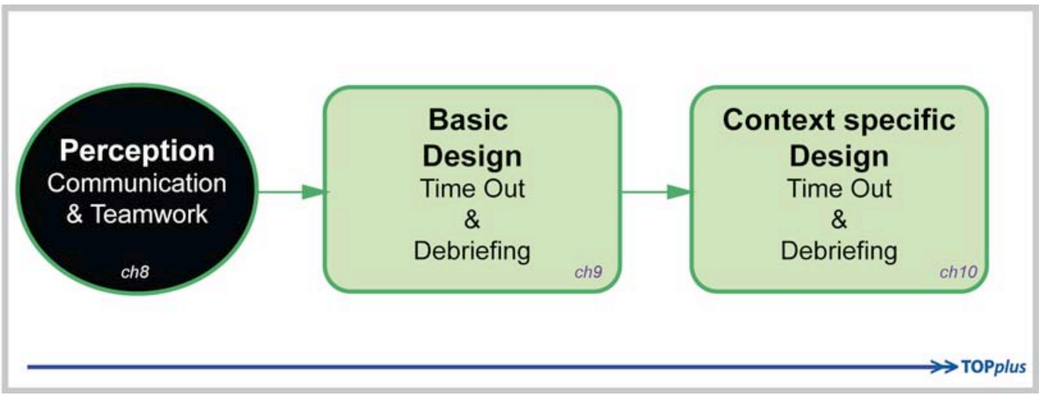
Introduction

A second factor contributing to the improvement of patient safety is the implementation of a **T**ime **O**ut **P**rocedure ***plus*** Debriefing (TOP*plus*). During the Time Out Procedure, just before surgery, the surgical team members will check surgical details and anaesthetic details, such as type of procedure, side, and patient information. This in order to prevent wrong side, wrong procedure, wrong person and wrong doses of medication. During the Time Out Procedure all members of the surgical team have the task of asking a question and answering those questions where (s)he is responsible for. During the Debriefing, immediately after surgery, the whole surgery is evaluated by the whole team.

The overall aim of the TOP*plus* project is to reduce errors and near misses, and to improve communication and teamwork in the operating theatre.

The part, chapter 8, describes the difference in perception of communication, teamwork, and situation awareness between surgeons, anaesthetists, nurse anaesthetists and nurses. Then, chapter 9 describes the basic design of the Time Out Procedure and Debriefing instrument by means of participatory design, and its implementation. Finally, chapter 10 elaborates on adapting the Time Out Procedure and Debriefing procedure to the local context of the hospital.

Chapter 8. Discrepant Perceptions among Surgical Team Members



Abstract

Objective: To assess surgical team members' differences in perception of non-technical skills.

Design: Questionnaire design

Setting: Operating theatres of one university hospital, three teaching hospitals and one general hospital in the Netherlands.

Participants: Sixty-six surgeons, 97 OT nurses, 18 anaesthetists and 40 nurse anaesthetists.

Methods: All surgical team members, of five hospitals, were asked to complete a questionnaire and state their opinion on the current state of communication, teamwork and situation awareness in the operating theatre (OT).

Results: Ratings for 'communication' were significantly different, particularly between surgeons and all other team members ($P \leq 0.001$). The ratings of 'teamwork' differed significantly between all team members ($P \leq 0.005$). Within 'situation awareness' all three sub-categories showed different results for the ratings: 'gathering information' differed significantly between surgeons and other team members ($P<0.001$); 'understanding information' differed significantly between surgeons and OT nurses and between surgeons and nurse anaesthetists ($P \leq 0.001$); 'projecting and anticipating future state', differed significantly between OT nurses compared with anaesthetists and nurse anaesthetists ($P \leq 0.002$). Finally, most team members rated routine team briefings- and debriefings as inadequate.

Conclusions: This study shows discrepancies on many aspects in perception between surgeons and other surgical team members concerning communication, teamwork and situation awareness. This inhibits teams to recognize failures, which could lead to adverse events, as these often have multiple causes related to process as well as systems failures. Team interventions should include multiple objectives related to the team as well as to the care process and support systems.

Submitted as: Wauben LSGL, Dekker-van Doorn CM, van Wijngaarden JDH, Goossens RHM, Huijsman R, Klein J, Lange JF. Discrepant Perceptions of Communication, Teamwork and Situation Awareness among Surgical Team Members.

8.1. Introduction

The surgical team consists of surgeons, anaesthetists, operating theatre nurses, and nurse anaesthetists and is a dynamic, multi-disciplinary team. In this article a surgeon is defined as: 'a medical specialist who performs surgery: a physician qualified to treat those diseases that are amenable to or require surgery' [168]. Performing safe surgery relies on the ability of the team members to combine professional knowledge and technical expertise with non-technical skills (e.g., communication, teamwork, situation awareness, leadership, decision making).[299]

Many errors that occur in the operating theatre (OT) are attributed to the non-technical skills of the surgical team.[54, 91-93, 115, 144, 155, 156, 172, 227, 299] In order to work safely and effectively, with a minimum of technical errors, the non-technical skills, communication, teamwork, and situation awareness are the most important.[91, 144, 148, 155, 172, 251, 299] In this context communication is defined as 'skills for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete the tasks effectively', and teamwork is defined as 'skills for working in a group context, in any role, to ensure effective joint tasks completion and team member satisfaction'.[253] Furthermore, situation awareness is defined as 'developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment, understanding what they mean and thinking ahead what might happen next'.[253]

Communication failures have also been reported to contribute to accidents in other high-complex and high-risk industries. In aviation, communication failures between flight crewmembers, rather than a lack of technical skills or malfunctioning of the airplane, were responsible for approximately 70% of accidents.[92, 115, 144, 172, 227]

Procedures in OT are complex and demand intense interaction between team members. Therefore, work processes should emphasize the interdependency of team members and support a good understanding of each team members' tasks, roles and responsibilities. This facilitates effective teamwork, ensures that action is linked to reflection, and creates a culture that is open to change.[79, 144, 172, 184, 251] Surgical teams should be cohesive and have similar perceptions of communication and teamwork; otherwise they cannot collaborate effectively, establish common goals for improving team performance, and ensure patient safety.[144, 170] The purpose of this study was to assess surgical team members' perception of their non-technical skills, specifically communication, teamwork, and situation awareness. Research questions were aimed at identifying the category or categories on which team members differed most and where the largest differences in perception between the different disciplines existed. As these non-technical skills are important for surgical teams to work safely and effectively, it is important to identify these discrepancies before introducing interventions for improvement and adjust implementation strategies accordingly.[111, 155, 156, 170, 243, 251, 299]

8.2. Methods

This study was designed as a multiple case study among five Dutch hospitals, covering six percent of all hospitals in the Netherlands. The researchers (LW, CD) visited each hospital and gave surgical team members oral and written information on the project and provided a questionnaire for all surgical team members to complete and elicit their opinion on the *current state* of communication, teamwork and situation awareness in OT. Approximately 600 questionnaires were distributed by mail / email by the contact persons of the participating hospitals to the team members. Selection at team level, to perform analysis at that level, was not possible, as in most hospitals in the Netherlands surgical teams are ad hoc rather than dedicated.

8.2.1. Questionnaire

The questionnaire elicited background information, such as date, details on the respondent (age category, gender, and function within the hospital), and respondents' opinion on statements about communication, teamwork, and situation awareness. The statements were based on two rating systems: the Non-Technical Skills of Surgeons (NOTSS) and the Anaesthetists' Non-Technical Skills (ANTS).[252, 253] Table 8.1 presents the definitions of categories and subcategories used in the questionnaire.

Table 8.1. Definitions for Communication, Teamwork and Situation Awareness [252, 253]

Subjects including number of statements in questionnaire (n=)
Communication: Skills for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete the tasks effectively.
C1-Exchanging information: giving and receiving knowledge and information in timely matter to aid establishment of a shared understanding among team members. (n=6) **C2-Establishing a shared understanding:** ensuring that the team not only has necessary and relevant information to carry out the operation, but that they understand it and that an acceptable shared 'big picture' of the case is held by team member. (n=7) **C3-Co-ordinating team activities:** working together with other team members to carry out cognitive and physical activities in a simultaneous and collaborative manner. (n=5)
Teamwork: skills for working in a group context, in any role, to ensure effective joint tasks completion and team member satisfaction. The focus is particularly on the team rather than the task. (n=11)
Situational Awareness: Developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment (patient, team, time, displays, and equipment): understanding what they mean and thinking ahead what might happen next.
S1-Gathering information: seeking information in the operating theatre from the operative findings, theatre environment, equipment, and people. (n=5) **S2-Understanding information:** updating one's mental picture by interpreting the information gathered, and comparing it with existing knowledge to identify the match or mismatch between the situation and the expected state. (n=2) **S3-Projecting and anticipating future state:** predicting what may happen in the near future as a result of possible actions, interventions or non-interventions. (n=1)

The questions were randomly distributed over the questionnaire. Each statement had options on a five-point Likert scale ranging from '1' (strongly disagree) to '5' (strongly agree). The questionnaires were voluntary and anonymous to team member's name, but not to team member's function or hospital. All data were analyzed confidentially.

Statistical analyses were performed using SPSS 16.0 for Mac. Comparisons between surgical team members per subcategory were performed using Mann-Whitney *U* tests. Bonferroni adjustment was applied for multiple comparisons.

8.3. Results

8.3.1. Survey sample

The five hospitals that volunteered to participate comprised: one university hospital, three teaching hospitals and one general hospital. In total, 235 questionnaires were returned. Response rates per hospital ranged between 29% and 60%, with an average response rate of 39% (Table 8.2).

The respondents represented all disciplines directly involved in surgical procedures: 66 surgeons (and residents), 97 OT nurses, 18 anaesthetists (and trainee anaesthetists), and 40 nurse anaesthetists (for distribution between hospitals, see Table 8.2). Fourteen participants did not include their function and were therefore excluded from the study. Within all hospitals the surgeons (78.5%) were predominately male and most OT nurses (87.2%) were female. Within the other two groups, men and women were represented equally (50% of anaesthetists and 59% of nurse anaesthetist were male). No significant differences were seen for gender between hospitals.

Table 8.2. Response to questionnaire

Hospital type	Questionnaires send out (estimate)	Questionnaires received	Response rate	Response per subgroup				
				Surgeons (& residents)	Anaesthetist (& in training)	OT Nurses	Nurse Anaesthetists	Function unknown
Academic	180	78	43%	33	7	27	9	2
Teaching 1	150	54	36%	15	4	18	11	6
Teaching 2	65	39	60%	3	4	18	11	3
Community 1	130	38	29%	8	3	21	5	1
Community 2	78	26	33%	7	0	13	4	2
Total	**603**	**235**	**39%**	**66**	**18**	**97**	**40**	**14**

Table 8.3 presents the statements most team members rated as inadequate, and Table 8.4 presents the mean ratings, standard deviation and median per subcategory. Additionally, Table 8.5 presents the significant differences of the team members' ratings per subcategory using Mann-Whitney *U* tests. Here, application of the Bonferroni correction for multiple comparisons suggests an appropriate level of $P < 0.008$.

Table 8.3. Statements within Communication, Teamwork and Situation Awareness rated inadequate by surgical team members

Statements rated 'inadequate' by most surgical team members per subgroup	**Surgeon**	**Anaesthetist**	**OT Nurse**	**Nurse Anaesthetist**
C1 | Exchanging information				
Anaesthetist / nurse anaesthetist communicating an update on the administered medication	x	x	x	x
Surgeon communicating that surgery is not going according to plan		x		
Anaesthetist communicating that surgery is not going according to plan			x	
C2 | Establishing a shared understanding				
Surgeon communicating planned procedure and actions		x	x	x
Anaesthetist communicating planned procedure and actions			x	
Pre-operative briefings with the whole team on the procedure	x	x	x	x
Debriefings with the whole team, discussing which problems occurred		x	x	x
C3 | Co-ordinating team activities				
Surgeon checking pre-operatively whether the whole team is ready to start the procedure		x	x	x
Anaesthetist checking pre-operatively whether the whole team is ready to start the procedure			x	x
Stopping the procedure when asked by the nurse		x	x	x
T | Teamwork				
Addressing the anaesthetist by his / her first name			x	
Contentment with the communication and teamwork in OT		x	x	x
Surgeon being a team player		x	x	x
Resident being a team player		x		x
Anaesthetist being a team player			x	
S1 | Gathering information				
Exchanging relevant patient data pre-operatively with the whole team		x	x	x
Surgeon asking the anaesthetic team for update on the patient's condition		x	x	x
S2 & S3 not applicable				

8.3.2. Communication

Within communication three different subcategories are addressed, which will be elaborated in the following paragraphs.

<u>C1 | Exchanging information</u>

Surgeons rated this subcategory as adequate, the mean rating was 3.95 (Table 8.4). The other team members rated this lower: mean 3.12-3.34. This difference of opinion between surgeons and other team members was significant ($P<0.001$, Table 8.5). No significant differences were found between the OT nurses and anaesthetists ($P=0.215$), between the OT nurses and nurse anaesthetists ($P=0.011$), or between anaesthetists and nurse anaesthetists ($P=0.677$).

All team members rated the statement 'Anaesthetist / nurse anaesthetist communicating an update on the administered medication' as inadequate (Table 8.3).

Table 8.4. Team members' ratings for the subcategories of communication, teamwork and situation awareness: Mean (on 1-5 scale, higher score = higher quality) Standard Deviation (STDEV) and Median

	Subcategory		Surgeon	Anaesthetist	OT Nurse	Nurse Anaesthetist	Total
Communication	C1	mean (STDEV)	3.95 (1.05)	3.26 (1.25)	3.12 (1.08)	3.34 (1.07)	3.41 (1.14)
		median	4.00	3.00	3.00	3.00	
	C2	mean (STDEV)	3.68 (1.14)	2.73 (1.15)	2.35 (0.99)	2.74 (0.97)	2.85 (1.19)
		median	4.00	3.00	2.00	3.00	
	C3	mean (STDEV)	3.83 (1.16)	3.33 (1.32)	2.77 (1.25)	3.04 (1.23)	3.18 (1.31)
		median	4.00	3.00	3.00	3.00	
Team-work	T	mean (STDEV)	3.78 (1.07)	3.47 (0.99)	3.06 (0.99)	3.26 (0.89)	3.32 (1.04)
		median	4.00	4.00	3.00	3.00	
Situation awareness	SA1	mean (STDEV)	3.84 (1.03)	2.84 (1.24)	3.15 (1.14)	3.14 (1.20)	3.30 (1.18)
		median	4.00	2.00	4.00	3.00	
	SA2	mean (STDEV)	4.35 (0.80)	4.11 (0.92)	3.91 (0.78)	4.05 (0.70)	4.07 (0.80)
		median	4.00	4.00	4.00	4.00	
	SA3	mean (STDEV)	3.41 (1.23)	2.67 (0.89)	3.74 (0.97)	3.28 (0.63)	3.51 (1.01)
		median	4.00	3.00	4.00	3.00	

Table 8.5. Significant differences between surgical team members (Mann Whitney *U* test with Bonferroni correction)*

	Communication			Team-work	Situation Awareness		
Subgroups compared:	**C1**	**C2**	**C3**	**T**	**SA1**	**SA2**	**SA3**
Surgeon - OT nurse	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.170
Surgeon - Anaesthetist	<0.001	<0.001	0.001	<0.001	<0.001	0.146	0.025
Surgeon - Nurse Anaesthetist	<0.001	<0.001	<0.001	<0.001	<0.001	0.001	0.237
Anaesthetist - OT nurse	0.215	<0.001	<0.001	<0.001	0.023	0.074	<0.001
Anaesthetist - Nurse Anaesthetist	0.677	0.811	0.079	0.005	0.055	0.389	0.350
OT nurse - Nurse Anaesthetist	0.011	<0.001	0.013	0.001	0.919	0.174	0.002

* Bonferroni correction for multiple comparisons suggests an appropriate level of P < 0.008

<u>C2 | Establishing a shared understanding</u>

Surgeons rated this subcategory as adequate: the mean was 3.68, versus a mean of 2.73 for the anaesthetists and 2.74 for the nurse anaesthetists. The OT nurses' mean ratings were lowest: 2.35. The difference of opinion between surgeons and other team members, and between OT nurses and other team members was significant (P<0.001). No significant difference was found between anaesthetists and nurse anaesthetists (P=0.811).

The statement 'Pre-operative briefings with the whole team' was rated as inadequate by all team members. Moreover, all team members except the surgeons rated 'Surgeon communicating planned procedure and actions' and 'Debriefings with the whole team' inadequate as well.

C3 | Co-ordinating team activities

Once more, these results showed the same overall pattern: the surgeons rated this subcategory highest (mean 3.83), followed by the anaesthetists (3.33) and nurse anaesthetists (3.04). Again, the OT nurses' ratings were lowest: 2.77. The difference of opinion between surgeons and other team members was significant ($P \leq 0.001$), as was the difference between OT nurses and anaesthetists ($P < 0.001$). No significant differences were found between the remaining team members.

The statements 'Surgeon checking readiness of team pre-operatively' and 'Stopping the procedure when asked by the nurse' were rated as inadequate by most team members, except the surgeons.

8.3.3. Teamwork

Within this subcategory the differences between all team members were significant ($P \leq 0.005$). Most surgeons and anaesthetists perceived 'teamwork' as adequate (group mean 3.78 and 3.47). The ratings of nurse anaesthetists and OT nurses were significantly lower (mean 3.26 and 3.06).

All respondents perceived themselves as team players, felt comfortable about expressing their opinion, and perceived the OT nurse and nurse anaesthetist as team players. However, the OT nurses did not see the surgeon or anaesthetist as team players and rated some statements related to this subject as inadequate (Table 8.3). Most team members, except the surgeons, rated 'Contentment with communication and teamwork in OT' as inadequate.

8.3.4. Situation Awareness

Within situation awareness three subcategories are addressed, which will be elaborated in the following paragraphs.

S1 | Gathering information

The ratings for this subcategory showed similar results as most (sub)categories within communication and teamwork. Surgeons awarded this subcategory an average rating of 3.84; the average ratings for the OT nurses and nurse anaesthetists were 3.15 and 3.14. The anaesthetists' ratings were lowest: 2.84. The only significant difference found, was between the surgeons and other team members ($P < 0.001$).

Most team members, except for the surgeons, rated the statements 'Exchanging relevant patient data pre-operatively with the whole team' and 'Surgeon asking the anaesthetic team for update on the patient's condition' as inadequate.

S2 | Understanding information

Most team members rated this subcategory as adequate: mean ratings for the groups ranged from 3.91 to 4.35. Significant differences ($P \leq 0.001$) were found only between the surgeons and OT nurses, and between the surgeons and nurse anaesthetists.

S3 | Projecting and anticipating future state

This subcategory entailed the statement 'During laparoscopic procedures, the instruments for a possible conversion are always present in OT'. Within this subcategory a lot of missing data were found: 50% of surgeons, 29% of anaesthetists, and 20% of nurse anaesthetists did not answer this question. In contrast, the OT nurses showed a near full response (98%) and most nurses rated this item as adequate (mean 3.74). If rated at all, the surgeons rated this statement as adequate, the mean being 3.41, which was higher than the mean of 3.28 awarded by the nurse anaesthetists. The anaesthetists' ratings were lowest: mean 2.67.

Significant differences were found only between the OT nurses and anaesthetists and between OT nurses and nurse anaesthetists ($P \leq 0.002$).

8.4. Discussion

The purpose of this study was to study the discrepancies in team members' perception of 1) communication, 2) teamwork, and 3) situation awareness. Having a shared perception on what to improve and why, is a necessary precondition to learn collectively and will facilitate the implementation of quality improvement initiatives.[37, 111, 155, 156, 170, 243, 251, 299] Overall, this study showed a significant discrepancy in perception between the surgical team members in all three categories. Throughout the questionnaire the surgeons rated most items as adequate (mean 3.41-4.35) in contrast to all other team members where more differences in opinion were found. All team members agreed on two statements being inadequate: 'Pre-operative briefings with the whole team on the procedure' and 'Anaesthetist / nurse anaesthetist communicating an update on the administered medication'. Pre-operative briefings create an opportunity, just before the start of the surgical intervention, to exchange information on the patient and on the surgical procedure with the whole team.

Within the category, 'communication' results showed a large variety in opinion between team members. The largest discrepancy was found in 'establishing a shared understanding', which is an important factor when performing complex procedures, such as surgery. All team members should understand and be well informed about the surgical procedure and about specific patient related subjects, such as allergies or co-morbidity. A lack in this 'shared understanding' among team members might result in adverse events.[170, 227] Errors are not always easy to solve, because usually they are complicated and rooted deeply in every day processes. Most team members experience a lack of communication on what to expect, whereas the majority of the surgeons' ratings on this subject were positive. In addition to that, surgeons do not recognize the error as a communication failure, in contrast to the other team members, which was confirmed in this study. Although human errors are inevitable, team members are reluctant to discuss failures. Surgeons might be hesitant to discuss failures because they find it hard to acknowledge that errors are made.[291] Other team members might be discouraged to speak up because of traditional hierarchical structures, authority, social barriers or differences in professional training and responsibility.[79, 156, 243, 291] Although there are fundamental differences like these between nurses and doctors, it is not fully understood yet why these discrepant attitudes exist.[243]

The overall ratings concerning 'teamwork', also differed between surgical team members. Most surgeons and anaesthetists rated these as adequate. However, the majority of both OT nurses and nurse anaesthetists rated these as inadequate. Experiencing poor teamwork could lead to team members' withdrawal from discussions, but also to decreased job satisfaction and efficiency, and finally result in communication failures and poor performance. In this situation not hierarchical status seems to be of influence, but not taking time out to discuss complications as a team or to perform a thorough analysis of what went wrong and why. Research in aviation shows that, regardless of workload, poor performing teams spend only 5% of their time to discuss possible complications compared to 33% of time spend by effective teams [228].

Most team members rated 'understanding information' one of the subcategories within 'situation awareness' as adequate. However, all team members, except the surgeons, rated 'gathering information' as inadequate. Room for improvement and time for a team discussion can only be created if team members share the same perception.[156, 170]

The overall findings of this study are consistent with prior research. The most common pattern being that surgeons have a positive perception of communication and teamwork and that nurses have the most negative perception.[91, 93, 156, 170, 184, 227, 243] OT nurses who have a poor perception of communication, sometimes have difficulties to speak up, and are afraid of confrontation. This could also withhold other team members from correcting errors before patients are harmed and inhibit discussing and learning from errors as a team.[79, 115, 184, 227, 243]

A limitation of this study was the number of centres involved; only five hospitals participated of the approximately 90 hospitals in the Netherlands (6%). However, these hospitals represent the whole spectrum of hospital types at a regional level and are comparable for quality of care. On the national list of quality indicators for patient care the volunteering hospital ranked from average to good, but changed positions annually when compared over the last five years.[105]

Additionally, this study's overall response rate, was relatively low compared to other related studies.[93, 156, 170] Although the OT nurses' response rates were lower compared to Mills et al. (2008), the response rates for the surgeon and anaesthesia 'crew' were higher compared to Makaray et al. and Mills et al.[156, 170] Overall, the sample is a good representation of the Dutch hospitals and of the population of surgical team members within the hospitals.

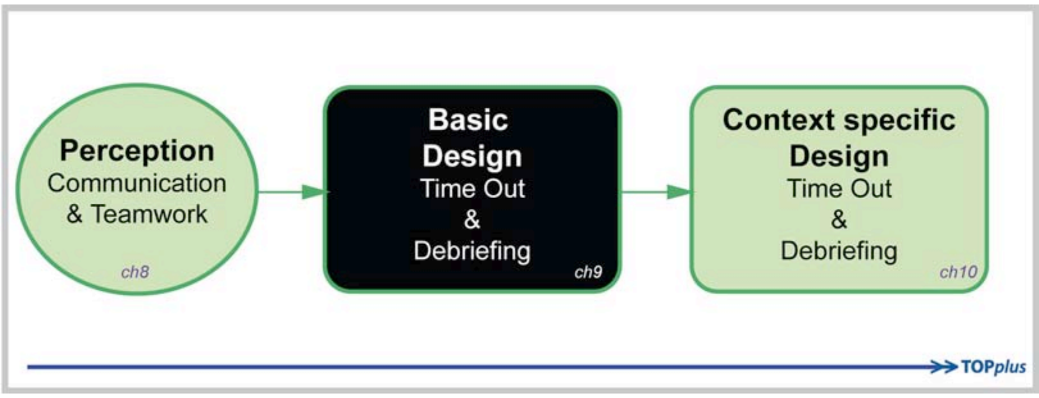
This study shows the difference in perception of surgical team members in relation to non-technical skills. Further research on patient safety should focus on team interventions for improvement that include technical as well as non-technical skills. As surgical procedures are complex and error prone, mastering non-technical skills is as important as mastering technical skills in order to perform safe surgery.[123] These interventions should support the dialogue between team members, create a shared mental model, and focus on team, process and system problems.[54, 79, 111, 115, 144, 148, 155, 156, 227, 287, 299] Interventions to improve communication and teamwork should thus include multiple objectives related to the team, the care process and to the support systems.

So far research shows very little evidence on positive results of team interventions on team effectiveness.[34] There is emerging evidence however, that team interventions that include technical as well as non-technical skills might lead to better outcomes.[111] If teams strengthen their ability to reflect collectively on problems encountered, it will improve learning from experience and create a shared understanding between team members. These are all necessary preconditions to prevent adverse events.[79] Interventions like a pre-operative briefing and postoperative debriefing include these different aspects and might be successful and lead to improved team performance.[111, 148, 155, 156, 227]

8.5. Acknowledgement

The authors would like to thank all contact persons from the participating hospitals for distributing and collecting the questionnaires.

Chapter 9. Participatory Design: Implementation of TOP*plus*



Abstract

Surgical patients are at risk for avoidable damage. A 'Time Out Procedure' *plus* Debriefing (TOP*plus*) to check relevant operative items systematically with all team members was designed for five Dutch hospitals in order to reduce avoidable damage during and after a surgical procedure. The aim of this study was to design TOP*plus* applying 'Participatory Design (PD)', test TOP*plus*'s content and usability, and evaluate the PD approach.

Design of the procedure with a multidisciplinary design-expert-team and adapting it to its local context with the hospital-expert-teams proved to be valuable, fast and easy. PD supported situation awareness on design specification and restrictions, and enabled the development of realistic expectations. However, resistance to chance was not reduced in all hospitals.

TOP*plus* started the dialogue between all members of the operating theatre team, and acted as a catalyst for improving the whole care process.

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9.1. Introduction

Healthcare is one of the most dynamic and expanding areas in the world. The number of chronically ill patients is increasing, leading to an increased demand for healthcare.[44] At the same time, (inter) national studies have shown that annually many medical errors occur. In 2000, it was estimated that 44 000 to 98 000 Americans die each year as a result of medical errors.[134] In the Netherlands, this accounts for 1735 deaths annually.[58] Half of these (possibly preventable) medical errors occur in the operating theatre (OT).[54, 58] The actual number of medical errors could be even higher, as errors are likely to be underreported.[141, 265]

Psychological and human factors research has shown that most errors are caused by defects in the system.[141, 209] Examples of these system defects are design failures (process, task and equipment design) and organization and environmental failures (psychological precursors, team building and training).[54, 141, 144, 209, 266, 269]

Today's OT's become even more complex systems that are comparable to other high-tech, high-risk industries such as aviation, nuclear, oil and offshore industry.[115, 172, 228] The increased use of more complex equipment (instruments and apparatus) and the growing complexity and continuing developments in surgical procedures, demands that knowledge and skills of the entire operating theatre team (OT-team; surgeons, nurses, anaesthetists, assistants, and residents) should increase accordingly.[42, 44, 113, 154, 251, 265] Furthermore, the OT-team should be more actively involved during surgery.[113, 251]

Although other industries have already introduced quality systems decades ago, these existing systems have to be adapted for optimal use in the healthcare sector. Besides improving the safety of equipment, literature shows that many underlying causes of errors originate on the system's 'team level'.[113, 172] Within the team level it is estimated that 70-80% of errors are caused by insufficient non-technical skills (e.g., communication, situation awareness, teamwork) rather than insufficient technical skills (e.g., knowledge of anatomy and pathology, dexterity, hand-eye coordination).[54, 115, 144, 154, 172, 228, 289, 299]

A proven method for improving these non-technical skills in aviation that has been applied in healthcare recently, is crew resource management (CRM). [54, 115, 144, 165, 228] This CRM-concept encompasses a wide range of knowledge, skills and attitudes including communication, situation awareness, problem solving, decision-making, and teamwork. Furthermore, the CRM-concept also includes team training, simulations, and development of checklists, briefings (time out procedure) and debriefings.[54, 115, 144, 165] Rather than introducing the whole CRM-concept at once, it was decided to introduce a Time Out Procedure *plus* a Debriefing procedure (TOP*plus*) as the first step.[141, 165]

The Time Out Procedure is the final step in a series of checks, which starts when the patient leaves the clinical ward. This double-check is performed in OT just before incision with the whole OT-team being present.[144, 154] In the Debriefing, just before closing the wound, 'incidents' occurred during surgery are reported.[144] These data provide a reliable base for a reporting system, which in turn provides the ability to learn from failures and enhance patient safety.[115] If incidents are reported, analysis might show similarities and patterns in sources of risk that may otherwise go unnoticed.[144, 287(p.3)]

The final TOP*plus* will be supported by two applications: a Procedure Support Application for the Time Out Procedure and a Feedback Application for the Debriefing (Figure 9.1). The Procedure Support Application should support the discussion within the OT-team of the double-check of patient and procedure related factors that are important to prevent errors.

The Feedback Application should support the discussion and reporting of patient, procedure, team and communication related details. This Feedback Application should then sent (e.g., weekly) its feedback to the surgical staff.

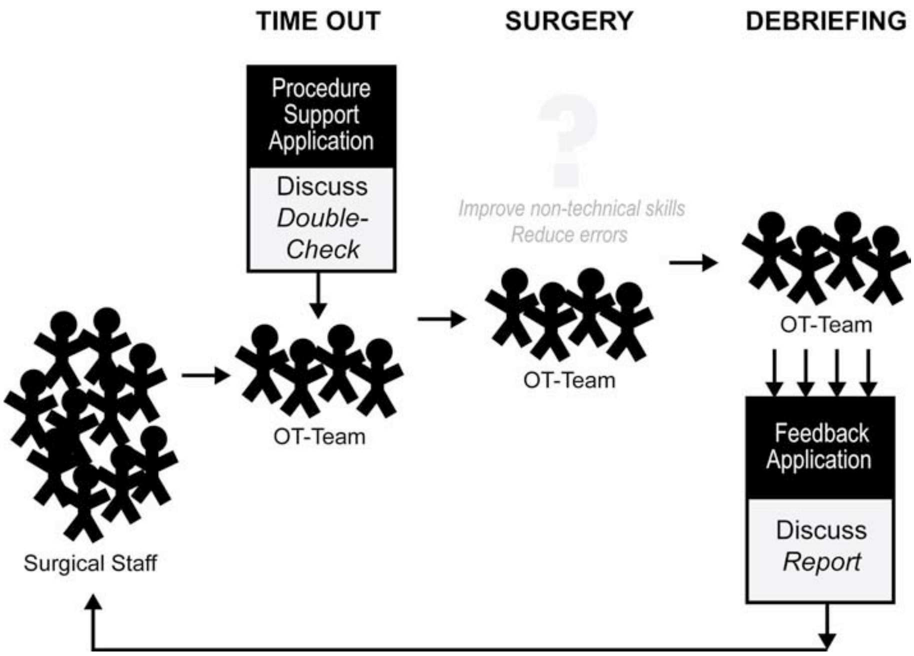


Figure 9.1. Overview of the applications to support the Time Out Procedure and Debriefing

Both applications aim to improve the non-technical skills 'communication' and 'teamwork' within the whole OT-team and reduce errors. The final applications will present their content and data by means of monitor screens in OT, enabling all team members to participate in both the Time Out Procedure and Debriefing. As this user interface thus becomes the connection between man and instruments, it has to be designed adequately. Especially in OT, it is important that the interface is intuitive to the team members, i.e. does not take too much time to understand and only addresses relevant items that are necessary at a specific moment.[63, 128] This makes the content of both applications very important.[63, 128, 266]

As all team members have to work with the applications, they should all be involved in the design process.[54, 266] Therefore, the 'Participatory Design' approach has been used. Participatory Design (PD) actively supports multi-disciplinary user participation and engagement into the design process, leading to a designed product that meets the users' specific needs.[183] Their input is important in order to reach good situation awareness on specifications of the design and the restrictions of the environment, enable development of realistic expectations, and reduce resistance to change.[44, 183, 270]

The aim of this study consisted of three parts: designing the Time Out Procedure and Debriefing (TOP*plus*) by means of PD, testing the design's content and usability, and evaluating if PD was an appropriate method for designing the TOP*plus*.

9.2. Design of TOP*plus*

In order to design, test and evaluate TOP*plus*, the model presented in Figure 9.2 was followed (see following paragraphs).

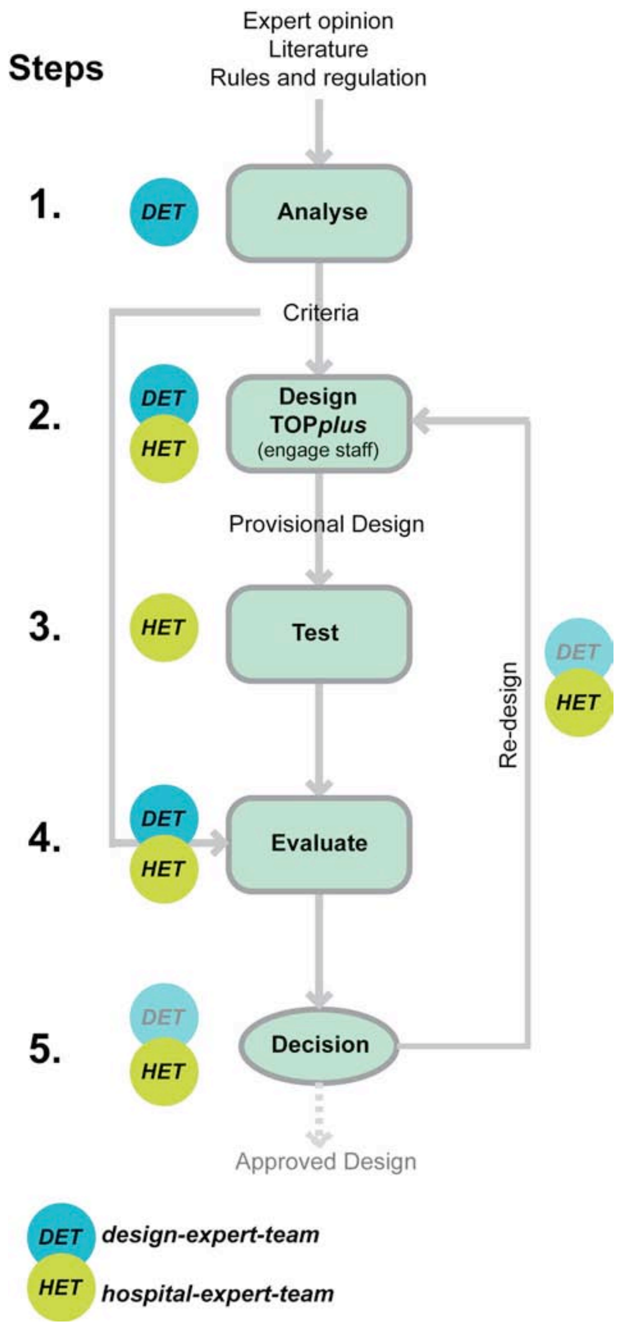


Figure 9.2. Model for designing, testing and evaluating TOP*plus*

9.2.1. Content

<u>Time Out Procedure (TOP)</u>

Preceding the demand of the Dutch Healthcare Inspectorate that each Dutch hospital has to perform a 'time out procedure' before each surgical procedure (starting 1 July 2009), we started with the first step - analysis - in September 2007 (Figure 9.2). The content of the 'time out procedure' was derived from several reports and expert opinions. The most contributing factors were:

- Universal Protocol by the Joint Commission on Accreditation of Health Care Organizations (JCAHCO). The protocol was based on three primary components: (1)

the pre-operative verification process, (2) marking the operative site, and (3) taking a 'time out procedure' immediately before starting the procedure, verifying patient, side and procedure.[129]

- Time out procedure of the 'Eye Hospital, Rotterdam'. This procedure was introduced in 2004 and is part of a series of checks. The time out just before incision entails verifying whether the patient is positioned on the right table, name and date of birth of the patient, patient's health status, operative side, procedure, and whether all equipment and material is present. The introduction in 2004 of the time out reduced their wrong site incidents to zero.
- General Guidelines for designing checklist.[63]
- Opinions of experts: surgeons, nurse anaesthetists, an anaesthetist, scrub nurses, a human factors specialist / technician, head of the OT department, managers, and researchers.

Furthermore, a taskforce was assembled; the design-expert-team. This team consisted of two surgeons, a nurse / educational scientist, an anaesthetist, a psychologist, a human factors specialist / technician, heads of two OT departments, and researchers. All members met during the kick-off meeting in September 2007 where the content of TOP*plus* was determined. Hereafter, the design-expert-team communicated mainly via email or meetings where most members were present. The researchers (LW, CD) coordinated this process.

Debriefing

Errors that occur during surgery are often not discussed as substantial pressure still exists to cover up mistakes.[228] However, in order to learn from errors made and prevent similar errors in the future, a debriefing was added to the procedure.[165] For the design of a surgical debriefing little literature was available at the moment of design.[165] It was decided with the design-expert-team to pilot the Debriefing simply by asking, *'Were there any details to be registered'* and also ask for a summary of the details in the conclusion.

Design

Before designing the actual applications, the content was first structured in a poster. Advantages of this approach are that people feel less obstructed to change items (high adaptability), less costs are involved with restructuring elements, and it is highly reliable.[128, 204, 266] Furthermore, not all OT's have appropriate infrastructure to view the applications yet.

In September 2007, the basic TOP*plus* poster (Figure 9.3) was designed with the design-expert-team (Step 2, Figure 9.2).[44] Here, the 'call-do-response' method, based on checklists used in aviation, was used.[63] Team members have to verify (cross-check) that an action was taken. This way all team members are involved and all items are checked systematically.

The coloured bars and corresponding bullets preceding the questions, indicated the team member who has to ask the question. The purpose of the questions was to engage in dialogue between team members and was not intended to memorize the questions.[63] The bullets at the end of each line indicated the team member(s) who should answer the question. The team members answering the questions are the ones responsible for specific tasks directly related to the surgical procedure. The anaesthetist and nurse anaesthetist were assigned to the same questions and answers. Due to Dutch working structures, the anaesthetist supervises two beds and in his absence the nurse anaesthetist takes over.

The colours used are the basic cooperate design colours of the Erasmus University Medical Center.

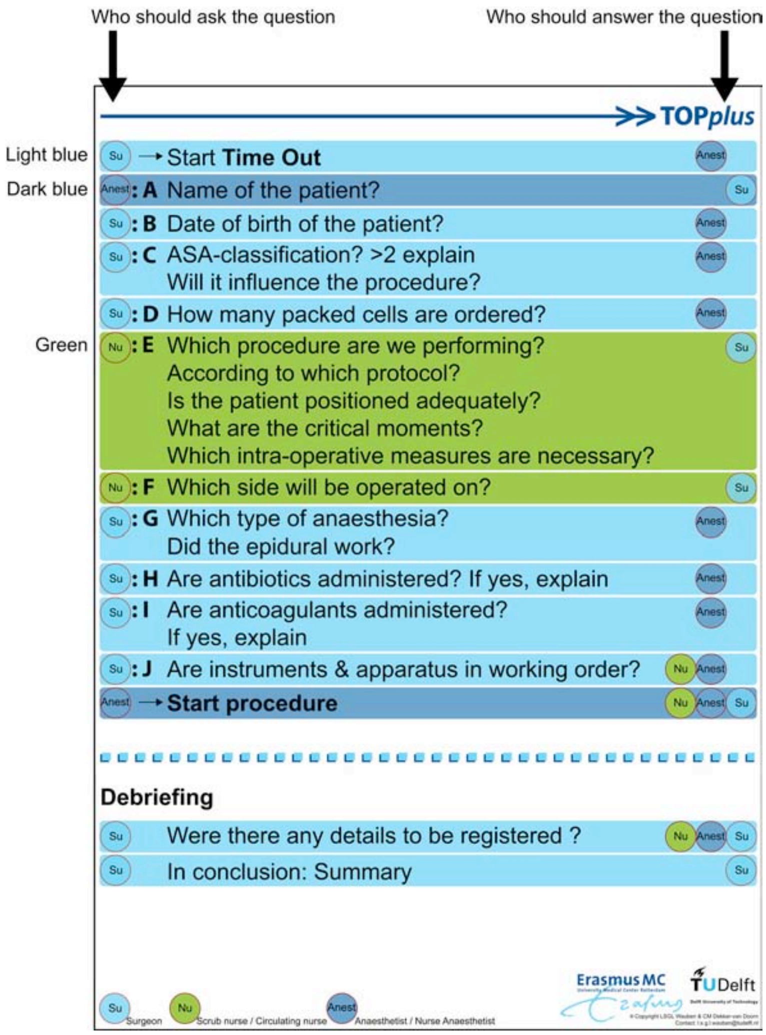


Figure 9.3. TOP*plus* basic poster

The Time Out Procedure was initiated when all team members were present in OT, just before the first incision.[266] Because the Time Out Procedure is a double-check, the patient did not have an active role, as (s)he could already be under anaesthesia or pre-medicated in addition to a regional block anaesthesia.[154]

The Debriefing had to take place just before closing the wound, as in academic and most teaching hospitals the supervising surgeon will then leave OT. The surgeon initiated the Debriefing and all team members were invited to randomly comment (both positive and negative) on the surgical process, on communication and teamwork, the TOP*plus* procedure itself, or other striking events.

9.3. Materials and Methods: testing content and usability, and evaluating PD approach

9.3.1. Participants

Five hospitals volunteered to participate in the pilot phase of this study: an academic hospital, two teaching hospitals and two community hospitals.

In each hospital the content of the poster was discussed with representatives of the OT-team; the hospital-expert-team.[44] This hospital-expert-team could adjust the content of the basic TOP*plus* poster to local needs when considered necessary (Step 2, Figure 9.2). They, in turn, engaged their staff and explained the project's aim and use of the poster to all team members by means of meetings and / or presentations. Furthermore, all participants received a letter with more detailed information.

Each hospital decided, which department(s) would start the TOP*plus* project.

9.3.2. Method

In the third step - test (Figure 9.2) - each hospital had to perform the TOP*plus*, as described on the poster, for at least 100 surgical procedures. This testing had to be performed and supervised by each local hospital-expert-team itself. During the TOP*plus* the nurse anaesthetist observed and registered the following aspects:

- Was the Time Out Procedure / Debriefing performed? - Yes / No: why not?
- How long did it take perform the Time Out Procedure / Debriefing?
- Did the designated team member ask and answer the questions in the Time Out Procedure / Debriefing? - Yes / No: why not?
- During the Time Out Procedure, were the questions asked as stated on the poster? - Yes / No: in what way?
- Did all team members participate in the Time Out Procedure? - Yes / No: who (function) did not participate and why?
- The remarks / incidents mentioned by the different team members in the Debriefing.

9.3.3. Evaluation with the hospital-expert-team

In the fourth step - Evaluate (Figure 9.2) - the design's content and usability was evaluated with the design-expert-team and the hospital-expert-teams by means of interactive discussions. Additional comments and remarks were discussed. When considered necessary, the basic TOP*plus* poster and procedure were adapted, leading back to re-designing the TOP*plus* poster (step 2, Figure 9.2).

9.4. Results

Although all hospitals started the project, community hospital C2 stopped after one day due to resistance of the surgical staff. Reasons mentioned were: '*this Time Out Procedure is too time-consuming', 'publication of the results could endanger the hospital's image', 'the Time Out Procedure is a double-check, but we do not have a check yet',* and *'the Time Out Procedure will probably lead to more errors; current processes are already well organised'*.

The other four hospitals did complete the pilot phase. The ambulatory care department of the academic hospital (A2) was analysed separately. In total 627 registration forms were obtained. Table 9.1 presents the participating departments, response and start date of the TOP*plus* for each hospital.

9.4.1. Time Out Procedure (TOP)

The Time Out Procedure was followed completely in 506 surgical procedures (81%), partially in 16 (2%), and not at all in 31 cases (5%). Documentation was missing for 74 procedures (12%). The main reasons for non-compliance with the Time Out Procedure protocol were:

- The surgeon does not fully cooperate; he does not see the ‘added value’ in performing a Time Out Procedure (n=9).
- There was no time; the surgeon was in a hurry (n=4).
- The team members forgot to perform the Time Out Procedure (n=4).

Table 9.1. Participating departments, response and start date TOP*plus*

Hospital type	Code	Department	Number of Registration forms	Start date
Academic	A1	All	150	2 July 2008
Academic	A2	Ambulatory care	100	2 July 2008
Teaching	T1	Surgery	180	16 October 2007
Teaching	T2	Surgery	97	16 July 2008
Non-academic	C1	Gynaecology	100	7 January 2008
Non-academic	C2	All	Stopped	1 June 2008
Total			**627**	

<u>Duration Time Out Procedure</u>

On average the Time Out Procedure took 96 seconds (STDEV = 63 seconds) (A1: 97 ± 56 sec; A2: 90 ± 61 sec; T1: 99 ± 67 sec; T2: 104 ± 74 sec; C1: 86 ± 60 sec).

<u>Coordination of procedure by designated team member</u>

This part of the registration form was completed for 596 procedures (partly) performed. Table 9.2 shows that in most cases, 57.9%-76.3%, the designated team member asked the questions. Differences in a team member asking a question other than the one indicated on the poster were minor and also improved during the course of the implementation. If the designated team member did not ask the question, other team members took the initiative.

Questions A to I were predominately answered by the designated team member (64.1-90.3%). The answer to question J was often not recorded (39.6%). However if answered, the nurse and (nurse) anaesthetist answered question J as intended (37.4% and 20.1%, respectively). In cases where a team member other than the designated one answered the question, most of the time the surgeon answered.

<u>Compliance with procedure as described on poster</u>

In 422 cases the questions were asked according to the poster (70.0%). In 87 cases it was unknown, and in 25 cases only the team member answering the question was reported. In the remaining 62 cases a different way of questioning was followed, such as:

- the questions were shortened or summarized (n=12),
- the surgeon asked and answered all questions (n=8),
- some questions were skipped (n=7),
- the surgeon did not cooperate (n=6), and
- a different, not reported way was used (n=15).

Table 9.2. Percentages of team members asking and answering the questions during the TOP

	Question [%]										
Asked by:	**Start**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
Surgeon	<u>68.1</u>	7.7	<u>76.3</u>	<u>74.7</u>	<u>73.5</u>	7.9	7.4	<u>71.1</u>	<u>73.8</u>	<u>74.0</u>	<u>73.8</u>
(Nurse) Anaesthetist	5.9	<u>73.0</u>	6.7	6.7	6.4	15.4	13.4	6.4	6.2	5.9	5.5
Scrub nurse	3.7	1.8	2.0	1.5	1.3	<u>62.8</u>	<u>57.9</u>	2.2	1.2	0.8	2.0
Missing data	22.3	17.4	14.9	17.1	18.8	13.9	21.3	20.3	18.8	19.3	18.6
	Answer to question [%]										
Answered by:	**Start**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**
Surgeon	5.9	<u>83.9</u>	6.5	3.0	5.4	<u>90.3</u>	<u>*83.2*</u>	4.0	3.9	2.9	2.9
(Nurse) Anaesthetist	<u>64.1</u>	6.5	<u>87.9</u>	<u>88.4</u>	<u>83.1</u>	3.5	2.3	<u>85.9</u>	<u>86.9</u>	<u>85.6</u>	<u>20.1</u>
Scrub nurse	0.3	0.7	0.7	0.3	0.2	1.5	1.0	0.2	0.2	0.0	<u>37.4</u>
Missing data	29.7	8.9	4.9	8.2	11.4	4.7	13.4	9.9	9.1	11.6	39.6

<u>Participation of team members</u>

During most procedures (n=378) all team members participated in the Time Out Procedure. In 119 cases no additional information was given on team members' participation. During the remaining 99 surgical procedures where Time Out Procedure was performed, one or more team members did not participate. In total, 143 team members did not participate: 15 surgeons, 19 nurses, 93 anaesthetists, 1 anaesthetist in training, 14 nurse anaesthetists, and 1 unidentified person. The high number of anaesthetists not participating was mainly the result of working structures, as (s)he was not present in OT at that specific moment. This was already foreseen in the design; the poster states that the anaesthetist and / or nurse anaesthetist has to ask or answer the question. Of the 143 team members not participating, 13 did not *want* to participate (6 surgeons, 1 nurse, 3 anaesthetists, and 3 nurse anaesthetists).

9.4.2. Debriefing

The Debriefing was performed completely in 341 cases. The nurse anaesthetist explicitly reported six cases in which the Debriefing was not followed; team members forgot to debrief (n=4), or most team members had already left OT (n=2).

<u>Duration Debriefing</u>

The duration of the Debriefing was recorded in all hospitals except hospital T1. On average the Debriefing took 58 seconds (STDEV = 58 sec) (A1: 68 ± 59 sec; A2: 73 ± 83 sec; T2: 54 ± 35 sec; C1: 30 ± 28 sec). However, there was a significant difference in duration of the Debriefing between the three locations. In the ambulatory care department of the academic hospital (A2, Average: 1.2 minutes) the Debriefing took more than twice as long as in the gynaecology department of the community hospital (C1, Average: 0.5 minutes). As with the Time Out Procedure no particular reason was indicated.

<u>Coordination of procedure by designated team member</u>

Only hospitals A1, A2 and T2 recorded if the designated team member asked and answered the questions. However, this part of the registration form was often (30.9-61.0%) not filled out

(Table 9.3). The remaining data show that the designated team member asked and answered the questions.

Table 9.3. Percentages of team members asking and answering the questions during the Debriefing

Asked by:	Question [%]	
	Details	Summary
Surgeon	60.4	36.7
(Nurse) Anaesthetist	6.7	2.1
Scrub nurse	1.2	0.3
Missing data	31.7	61.0
Answered by:	**Answer to question** [%]	
	Details	**Summary**
Surgeon	23.6	44.9
(Nurse) Anaesthetist	24.3	0.3
Scrub nurse	21.2	0.9
Missing data	30.9	54.0

Remarks / incidents

During the Debriefing 228 details were recorded. Seventy details encompassed 'Time Out Procedure remarks' (general remarks on the procedure) e.g., Time Out Procedure not performed, Debriefing partly or not performed, registration forms not completed. Twenty-three of these 'Time Out Procedure remarks' concerned the design or content of the TOP*plus* poster. For the Time Out Procedure this entailed:

- Add questions concerning: patient's allergies (n=7), previous surgeries (n=2), prosthesis (n=2), blood type (n=1), catheter inserted (n=1), lab test on drug resistant bacteria (n=2), medication (to be) given (n=1), availability of charts (n=2), and duration of procedure (n=1).
- Phrasing: replace 'epidural' with 'regional anaesthesia' (n=1).
- Some questions seem to be superfluous and other questions have to be added for specific procedures (n=5).
- Question E 'Which intra operative measures are necessary' is unclear (n=1).

For the Debriefing this entailed adding questions concerning: teamwork (n=1), surgical process (n=1), and postoperative measures (n=1).

Furthermore, one general comment was made: *'The fact that everyone should ask a question seems disorderly, but I guess I have to get accustomed to this'.*

Of the remaining 158 remarks, nine positive remarks were made, such as good communication and teamwork, and surgeon timely present.

Figure 9.4 presents the classification of the remaining 149 remarks. Fifty-one percent (n=76) entailed aspects relating to the non-technical skills communication and teamwork, leadership and situation awareness. The most frequent mentioned remarks are described below (for definitions see University of Aberdeen, 2006 [253]).

- Communication and teamwork: Lacking information on patient characteristics, surgical day schedule, necessary equipment, and surgical approach (n=21).
- Leadership: The surgeon does not (take the initiatives to) perform the Time Out Procedure adequately (n=13), and the surgeon is too late (n=2).
- Situation awareness: The Time Out Procedure was not performed adequately (n=11), the patient was not prepared adequately (e.g., markings, positioning) (n=8), and information in charts and on the computer was incorrect or missing (n=8).

Another substantial part of the remarks entailed the instruments / material. Of the 25 remarks, 15 reported defects and four reported incomplete instruments / material.

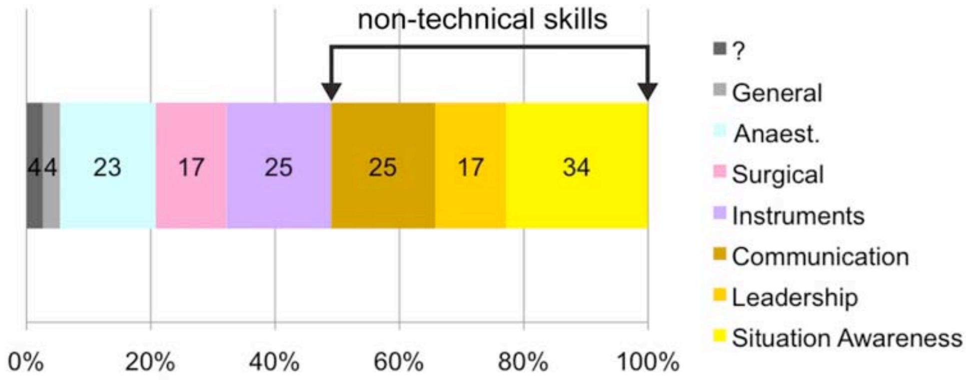


Figure 9.4. Classification of the 158 remarks concerning the procedure (anaesthesiological, surgical), the instruments or non-technical skills

9.4.3. Evaluation with the hospital-expert-team and adaptation of the poster by means of PD techniques

As a first step in the PD-process, before starting TOP*plus* in OT, the basic TOP*plus* poster was discussed in interactive discussions with the hospital-expert-teams (step 2, Figure 9.2). All hospitals decided to use the poster in the pilot phase without any alterations.

Following the pilot, a report was drawn up, describing all relevant items as discussed in the paragraphs above. After testing TOP*plus*, interactive discussions were conducted with the hospital-expert-team, asking them if the results portrayed the situation accurately (step 4, Figure 9.2). Most of the results were in line with their experiences. However, although they knew errors happened, team members were sometimes surprised by the amount of identical errors mentioned in the Debriefing.

Important items for redesigning the poster were the data on ‘coordination of the procedure by the designated team member’, ‘compliance with the poster’, and the remarks on the TOP*plus* design. Also the ‘incidents’ mentioned in the Debriefing were important as in case identical ‘incidents’ occurred rather frequently, it could be advantageous to add these (temporally) to the poster to improve situation awareness.

Table 9.4. Adaptations to basic TOP*plus* posters

Hospital	Question	T1	T2	C1
→	Start Time Out	√	√	√
A.	Name of the patient?	√	√	√
B.	Date of birth of the patient?	√	Add: Patient ID number & date of birth; check with wristband	√
C.	ASA classification? ≥2 explain	√	√	√
	Will it influence the procedure?	√	Add: Allergies	Add: Blood type, rhesus factor, anaesthetic details
D.	How many packed cells are ordered?	X	√	Moved to C
E	Which procedure are we performing	√	√	√
	According to which protocol?	X	X	X
	Is the patient positioned adequately?	√	√	√
	What are the critical moments?	√	√	√
	Which intra-operative measures are necessary?	√	X	X
F.	Which side will be operated on?	√	√	Moved to E
G.	Which type of anaesthesia?	√	√	√
	Did the epidural work?	X	√	√
H.	Are antibiotics administered? If yes, explain	√	√	Moved to C
I.	Are anticoagulants administered? If yes, explain.	Moved to C	√	Moved to C
J.	Are instruments & apparatus in working order?	√	√	√

√ question kept as if
X question deleted

The results showed that most questions were asked and answered as stated on the poster by the designated team member. The hospital-expert-teams of hospitals T1, T2, and C1 confirmed this, so there was no need to change the basic structure of the poster. However, the hospital-expert-team of hospital A (1&2) adapted the designated team member asking the questions, as they felt the current way of questioning / answering was counterintuitive and disruptive. It was decided to assign the nurse anaesthetist as designated team member for asking the questions. As a result, questions where the nurse anaesthetist was supposed to answer, the anaesthetist took over (see Figure 9.5).

Further evaluation of the remarks and incidents mentioned in the Debriefing resulted in deleting some questions, which were considered irrelevant and adding some questions which were not addressed in the Time Out Procedure, but perceived as being important in a specific local context of hospitals T1, T2, and C1. The most important adjustments for hospitals T1, T2, and C1 are presented in Table 9.4.

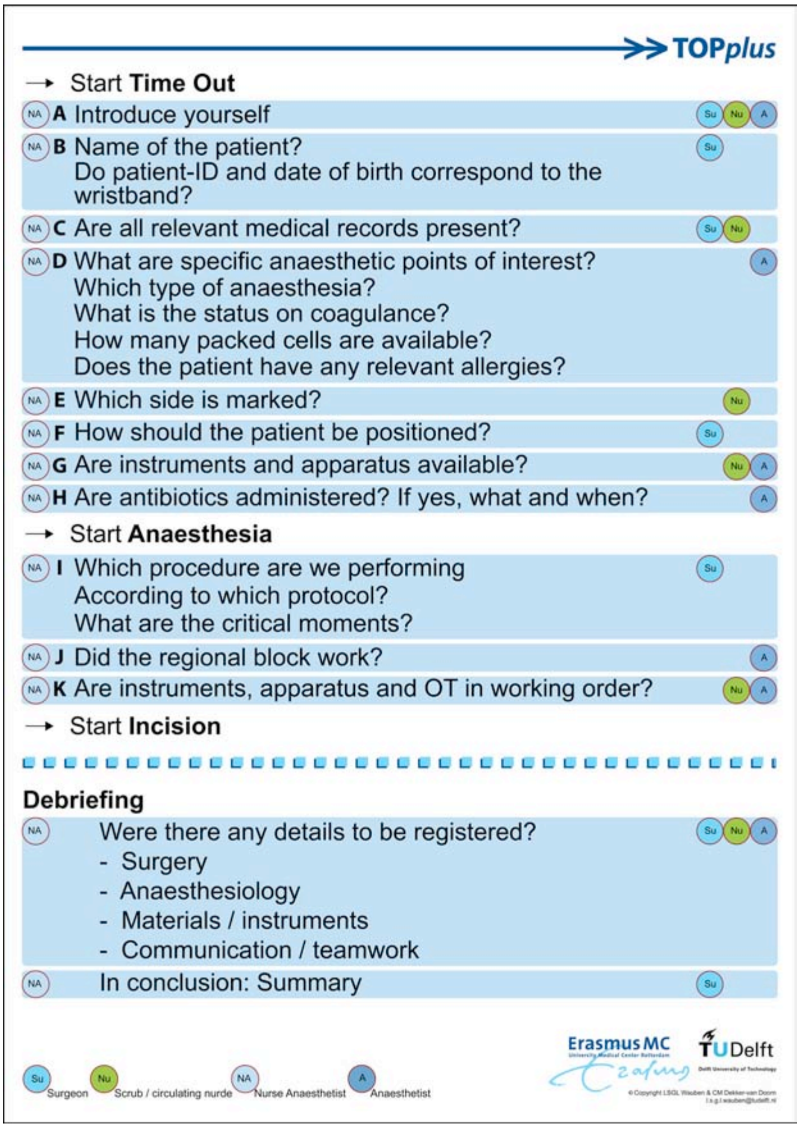


Figure 9.5. Redesign TOP*plus* poster for hospital A1&2

Another point of interest discussed with the hospital-expert-teams was when to perform the Time Out Procedure; just before incision? or before administering total or local anaesthesia? Hospitals T1, T2, and C1 decided to keep the original moment of the Time Out Procedure (just before incision), as all team members are present in OT and able to participate. In order to prevent incidents to occur however, they developed multi-disciplinary checklists carried out by two or more professionals during the transfer moments in the pre-operative process.

Rather than developing pre-operative checklists, hospital A decided to split the Time Out Procedure into two parts (Figure 9.5), as the results of the Debriefing showed that a significant part of the incidents (e.g., postponement of surgery, extra anaesthesia, repositioning the patient) could possibly be avoided if the Time Out Procedure would take place before anaesthesia.

Finally, another interesting point discussed with the hospital-expert-teams was related to the registration of the 'incidents'. The recorded incidents showed that a more detailed registration was necessary for adequate action. Therefore, all hospitals adapted the registration, creating four categories, as these incidents were the most frequent reported:

incidents related to surgery, anaesthesiology, materials & instruments and communication & teamwork (Figure 9.5).

9.5. Discussion

In order to reduce incidents and improve non-technical skills it was decided to design and implement the Time Out Procedure and Debriefing, one of the items of the CRM-concept, as the first step.[141, 165] This is important to create a fertile ground for other initiatives, such as team training and the introduction of checklist. Starting with TOP*plus* also provided team members with information about the whole peri-operative phase, and created awareness about the gaps in information transfer between team members and departments.

The first aim of this study was to design the TOP*plus* by means of participatory design (PD). Designing the basic TOP*plus* poster proved to be valuable and relatively fast and easy as the content was more or less provided. However, assigning the questions to the designated team members required the opinion of field experts. This resulted in most team member's tasks feeling appropriated and intuitive. This was also confirmed during the presentation in the participating hospitals. Here, the team members were invited to ask questions or post remarks on this basic TOP*plus* design. However, most comments were related to the duration and when to perform the Time Out Procedure and Debriefing and not to the design.

The second aim was to test the design's content and usability. During the pilots a large amount of registration forms was not (completely) filled out. This was probably caused by the high workload of the nurse anaesthetists. However, the recorded data showed that the TOP*plus* poster design was mostly used as intended and most team members participated in the process. Most hospitals only changed the order or the phrasing of the questions. However, hospital A also changed the designated team member asking the questions and the moment of performing the Time Out Procedure. The second version of the Time Out Procedure of hospital A seems similar to the first two parts, 'sign in' and 'time out, of the recently published 'Surgical Safety Checklist' of the WHO.[289]

When to perform the Time Out Procedure was also subject to discussion in the other hospitals. However, they chose to keep the original moment of the Time Out Procedure, as all team members would be able to be present in OT. However, they are now developing pre-operative checks (similar to check 1 of the WHO) to safeguard the process before induction of anaesthesia. Changing the moment of the Time Out Procedure will also require changes in other routine procedures e.g., the surgeon now has to be present before anaesthesia and has to bridge the time in the surgical department between the start of anaesthesia and incision. This means that the workflow and the work environment have to change accordingly (e.g., providing extra computers to perform administrative work during waiting).

The Debriefing was relatively undefined first, which probably explains the large amount of missing data for this part. Furthermore, this part of the registration could also be forgotten due to daily routines or activities to be performed by the nurse anaesthetist after the procedure. The results also showed a difference in duration of the Debriefing for the different hospitals. A logical explanation might be the number of people present in OT as of teaching aspects, and the fact that new people (residents, assistants) join the OT-team regularly. This might influence the time it takes for new work procedures to become a standard operating procedure. Another explanation might be the procedure's complexity, where standard protocols are not applicable.

During the Debriefing many details were (self) reported in contrast to the official error reporting systems, which only included incidents leading to direct patient harm. It seems that the threshold for reporting these details in the Debriefing was relatively low, partly caused by the 'pilot' character (without punishment) of the study.[141] Performing a Debriefing is important, since this is the part in which (small) defects in the procedure can be expressed and reported, providing insight in the 'errors' made. Furthermore, reporting makes it more visible for other people and departments, and it enables quantitative analysis.[54, 287] Reducing reported incidents could improve the operative process, as they often are relatively easy to solve, e.g., instrument related details, administration of antibiotics, surgical site infection.[62, 111, 265]

In this study, most incidents mentioned during the Debriefing were related to 'surgery', 'anaesthesia' and / or 'instruments'. Seeing that the TOP*plus* project focuses on reducing non-technical skills, 'team and communication' was added. The hospital-expert-teams and the design-expert-team therefore decided during the interactive discussions to add these four items to the Debriefing in order to remind the OT-team on reporting these incidents. The Debriefing is also comparable to the third part, the 'sign out', of the 'Surgical Safety Checklist'.[289] Moreover, future evaluation by means of case studies with the hospital-expert-teams will provide information if these four items are sufficient for reporting incidents. However, the registration in this study already provided valuable input for designing pre- and postoperative checks. Therefore, TOP*plus* acted as a catalyst for improving and checking the care process.

The final aim was to evaluate whether PD was an appropriate method for designing the TOP*plus*. PD proved to support situation awareness on design's specifications and the restrictions of the environment, and enabled the development of realistic expectations. Most professionals perceived the development of TOP*plus* as a very good initiative. Especially the ability to discuss the questions and adapt the content subsequently was much appreciated. Making small changes and making TOP*plus* context-specific is an important condition for establishing commitment and support of all parties involved, as ambulatory care, clinical care and some specific medical specialties have different requirements.[154, 266] The poster, and later the applications, should provide a template including basic questions (an 'in-addition-to' format). Hospitals and departments should then adapt the poster: add specific questions and topics relating to their local context and wishes. The questions on the poster should be 'owned' by all team members. However, the adaptations have to fit the original design: the Time Out Procedure is a double-check, all team members have to be present, and open questions have to be asked. Having a hospital specific design also contributes to a higher acceptance of this design. Other factors contributing to the acceptance is good communication (both presentations and documentation) before implementation, and enthusiasm of local hospital-expert-teams. This resulted in a relative high rate of participation; only 13 team members did not participate during the pilot.

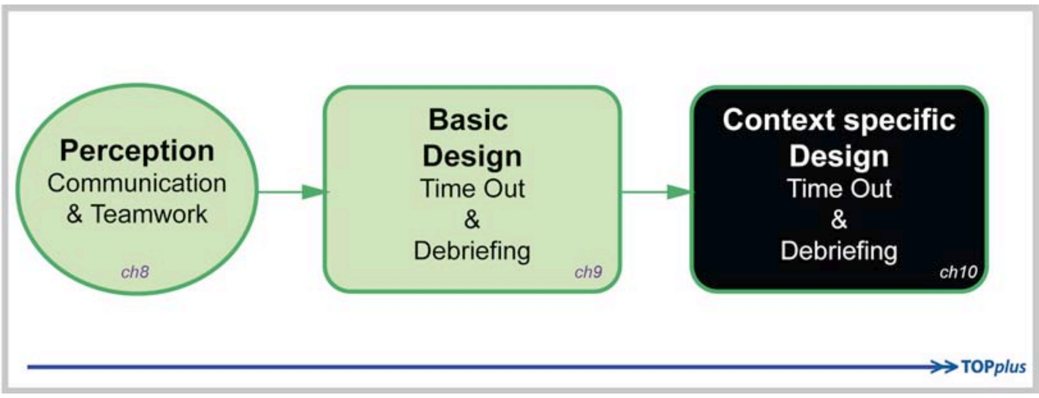
Another advantage of PD is the reduction of resistance to change. In most hospitals this was the case, as besides the basic design developed by the design-expert-team, the hospital-expert-team could also adapt the poster. This eliminated the resistance caused by 'not designed here'. Although at first 13 team members did not participate, it is expected that they will participate once working with the context-specific procedures. Nevertheless, PD proved to be insufficient for one hospital to fully implement the TOP*plus* as they did not finish the pilot. However, although TOP*plus* was not fully implemented at that moment, it started the dialogue between all surgical staff involved. In addition, it also acted as a catalyst for designing the pre-operative checks first, before further developing the double-check (Time Out Procedure).

The content and usability of the TOP*plus* proved feasible. Designing the procedure and content by means of the poster first proved advantageous, as the low costs enabled a fast introduction of the TOP*plus*. Now the next step is to design the applications using the PD approach, starting with digitalising the poster's content for performing the TOP*plus.*[128] Expected advantages of digitalisation will be the automatic registration of duration of the Time Out Procedure and Debriefing, built in barriers that prevent the procedure to be started before all necessary information and equipment is available and (double) checked, integration with the patient's electronic patient records, improve data collection, and the ability to design procedure specific Time Out Procedures and Debriefings.[62, 115, 257, 266] The ultimate goal of this instrument is however to reduce incidents in the peri-operative period and thereby improve patient safety.

9.6. Acknowledgement

The authors would like to thank the hospital-expert-teams and all team members of the participating hospitals for collecting all data and their input.

Chapter 10. From User-centred Participatory Design to Context-specific Design



Abstract

Initiatives to improve patient care in hospitals are often introduced without taking the human factor and the context into account. This then results in unsustainable improvements. In order to improve implementation and sustainability the overall objective of this study was to investigate the feasibility of context-specific design principles in addition to User-centred Participatory Design (UPC-Design method). In this study, the introduction and further development of a Time Out Procedure *plus* Debriefing (TOP*plus*) was taken as a case.

Based on the results it was demonstrated that UPC-Design can be of value for patient safety initiatives. It creates a structure to include most professionals in the design process and stimulates the adaptation of the 'product' to the needs of all team members, taking the internal and external environment into account.

Submitted as: Dekker-van Doorn CM, Wauben LSGL, van Wijngaarden JDH, Huijsman R, Lange JF, Goossens RHM. From User-centred Participatory Design to Context-specific Design in the Operating Theatre.

10.1. Introduction

Initiatives to improve patient care in hospitals are often introduced without taking the human factor and the context into account.[26, 96, 134, 140, 269] Initiatives like the introduction of incident reporting systems and redesign of care processes are usually developed with only a small group of people. As a result the new systems or processes do not support the professionals' tasks and responsibilities in their daily work providing patient care.[33, 135] Consequentially, these improvements are not always regarded as meaningful by the local professionals and therefore not fully implemented and not sustainable.[33, 135, 140] To achieve meaningful improvements Leape et al. (2009) concluded that healthcare organizations should pay attention to the human factor, look at the organization as a whole and create a culture of trust, reporting, transparency and discipline.

Innovative initiatives to improve patient care are hard to implement and problems encountered with implementation are diverse. Problems can be related to the complexity of the healthcare environment, to the resistance to change among healthcare providers, but also to the difficulty of standardizing the design and delivery of the interventions, and / or to their sensitivity to the needs and characteristics of the local context.[96, 110, 213, 217, 284] Another factor that could inhibit implementation of innovations in healthcare is 'the autonomous professional' working in a complex and dynamic environment.[96] In the World Health Organization's (WHO, 2008) report on safety issues two important organizational factors were identified as contributors to unsafe care.[288] First, a belief in trained perfectibility; after a number of years of long and intensive training, healthcare professionals are expected and expect to do the right thing and do it right. Second, there is a tendency to stigmatize and sanction the individual professional for failures. Errors are directly related to incompetence rather than a human error or system failure, which makes it hard on professionals to admit and discuss errors.[288]

Patient safety has received much attention over the last decade.[134, 273] The Institute Of Medicine's (2000)[134] publication 'To Err is Human' was the first of many international publications and worldwide initiatives to improve patient safety by taking both the human factor and the context into account.[58, 134, 273] One of the clinical areas in which patient safety has been under scrutiny is surgical care. More than 50% of patients hospitalized for surgical care are subject to an adverse event.[54, 58] The lack of standardized procedures, protocols, inadequate coordination of care and poor communication and teamwork appeared to be the main contributors.[58, 71-73] Because these contributors are located at different levels in the healthcare environment the need for a systems approach was emphasized.[71-73] Bogner (2003: p 122) stated that: *'…without addressing the environment as well as the person, consideration of safety issues is incomplete and misleading'.* Reason's 'Swiss cheese' model was one of the first models used in patient safety literature that included contextual factors and emphasized a systems approach.[210]

In the field of industrial design engineering (IDE) theories are developed to design products and systems from a users' perspective, so these can be used in a comfortable, efficient, and safe way. One of the leading theories used by designers is the theory of user-centred Participatory Design (PD).[182, 201, 224, 233] PD started in the field of computer science, and emphasizes active involvement of users in the design and decision-making processes.[50, 96, 201, 224, 233, 279] Furthermore, when designing products the context has to be taken into account as well. Research shows that applying these principles leads to user-oriented designs and to improved actual usage, compliance, and sustainability.[96, 201, 279] However, the authors could not find any research on the use of these theoretical approaches to design process support tools within a healthcare environment.

The overall objective of this study was to investigate the feasibility of context-specific design in addition to user-centred PD to improve patient safety in a surgical setting. In this study, the introduction and further development of a Time Out Procedure *plus* Debriefing (TOP*plus*) was taken as a case. Feasibility was defined as a) the possibility to introduce TOP*plus* involving all team members working in the operating theatre (OT), b) to fit the content of TOP*plus* to patient and context specific aspects and c) the willingness of OT team members to adapt their own working processes to incorporate the TOP*plus.*

10.2. TOP*plus* case

TOP*plus* aimed to decrease errors and improve communication and teamwork among team members working in OT.[111] Based on expert opinion and literature TOP*plus* was developed, to carry out a double-check in the presence of the whole team just before the start of the surgical procedure. A provisional poster, Figure 10.1, was developed to support the process and included all questions that are required to ensure patient safety during a surgical procedure.[71-73, 111, 288] On the poster it was indicated which team member had to ask or answer the question. The overall aim was to develop a simple procedure to catch and correct errors in OT before harm is done, and learn from it, leading to sustainable improvement.[79, 111]

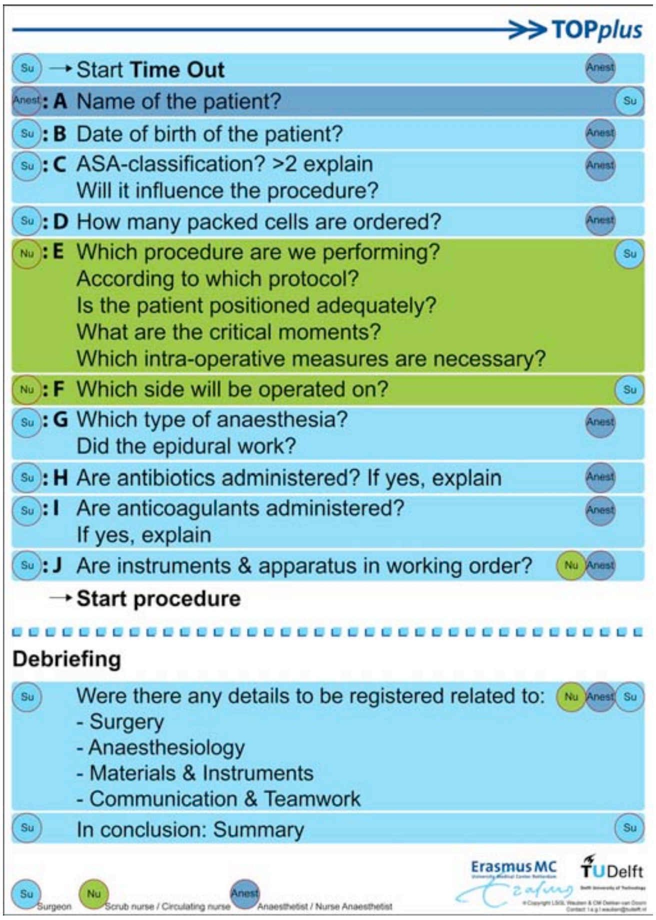


Figure 10.1. Basic TOP*plus* poster

The implementation process included the following steps:

- Introduction of TOP*plus* to OT team members of participating hospitals. Design provisional TOP*plus* poster with OT team members (1-2 months),
- Pilot TOP*plus* in one hundred surgical procedures (1 month),
- Analysis of pilot and redesign poster (1 month),
- Hospital-wide implementation of TOP*plus* (6-8 months),
- Final analysis and possible re-design poster (1 month).

10.3. Theoretical background

In order to improve implementation of new systems or processes, an optimal fit between the innovation and the local context has to be established. This requires both a redesign of work processes and a change in routine behaviour, taking different contextual levels into account, a so-called systems approach.

Although PD requires active participation of all users [50, 96, 224, 233, 279] it does not include a systems approach as such. Within the field of design looking from a systems perspective, the impact of new products, procedures or protocols can be expected at several contextual levels. The 'users' dealing with these factors have to participate actively during each design and implementation phase. The systems approaches proposed by Kim Vicente (Human-tech approach) and Bogner (Artichoke model) focus on the interaction between the users and their environment.[26, 269] Both approaches include several levels to be taken into consideration during the design process including the work environment, the physical environment, the social (team), the organizational environment and the overarching external environment (e.g., legal, cultural factors).

In addition to changes in work processes and procedures at different levels of the organization, there is also an impact at the individual level in changing routine behaviour. In the TOP*plus* case, two extra steps in the surgical process (performing the Time Out Procedure and Debriefing) and the presence of the whole OT team were required. Changing work processes also means unlearning routine behaviour and learning new procedures and demands special attention to reduce resistance during the process of implementation. When designing new systems or processes, user-centred PD should be completed with theories on learning and change.[37, 135]

Where Vicente and Bogner addressed the systems approach, Kotter (1996) looked at how this should be done. Looking at implementation of innovations from a learning and change perspective, he identified eight 'errors', which have a strong influence on organizational change efforts and the system as a whole (Table 10.1). He developed an eight-stage process to support change processes and leading change, as opposed to managing change. Rather than harnessing the implementation process in rules and regulations, his model emphasizes the necessity to involve all team members, to start with small incremental initiatives and to provide a lot of information and feedback beforehand and during the implementation process.

To improve implementation and adoption of TOP*plus*, the authors combined the user-centred PD design theory and Kotter's model on learning and change and developed the concept of User-centred Participatory Context-specific Design (UPC-Design).

Table 10.1. Eight-Stage Process of creating major change [135]

	Errors	Factors to support change processes and leading change	
1	Allowing too much complacency	Establishing a sense of urgency	Creating fertile ground for change
2	Failing to create a sufficiently powerful guiding coalition	Creating a guiding coalition	
3	Underestimating the power of vision	Developing a vision and strategy	
4	Under-communicating the vision	Communicating the change vision	
5	Permitting obstacles to block the new vision	Empowering broad-based action	
6	Failing to create short term wins	Generating short-term wins	Introducing new practices / procedures
7	Declaring victory too soon	Consolidating gains and producing more change	
8	Neglecting to anchor changes firmly in the corporate culture	Anchoring the new approach in the culture	Anchoring

10.4. Methods

10.4.1. Model of criteria and product characteristics

Using the design and learning and change theories requires active participation of the OT team members at all levels of the design and implementation process.[50, 96, 224, 233, 279] To visualise the user's influence in relation to the different levels of participation, the authors developed a model of product characteristics, presenting four different levels of users' influence: criteria, content, process and design (Figure 10.2). The users' influence on the level of criteria is nil, as these criteria should not be adjusted during the process of implementation. However, the user's influence increases with each level of product characteristics. At each level, the 'product' can be modified, to reach the users' expectations. To prevent loosing control and not achieving the desired end-product it is important to make sure that team members agree on the basic criteria underlying the innovation.[233] The basic criteria include underlying assumptions, but also rules or regulations required by law, professional associations or e.g., the Netherlands Health Care Inspectorate. Project leaders should safeguard these criteria and objectives during the process of implementation.[96]

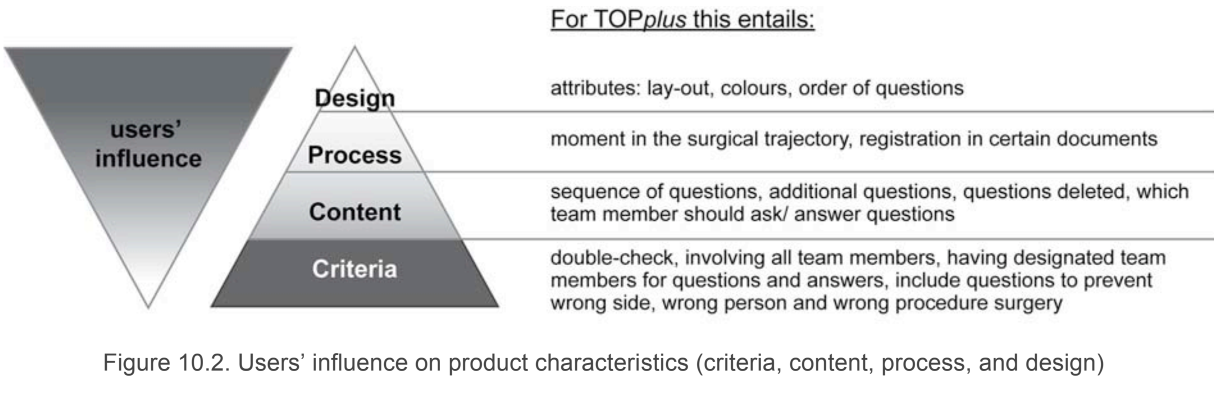


Figure 10.2. Users' influence on product characteristics (criteria, content, process, and design)

10.4.2. User-centred Participatory Context-specific Design (UPC-Design).

Figure 10.3 describes the process steps for UPC-Design. With UPC-Design three main groups are actively involved in the design and implementation process: 1) a design expert team (DET) - a small team of designers and key-users, 2) a local expert team (LET) - a delegation of the main users and 3) a local committee on quality assurance (for TOP*plus* a patient safety committee - PSC) to evaluate and, if necessary, redesign the innovation on a structural basis. It is important to involve a structural committee in the decision making process and make them accountable for evaluation and, if necessary, adjustment of the innovation. Evaluation on a structural basis prevents working procedures from becoming obsolete. Changes in the working environment, at the individual, organizational or overarching level, including legal, regulatory, reimbursement or cultural aspects, may require adjustments. In the TOP*plus* case the introduction of the electronic patient record led to e.g., changing the question: 'Are medical and nursing records available?' into: 'Is information from the medical and nursing record available?'

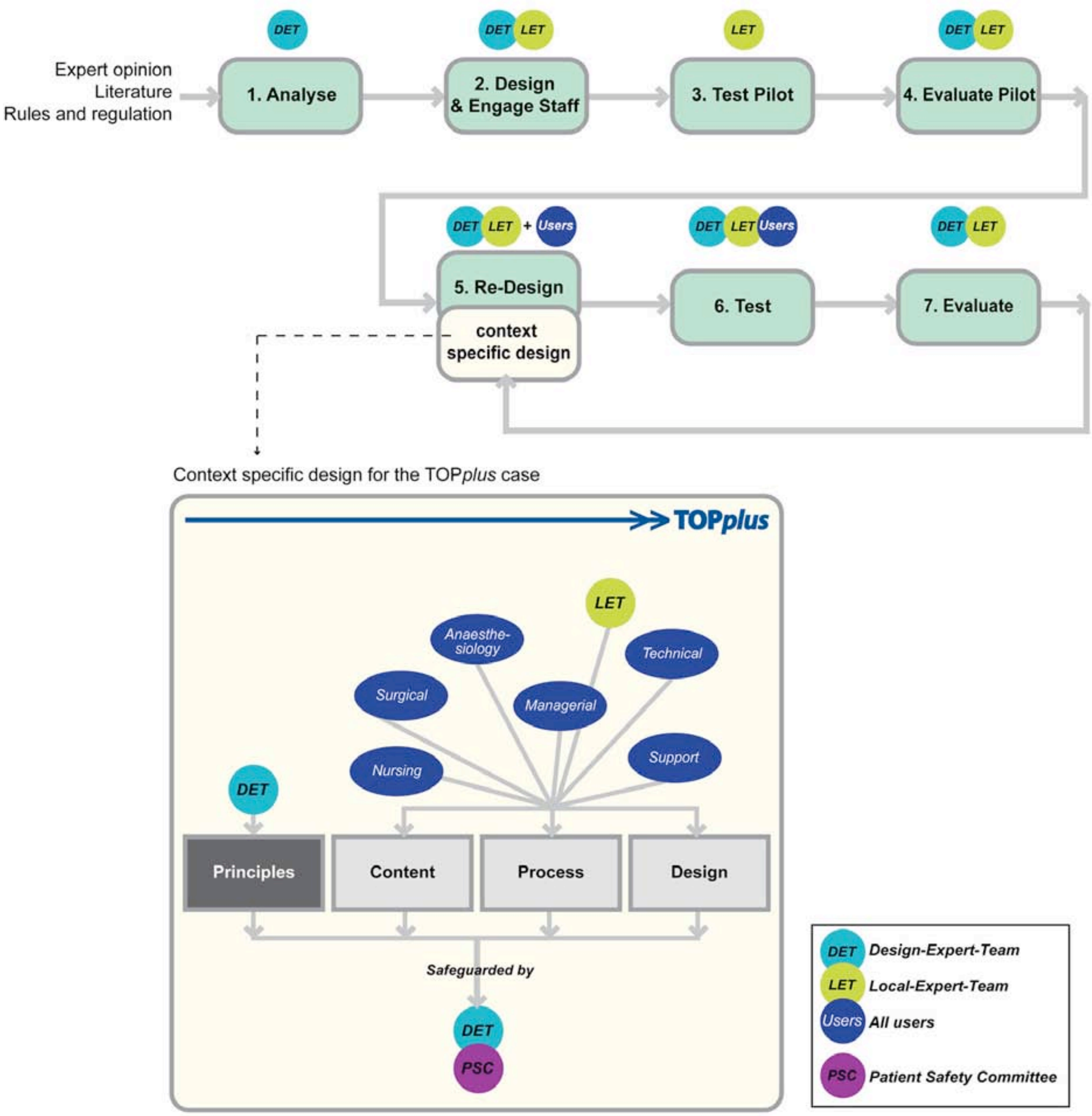


Figure 10.3. Process steps: User-centred Participatory Context-specific Design (UPC-Design)

Applying the UPC-Design model to TOP*plus* resulted in the following steps (Figure 10.3):

1. This step, analysing and gaining insight in the current situation, is initiated and carried out by the DET.[201, 279] Based on expert opinion and literature search a basic format for TOP*plus* (Figure 10.1) was developed and used as the first step for all participating hospitals.
2. Designing and engaging staff: within each hospital, a LET was established with representatives from each professional discipline involved in surgical care (e.g., surgical, nursing, anaesthesiology, managerial, support staff). Both the LET and the DET designed a provisional poster. The professionals directly involved in the surgical care of the patient (the LET) were encouraged to provide background information and the DET safeguarded the criteria.
3. Subsequently the LET tested the provisional design during one hundred surgical procedures. OT team members were invited to give feedback on the poster as well as on the procedure itself. Data on users and context specific aspects, including the willingness of users to change their own working processes, were gathered.
4. In this step, the results were evaluated by the LET and the DET. Suggestions to change the content of the poster or the surgical process (e.g., the presence of the whole OT team, the moment to perform the Time Out Procedure before or after anaesthesia, with or without the patient) were discussed to ensure the best possible introduction of TOP*plus* hospital-wide.

Following this first design cycle the poster needed to be redesigned. At this point, the context-specific design principles were included:

1. The DET provided written documents on the results of the pilot study and based on these results the LET and DET re-designed the poster. In case of hospital-wide implementation, *all* users provided input for the redesign.
2. Then the redesign was tested again. During this test cycle *all* users were invited to provide input on the three levels of product characteristics for redesigning the 'innovation'. Again, the DET safeguarded the basic criteria.[96]
3. The results of step 7 were communicated to the LET. Then the PSC, a structural committee often involving the members of the LET, monitors TOP*plus* as a structural element of daily processes. Both LET and PSC decided on the redesign, which was the start for a new cycle. Again the DET supervised the process.

The whole cycle will then be continued on a structural basis.

10.4.3. Data collection

Throughout the course of the project, data were gathered related to:

- Steps taken in the process of introducing TOP*plus* (i.e. number of meetings, emails, presentation, visits),
- Alterations in the content of the TOP*plus* poster (i.e. questions to be deleted / added, rephrasing of questions, re-ordering questions, assigning designated team member asking and answering questions),
- Alterations in the moment of performing the Time Out Procedure (before or after administering anaesthesia (induction)),
- Time needed for implementation hospital-wide.

10.5. Results

10.5.1. Participants

Twelve hospitals participated in the study: one university hospital with four locations (U1-4), five teaching hospitals (T1-5) and six general hospitals (G1-5). The locations of the university hospital are regarded as separate hospitals because of differences in size, patient population and medical staff and two of them (U1, U2) used to be so-called ‘categorical hospitals’ providing care to a specific patient category. One general hospital (G6) decided to quit the project just before the start of the pilot, partly due to resistance within the medical staff, partly to changes in management.

Six hospitals started the implementation of TOP*plus* with only one or two surgical disciplines (U1, T1, T2, T5, G1, G2) and eight hospitals with all surgical disciplines (U2, U3, U4, T3, T4, G3, G4, G5).

10.5.2. UPC-Design

Start project

After analysing the problem, designing the provisional poster (Figure 10.1) and deciding on the implementation process, a crucial element of step 2 (the pilot phase), was engaging the staff. The researchers (LW / CD) provided oral and written information to all OT team members.

Table 10.2. Users involved and support throughout the project

Hospital	**PowerPoint presentation**	**Project protocol**	**Email**	**Letter**	**Work floor visit***	**Support throughout the whole project with the hospital’s contact person.** Estimate number of:	
	- Background information patient safety - TOP*plus* principles - Aim - Phases - Timeline		- Background information - Aim - Usage poster			**Emails**	**Phone calls**
U1	All	All	All	All	All	100-150	10-20
U2	LET	All	All	All	n/a	50-100	10-20
U3	All	All	All	All	All	150-200	20-30
U4	All	All	All	All	n/a	50-100	10-20
T1	LET	All	-	-	n/a	50-100	10-20
T2	Surgeons	All	-	-	n/a	20-50	10-20
T3	All	All	All	-	All	50-100	20-30
T4	All	All	All	-	All	150-200	20-30
T5	All	All	All	-	n/a	20-50	10-20
G1	LET	All	-	-	n/a	20-50	10-20
G2	All	All	All	-	n/a	50-100	10-20
G3	All	All	All	All	n/a	20-50	10-20
G4	All	All	All	-	n/a	50-100	10-20
G5	All	All	All	-	n/a	20-50	10-20

All= Delegates from all professional disciplines (surgeons, anaesthetist, residents, nursing staff, managerial staff)

LET = Local Expert Team

n/a = not applicable

* Researcher was present at OT department during the pilot phase to answer questions

During the meetings preceding the pilot phase, the researchers provided additional information on the project (Table 10.2). During the course of the project, questions were answered via e-mail and telephone. The number of meetings and the content of written information were tailored to the needs of the team members of each hospital (Table 10.2).

Evaluation

After testing the provisional poster, the whole procedure and the content of the poster were evaluated based on the written feedback given by the OT team members. The results of the pilot were discussed in a meeting with the LET and the DET 4 to 6 weeks after the pilot phase. Written communication included evaluation of the TOP*plus* and detailed information on the use and usability of the poster.

Topics for discussion

During the meetings two main topics were discussed: the timing of the Time Out Procedure, before or after induction and the presence of all OT team members when performing the Time Out Procedure.

Eight hospitals decided to perform the Time Out Procedure just before skin incision, when the whole team would be present (T1, T2, T3, T5, G1, G2, G3, G5). Two hospitals split the Time Out Procedure into two parts (T4, G4). One hospital (U3) decided to initiate a pilot study performing the Time Out Procedure just before skin incision to see how the timing affected the number of errors. Figure 10.4 shows that in total 361 errors were registered during 1900 surgical procedures (e.g., no patient identification, sets of instruments incomplete, confusion about positioning of the patient). Half of these could have been prevented if the Time Out Procedure was performed before induction. As a result, it was decided to perform the Time Out Procedure before induction. This information was valuable input for discussion in other participating hospitals. Hospitals would then decide to perform the Time Out Procedure before induction or to adjust the pre-operative trajectory by introducing an extra check before induction. Both are adequate solutions to catch and prevent errors.

In the redesigns, nine hospitals kept the original moment of performing the Time Out Procedure just before skin incision. Five hospitals decided to split the Time Out Procedure into two parts (U1, U3, T3, T4, T5): one part before induction and one part before skin incision. Precondition was that all team members would be present in OT during both parts of the Time Out Procedure.

Another topic for discussion was the presence of the surgeon when performing the Time Out Procedure before induction. Three hospital locations (U1, U2, U4) decided to have one of the residents present instead of the surgeon to perform the Time Out Procedure, providing the resident was well informed about both the patient and the surgical procedure. If residents are well informed and are assisting in the surgical procedure, this solution is more than adequate.

Another point for discussion was whether to perform the Time Out Procedure with the patient present and not yet under anaesthesia or without the patient. One of the participants, U1- children's hospital, decided to perform the Time Out Procedure in OT with the whole team but without the patient. For some categories of patients undergoing critical surgery it is still not decided which solution would be best.

Figure 10.4. Errors (n=361) registered during pilot phase of hospital U3

Adapting TOP*plus* to the Context

Adapting TOP*plus* to the local context was introduced as an additional step to ensure that all questions and remarks given as feedback were addressed and discussed. The LET communicated the results to all OT team members including all surgical disciplines. They were invited to comment on the product characteristics. The DET made sure the basic criteria were safeguarded. If there was consensus among team members, TOP*plus* was adapted.

The DET would take care that useful information gathered in one hospital would become available to all participating hospitals and lessons learnt in one hospital would be taken into account when discussing alterations to the poster or adapting TOP*plus* with expert teams in other hospitals.

Redesign of Time Out Procedure

The hospitals made several changes in the posters that were used for the Time Out Procedure (Table 10.3). The order of questions remained the same in most redesigned context-specific posters. Hospitals U1, U2, U3, T5 and G1 clustered the questions and therefore changed the order. Changing the order of the questions does not present any problems, since all questions will be answered at that specific moment. Four hospitals also changed the designated team member asking questions. In hospitals U1, U3 and T5 it was decided that the nurse anaesthetist would ask all questions, and in hospital U4 the circulating nurse as they experienced that having different team members asking questions was confusing. As long as all OT team members were involved in answering the questions, the Time Out Procedure would still be a team effort, which is one of the objectives of the project. The designated team member answering questions remained the same for most questions.

In most redesigns of the Time Out Procedure, elements were added or deleted. Again the DET safeguarded the criteria. On average three questions were deleted and three questions were added (Table 10.3). Some of the Time Out Procedure questions were rephrased and adjusted to the local context.

Table 10.3. Changes in the Time Out Procedure

Questions deleted:		U 1	U 2	U 3	U 4	T 1	T 2	T 3	T 4	T 5	G 1	G 2	G 3	G 4	G 5
A:	Name of the patient?														
B:	Date of birth of the patient?														
C:	ASA classification? ≥2 explain	D	D	D	D									D	
	Will it influence the procedure?	D	D								D		D		D
D:	How many packed cells are ordered?	R		R	R	D	R	R	R	R			R	R	D
E:	Which procedure are we performing														
	According to which protocol?		D		D	D	D	D	D		D			D	
	Is the patient positioned adequately?				D			R	R						
	What are the critical moments?		R		R		R	R	R		R		R	D	R
	Which intra-operative measures are necessary?	D	D	D	D		D			D	D		D	D	
F:	Which side will be operated on?														
G:	Which type of anaesthesia?		D												
	Did the epidural work?	R	D	R	D	D	R	D	R	R	D	D		D	
H:	Are antibiotics administered? If yes, explain														
I:	Are anticoagulants administered? If yes, explain.	D	R	R	R		R			R					
J:	Are instruments & apparatus in working order?														
Elements / Questions added:		**U 1**	**U 2**	**U 3**	**U 4**	**T 1**	**T 2**	**T 3**	**T 4**	**T 5**	**G 1**	**G 2**	**G 3**	**G 4**	**G 5**
	Relevant allergies	A					A	A	A	A		A	A	A	
	Compare name and date of birth with identification (wrist band)	A		A	A		A		A						
	Implants, prostheses				A		A			A	A	A			
	Right side marked?	A		A						A		A			
	Does everybody know each other?	A		A	A										
	Co-practitioners informed	A						A	A						
	Anaesthetic points of interest			A							A				
	Anamnesis	A													
	Lab results known	A													
	Medical and nursing record available / present			A											
	Infections				A										
	Study patient								A						
	Blood group / rhesus factor										A				
	Diathermy plate placed											A			
	Are blood products requires? If yes, are these present?														A

D=question deleted, R= question rephrased, A= question added

Alterations were regarded as improvements. Questions deleted concerned questions that, for a specific medical discipline or patient care process, were obsolete (e.g., the question about blood products being present or ordered, while these are never needed when performing surgical procedures in ambulatory care). Rephrasing questions was most of the time related to the specific patient and information flow (e.g., changing the question: ‘which side is operated on’ in ‘which side is marked’). Adding questions was often related to communication failures in the surgical process in that specific hospital (e.g., subjects like informing support staff like radiology with the start of the operation, or making sure that postoperative assignments are communicated). The DET supervised the process to safeguard the questions that are obligatory and took care that the proposed changes were discussed in depth and would improve the surgical process.

Redesign of Debriefing

Six hospitals (U3, T1, G1, G2, G3, G5) kept the original format for the Debriefing (except the designated team member asking the question, which was changed similar to the Time Out Procedure). Hospital U2 deleted 'In conclusion: summary' and hospital G4 deleted 'details on communication and teamwork'.

Five hospitals added one question and one hospital added two questions. The questions added were: 'Postoperative instructions?' (U1, T2, T3, T4, T5), 'Patient transferred in patient data management systems' (U1) and 'details on perfusion' (U4). These were added as these topics often presented problems in these specific hospitals. By adding them to the Debriefing, the LET solved these problems and prevented errors in the postoperative trajectory.

10.5.3. More time to implementation

Context-specific design requires allowing more steps in the design process and more time for discussion to be able to adapt the poster to the needs of the local OT team. Therefore, it is important to evaluate the amount of time needed for implementation.

Initially, it was expected that the project would take about one year from the first introduction using the provisional poster to hospital-wide implementation of the final version of the poster adjusted to the local context. Looking at the results, most hospitals exceeded the planned time schedule. Analysis included four elements (Figure 10.5):

- 'Time to implementation': the time from first meeting with the LET till implementation on a small scale, the pilot. Analysis showed large differences in time to implementation. In five hospitals (U1, T1, G1, G3, G5) time to implementation took two to four months, in six hospitals (U4, T2, T4, T5, G2, G4) five to eight months, and in three hospitals (U2, U3, T3) one year or longer. There was no difference in number of adjustments related to exceeding the planned 'time to implementation'. In fact all three hospitals where time to implementation was one year or longer, started implementation using the basic design of the poster without any alterations. Most of the extra time was spent on extra meetings with OT team members and to discuss the consequences of the project.
- Pilot: Each pilot phase took approximately one month.
- 'Small scale implementation': implementation of the re-designed TOP*plus* including the same OT team members. This was not applicable for five hospitals (U2, U3, U4, G4, G5) as they decided to implement TOP*plus* hospital-wide from the start of the pilot. In five hospitals (T1, T2, T4, T5, G1) this phase took two to four months, in four hospitals (U1, T3, G2, G3) five to eight months.
- 'Hospital-wide implementation': involves the start of implementation of TOP*plus* in all OT's with all surgical procedures. Nine hospitals (U1, U4, T1, T4, T5, G1, G3, G4,

G5) implemented TOP*plus* hospital-wide within one year as planned. Five hospitals (U2, U3, T2, T3, G2) exceeded the predicted period of one year.

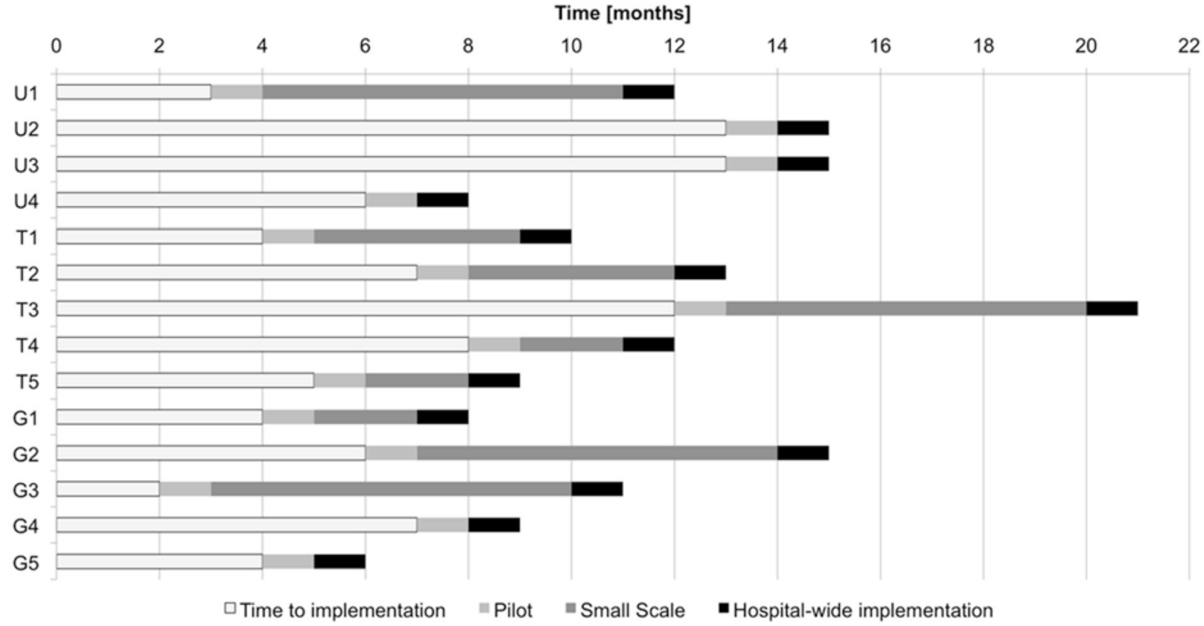


Figure 10.5. Time from the start of the project to hospital-wide implementation

10.6. Discussion

10.6.1. Pre-anaesthesia check

In general the TOP*plus* project can be described as successful in several ways. Using the UPC-Design method improved team discussion and active participation of *all* team members during the design and implementation process. UPC-Design also improved adapting the procedure to the needs of the local context, which in turn improved implementation of the project hospital-wide and including adapting work procedure accordingly.

The discussion on the pre-anaesthesia check has improved the surgical process in all hospitals. Hospitals that decided to keep the Time Out Procedure with the whole team present just before skin incision developed an extra check before induction, involving at least two team members including the anaesthetist. With this procedure, they were capable of catching and correcting errors before harm was done. As explained above the changes in the questions also added value to the procedure. The large amount of feedback given by all team members provided a lot of information on failures in the local processes. Adding or rephrasing questions often meant addressing specific problems within the local context and correcting procedures where possible.

10.6.2. Team discussion and active participation of all team members

The Time Out Procedure designed as a team effort stimulates all OT team members to speak up and voice concerns and questions, thus improving interdisciplinary communication and team learning.[79, 111] By stimulating team discussion it also stimulates working in multi-disciplinary teams rather than professional silos.[79] Using UPC-Design facilitates and structures team discussion and participation of all team members, rather than one or two dominating professional disciplines.[233] As a spill-over it also improved insight into each other's roles and responsibilities in the surgical process.

10.6.3. Hospital-wide implementation

With the necessary context-specific adaptations, TOP*plus* is integrated into daily routine procedures hospital-wide in all participating hospitals. This in spite of the inconvenience it causes for some surgical disciplines. Discussing patients early in the morning is a longstanding daily routine for most surgical disciplines and does request the presence of all surgeons and residents. Adapting this process so the surgeon or resident can be present in OT when performing the Time Out Procedure, is difficult and interferes with the normal routine.

TOP*plus* is a simple procedure and the benefit is evident for most professionals. The concept of UPC-Design provided the necessary steps and data to facilitate implementation.[102] The different steps provided the necessary time and opportunities to adapt TOP*plus* (trial-ability, reinvention).[33, 96, 102, 279] The data of the first pilot phase showed clear evidence that TOP*plus* improved both the clinical process and patient outcomes (observe-ability).[102] These are also the most often reported facilitators for implementation, thus creating awareness and reducing resistance.[101] In most cases the focus in the discussions with the OT team was related to the moment of the Time Out Procedure and not *if* a Time Out Procedure should be introduced.

Other elements that facilitate adoption are the internal and external fit.[26] Disciplines that found it difficult to organize the presence of the surgeon to perform the Time Out Procedure before induction, tried to find alternative solutions. One discipline (neurosurgery) proposed to perform the Time Out Procedure the day preceding the surgical procedure and to adapt work processes accordingly (internal fit).[26]

An element that facilitated the acceptance of TOP*plus* from an external source came from the Netherlands Healthcare Inspectorate, which audited 28% of OT-departments.[71-73] One of the recommendations was the introduction of a time out procedure in OT (external fit).[26] This underscores the importance of looking at innovations from a systems perspective and focus on the interaction between the 'users' and their environment, internal as well as external.[26, 111, 269]

Since there are different solutions to solve problems there is not one best solution. The solution that leads to 'catching and correcting errors before harm is done' presents the best solution for that specific hospital in that specific situation.

10.6.4. Spill-over

An additional and valuable spill-over was the creation of a learning network involving several hospitals, including hospitals that were not involved in the project. OT teams from different hospitals easily exchanged ideas and information on procedures or protocols, like development of a checklist covering the whole operative trajectory. Other hospitals contacted the researchers for additional information. Five additional hospitals are now using the same procedure.

10.6.5. Limitations

The voluntary basis on which hospitals participated in the project, might have influenced the results in a positive way to a certain extent. In most hospitals some resistance of OT team members was present, which resulted in more time needed for introducing TOP*plus* hospital-wide.[279]

Although participating on a voluntary basis might be of influence, the role of the project initiator and including the medical professional might even be more important for implementation.[201, 279] One hospital (G6) decided to quit participation in the project. However, it did start the dialogue between all surgical staff involved and acted as a catalyst for designing the pre-operative checks first, before further developing the Time Out Procedure. In this hospital, the managers were the initiators of the project and the professionals were not actively involved in the design. In most hospitals, the initiative originated from one of the medical disciplines, which might have facilitated implementation. Looking at the elements to create 'a fertile ground' for 'change' it is important to put the professional in the lead and actively involve all team members.[96, 135, 201, 233]

Another limitation of the study is the lack of patient participation. Although the whole project aims at improving patient care, the patient perspective was not represented by membership in the design team. In this project it was decided to focus on participation of the professionals and the fit to their local context.

10.6.6. Recommendations for implementation of innovations in healthcare

Based on this case study, using the UPC-Design method in healthcare, the authors recommend going through all the steps of the UPC-Design model for a full adoption in each hospital. This is necessary as the requirements are context specific and loosely coupled. Secondly, extra iterations should be allowed if necessary. Thirdly, participation of all OT team members through the whole process and patient participation from the start has to be encouraged. Fourthly, the project's objectives and its underlying criteria should be safeguarded, and finally a structural committee (PSC) should take responsibility to initiate iterations on a structural basis and continue the redesign process.

This study included fifteen locations in a hospital environment. Further research on the use of UPC-Design should focus on effective use of this concept in the whole surgical trajectory (from patient admission to discharge). The same result might be expected since the principles and theories underlying the concept of UPC-Design are universal.[135] A second area for research is sustainability and adaptation of the procedure over time. In this project, the time for implementation exceeded the predicted period of one year in five out of 14 cases, but finding results for a longer period of time and looking at adaptations following hospital-wide implementation over a period of time would be interesting.

10.7. Conclusions

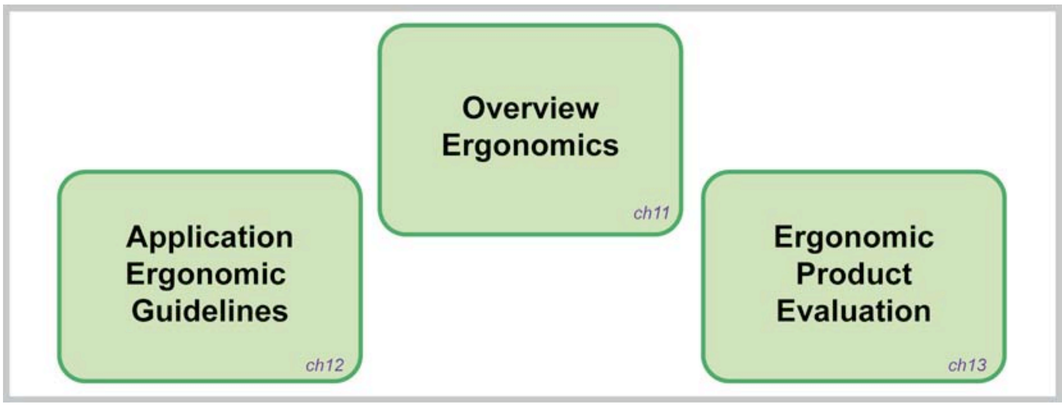
Although time will show if the implementation using UPC-Design in a surgical setting leads to real sustainability, the first results are promising. Based on the TOP*plus* case it was demonstrated that this method can be of value for patient safety initiatives. It creates a structure to include the majority of the professionals in the design process and adapt the 'product' to the needs of all team members, taking the internal and external environment into account. UPC-Design also provides a mean to integrate these elements in the process of implementation in a structured and controlled way. Although eighteen posters were developed, no significant differences were found between the posters. All the required elements to ensure patient safety during the surgical process were present. As TOP*plus* is a process guideline and not a medical protocol slight alterations, respecting the principles, are allowed. In this study, the researchers took the role of the ‘reflective practitioner’ safeguarding the underlying criteria and objectives. When using UPC-Design in daily practice one of the clinical professionals should take this role.

10.8. Acknowledgement

The authors would like to thank the local expert teams and all team members of the participating hospitals for collecting all data and their input.

Part C

Ergonomics in the Operating Theatre



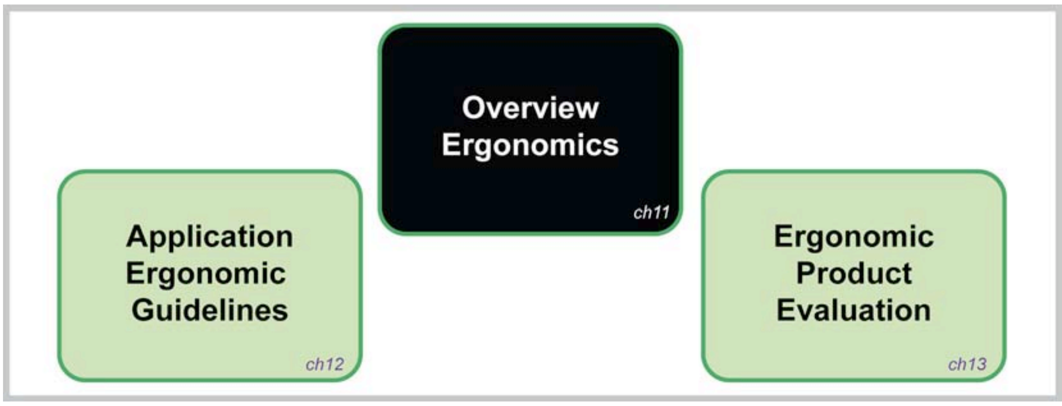
Introduction

A third factor contributing to improving patient safety is applying ergonomics in the operating room. When a focus is put on ergonomics of the operating theatre, 'the environment has to be adapted to the operating team members instead of asking adaptation from the team members to their environment'. Improvement of ergonomics leads to less stress, less strain, and reduces fatigue, which prevents injuries to the surgical team and enhances their performance.

The classic way to define domains in ergonomics is to define clusters along the different human capacities when interacting with products. These activities take place in the physical and mental domain, and require transformation of information from physical to mental via the senses. Therefore, physical, sensorial and cognitive ergonomics is a good basis to be used towards understanding the interaction in the operating theatre. As the environment is an important factor for the operating theatre, environmental ergonomics is added to this basis.

This part first provides an overview of ergonomics for both open and minimally invasive surgery in the operating theatre (chapter 11), followed the application of ergonomic guidelines during minimally invasive surgery (chapter 12). Finally, chapter 13 describes the product evaluation of surgical lights during open surgical procedures.

Chapter 11. Overview of Ergonomics in the Operating Theatre



Abstract

Due to the growing variety of technical machines, products and increasing safety awareness, many ergonomic specializations have evolved, i.e. ergonomics of the operating theatre (OT). Ergonomics is aimed to adapt the environment and its products to its users, however, currently there is a gap between this aim and reality in OT.

The importance of ergonomics becomes obvious realizing that new products and environments are developed continuously and that the guidelines to be used by designers are partly based on scientific data of ergonomic studies. To introduce a new product design without the use of these findings can create (health) risks and inefficiency in processes. Especially in activities that demand a long, intense, and complex interaction with products, as in OT, ergonomics has to play a major role, especially in the light of safety.

The three main domains of specialization of ergonomics are related to sensorial, cognitive and physical ergonomics. This chapter provides an overview of these aspects and its problems in OT. In addition, brief attention will be paid to a new domain 'environmental ergonomics'.

In conclusion, the OT environment is changing drastically, from OTs designed for open procedures solely, to specially designed surgical suites focusing on Minimally Invasive Surgery and / or robotic surgery. More and more technology is incorporated, making OT a more complex and high-risk environment. With this complexity increasing, design teams have to be multi-disciplinary, consisting of e.g., technicians, ergonomists, medical staff, jurists, software designers, hardware designers, user interface specialist, end-users. They all have to be included and participate in the whole design cycle: from first hunch until prototyping taken all ergonomic domains into account. In the end, ergonomics should make sure that the advances in technology are to facilitate surgery and not to complicate it, because at the sharp end of these technologies lie patients whose well being is the first priority.

Adapted from: Wauben LSGL, Albayrak A, Goossens RHM. (2009). Ergonomics in the Operating Room - An overview. In Ergonomics: Design, Integration and Implementation. *Nova Publishers, New York.* (ISBN 978-1-60692-327-6).

11.1. Ergonomics domains

The word ergonomics originates from the Greek words 'ergon' (labor) and 'nomos' (law). Ergonomics (or human factors) is a rather young discipline that exists just 60 years as a formal body of knowledge. Ergonomics studies and seeks to minimize risk factors between human beings and the tasks and environment that occupy them.[18, 142]

The International Ergonomics Association defines the discipline of ergonomics and the ergonomist as follows:[295]

'Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human wellbeing and overall system performance'.

'Ergonomists contribute to the design and evaluation of tasks, jobs, products, environments and systems in order to make them compatible with the needs, abilities and limitations of people'.

The still growing variation in products that are used nowadays requires lots of knowledge from both human and technical sciences. This implies that nowadays many new specializations of ergonomics can be found. Furthermore, this means that a lot of uncertainty is met when ergonomics is applied to a new field at the frontiers of knowledge, like in surgery.

Focussing on ergonomics in the operating theatre (OT), product designers should 'adapt the environment to the operating team members instead of asking adaptation from the team members to their environment'.[98, 277] This focus means aspects like physical ergonomics, interactions within the operating team and the interaction with the over 100 products that surround them, should be studied. Some of these products are very low-tech and easy to learn, but others are very complex and require days and sometimes weeks of practice before these can be used in a safe way. Especially with the introduction and widespread acceptance of minimally invasive surgery (MIS), ergonomics has acquired an increased importance.[142] The classic division of ergonomics into physical, cognitive and sensorial is also applicable during both open surgery and MIS (Figure 11.1). However, the environment is an important factor for the OT. Therefore environmental ergonomics is added to this basis.

The following sections will describe the major ergonomic problems encountered during surgery as improvement of ergonomics leads to less stress, less strain, and reduces fatigue, which prevents injuries to the surgical team and enhances their performance, thus lowering error rates.[176, 211]

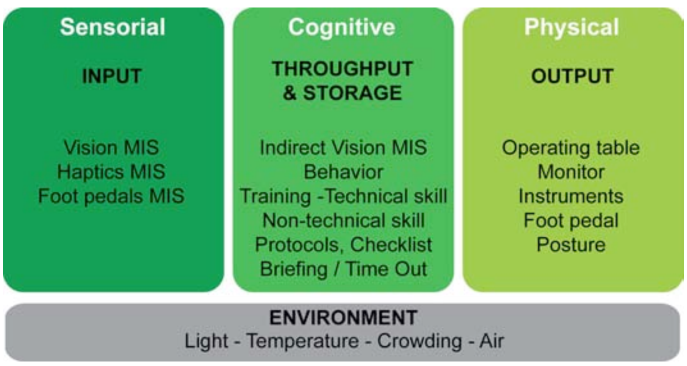


Figure 11.1. Overview ergonomics during surgery

11.2. Sensorial ergonomics

Sensorial ergonomics focuses on human senses, human perception and factors influencing these. Problems occur when there are difficulties getting the necessary information from the environment. As most of the sensorial problems are seen during MIS, this section focuses on MIS procedures.

11.2.1. Vision

The indirect vision and indirect control on the internal organs limits the visual feedback.[283] This 2D vision of a 3D environment makes accurate spatial orientation and ensuring manoeuvres very difficult.[95, 160] The surgeon's perception and performance is affected and errors can occur due to misinterpretation and false perceptual information of the video images rather than errors in skill, knowledge or judgment.[237, 278] Furthermore, coordination problems during movements occur, as the displayed is not aligned with the operating field.

Annoyingly, sometimes (0-10 times per procedure) the lens of the endoscope becomes unclear due to soiling of the lens (e.g., fog, smoke, blood).[223] This requires extra cleaning and could lead to a longer operative time because the endoscope has to be retracted, cleaned (mostly with warm saline solution) and re-introduced in the trocar each time.

Other factors influencing the view are: unintentional movements of the endoscope by an in-experienced camera assistant,[95] obstruction of the sight on the monitor by other persons or equipment, and inadequate angle of incidence on the monitor (causes mainly problems with flat screens).

11.2.2. Instrument's haptics

Haptics are the combination of tactile perception (through skin receptors, sensing pressure, vibration, and texture) and kinesthetic perception (through muscle, tendons and joints sensing position, movement and forces).[283] Lack of good haptics endangers patient safety, e.g., instruments could damage tissue or organs by grasping too firm.[255, 272]

MIS instruments reduce the haptic feedback considerably (tactile feedback is eight times lower than of bare fingers).[65, 283] Several other factors also interfere the haptic perception:[234, 283]

1. Friction between the trocar and instrument shaft.[52, 234]
2. Resistance of the abdominal wall during a lever movement.
3. Scaling and mirroring of the tip forces (0.2-4.5 times the force generated by loss of force transmission, up to 50%.[17]
    - Variable force transmission, uncertainty about the grasp force exerted on the surgeon's hand when using the same operating force.
    - Lower mechanical efficiency than open instruments.[17, 19]
4. Reduced haptic sensation due to:
    - High velocity of translation movements.
    - Large angle of tilt.
    - Inefficient-accurate mechanical mechanism.

Although some product solutions are available, still the instruments do no have full haptic feedback comparable to open surgery.

11.2.3. Foot pedals

Foot pedals are mainly used to operate devices for coagulation, suction and irrigation.[277] Diathermy is used to separate tissue and small vessels.

There are two methods (each with two speeds) to reach this transformation of tissue: High Frequency electro surgery (HF) and Ultrasonic Dissection (UD), which uses ultrasonic vibrations. The pedal placement for variable power (coagulating) versus full power (cutting) of the UD are opposite from the placement for HF. This could be confusing as both types can be used during a procedure.

Other sensorial problems are:[159, 162, 262, 277]

1. There is no direct view of the pedals, as these are on the floor under the operating table, which is covered with sterile sheets in weak light (especially during MIS). The pedals get lost increasing the risk of hitting the wrong pedal, which is annoying and potentially dangerous for the patient.
2. Pedals can move unintentionally farther under the table, so that contact is lost and the surgeon has to look down to restore the right position of the foot.

11.3. Cognitive (perceptional) ergonomics

Cognitive ergonomics studies the throughput and storage of information. Problems occur when the offered information is difficult to interpret.

During surgery the surgeon has to execute a primary and a secondary task (Figure 11.2). However, the surgeon only has a limited amount of mental workload.[38] In addition, parallel tasks require attention to several things and time pressure and stress makes completing several tasks even more difficult.[38, 244] Therefore, product design, instruments and training should reduce the mental workload required to maintain acceptable performance levels in the primary surgical task. Design features should be included that reduce the amount of time the surgeon must hold information in working memory prior to its use, and reduce the non-essential, error-prone mental operations that surgeons must perform.[38]

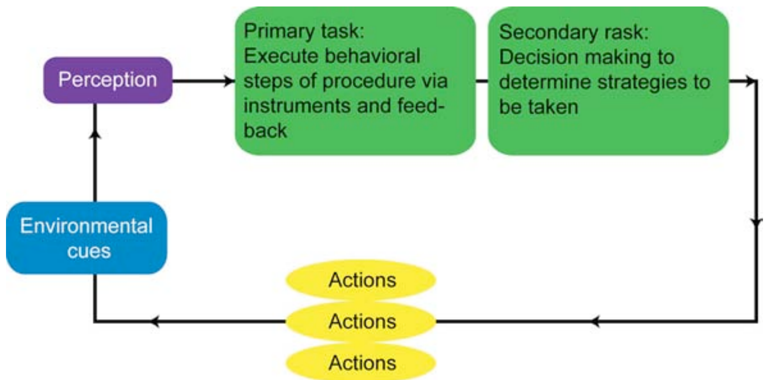


Figure 11.2. Simplified procedure during surgery (adapted from Carswell 2005)[38]

11.3.1. Vision

The indirect view during MIS causes cognitive problems, such as [6, 29, 95, 107, 229, 234, 280, 281]

1. Need for high concentration levels of the surgical team.
2. Interpretation of the 2D image of a 3D environment.
3. Magnified view (which also can be an advantage).

4. Limited, small field of view.
5. Insufficient resolution.
6. Insufficient light.
7. Disturbed hand-eye coordination due to:
   - Loss of depth perception.
   - Misallocation of the visual and motor axis.
   - Disorientation of instruments (fulcrum effect: mirroring and scaling of the actions).
   - Indirect control of endoscope (controlled by the camera assistant).
8. Movement and rotation of the endoscope due to inexperience, or loss of concentration of the camera assistant.

11.3.2. Instruments / equipment

Foot pedals also cause cognitive problems, such as: identical pedals force the surgeon to look down to see which pedal (s)he is pushing, restoring contact interrupts the concentration, and the interpretation of the pedals' function and use is not intuitive (which could lead to accidently pressing the wrong pedal).[159, 162, 262, 277]

Changing instruments and repositioning within the abdomen also poses a safety risk to the patient, because it disrupts the flow of the procedure, which can break the surgeon's concentration.[162, 166]

Finally, the indirect control over the position and orientation of the endoscope could lead to disorientation and misinterpretation of the position of the target organs.[95]

11.3.3. Behaviour

A model to describe human behaviour is Rasmussen's model, distinguishing three levels of behaviour: skill-, rule-, and knowledge based (Figure 11.3).

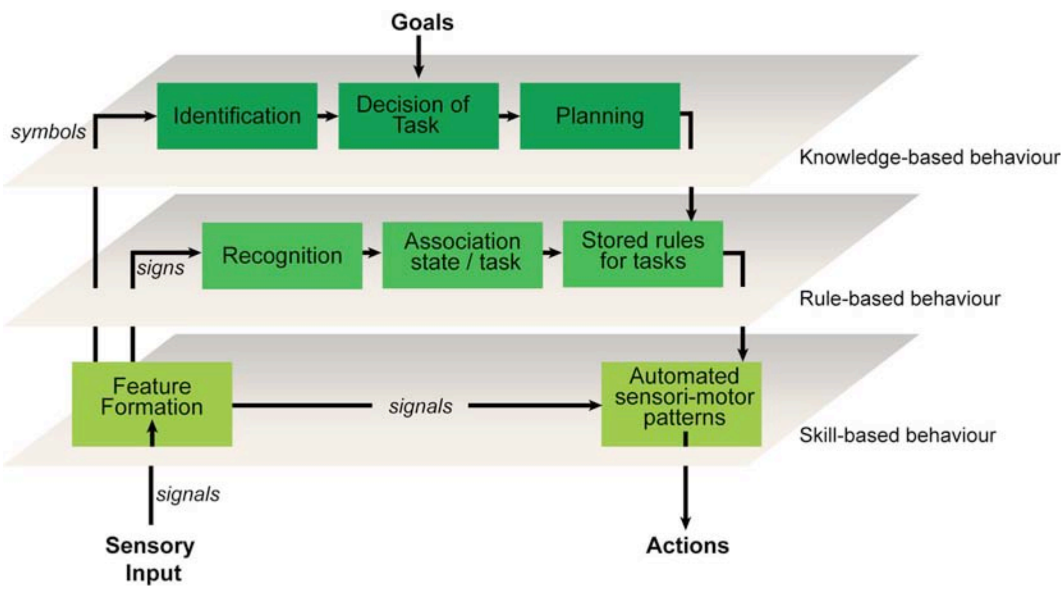


Figure 11.3. Three level behaviour model (adapted from Rasmussen 1983)

Skill based behaviour is the human behaviour that takes place without conscious control. The task execution is highly automated and is based on fast selection of motor programs, which control the appropriate muscles. Many tasks in surgery are a sequence of skilled acts (e.g., suturing). During skill-based behaviour the sensory information is seen as continuous signals. This behaviour can be trained by means of a training in for instance a surgical simulator, pelvitrainer and animal models.[282] During MIS the surgeon's motor skills are hampered and therefore have to be learnt by intensive training to perform a successful safe procedure.[234] Factors that improve skill-based behaviour are active or passive feedback of the instrument's forces and increasing the number of degrees of freedom (DOF) comparable to the functions available during open surgery.[234]

During rule-based behaviour task execution is controlled by stored rules or procedures, which have been derived from previous cases, other people's expertise and instructions. Examples of rule-based behaviour during surgery are the procedural steps and the recognition of anatomy and pathology. During rule-based behaviour the information is seen as discrete signs, which serve to trigger or activate a stored rule. This behaviour can be trained and improved by means of lectures, textbooks, video instructions, integration of per- and pre-operative information and better logistics.[234, 282] During MIS the rule-based behaviour can be improved by means improving dept perception (e.g., improving pictorial information, parallax and visuomotor cues) and enabling the surgeon to control the endoscope himself.[234]

In unfamiliar, new situations and unexpected events human behaviour is knowledge based. During this behaviour, which cannot be automated, the aim is explicitly formulated, based on the analysis of the overall aim.[234] Then the best strategy is selected, by means of mental processing and the appropriate actions are taken. At this level the information is perceived as symbols, referring to chunks of conceptual information. During MIS the four major knowledge-based behaviour activities are:[234]

1. Transformation of the endoscope's and instruments' coordinate system.
2. 3D reconstruction and the remembrance of 2D CT and MRI pictures.
3. Interpretation of pre-operative images in relation to the endoscope's image.
4. Interventions needed during unexpected events.

Knowledge based behaviour can be trained during actual procedures in OT or via living animal models outside the OT.[282] Solutions, such as augmented reality and a 3D endoscope, could take away a lot of mental burden during MIS, leaving the surgeon the cognitive data processing capacity for the real task.[234]

11.3.4. Training of technical skills

Technical skills (e.g., knowledge of anatomy and pathology, dexterity, hand-eye coordination, technical proficiency) are essential to surgical training.[54, 178, 225] In order to perform MIS the surgeon needs highly developed motor skills.[157, 162] In the past motor skills for open surgery were learned in OT directly on the patient by means of the apprenticeship model. However, although this method is effective it may be inefficient, costly, and may endanger patient safety.[225] Also, this method could not accommodate the new skills required for MIS.[1] Therefore, basic (and also intermediate) MIS skills are also being trained before-the-job in addition to on-the-job, replacing the actual patient by bench models, Augmented Reality simulators and Virtual Reality simulators.[142, 225] Advantages of the simulated environments are that objective assessment and direct feedback during training can be given to the trainee, these are safe, reproducible, readily available, offer unlimited practice and require no supervision.[28, 178, 225] In this way, novice surgeons can progress along the early part of the learning curve before entering OT and improve their performance in OT.[1, 225] However, simulation programs should be seen as an adjunct to traditional training methods, and not as an alternative.[1]

11.3.5. Non-technical skills

The surgical team is a dynamic multi-disciplinary team, consisting of staff and trainees.[113, 149, 251] To perform safe surgery, the surgical team has to depend on their technical and non-technical skills.[178, 299] Non-technical skills are the important cognitive and interpersonal skills (e.g., communication, situational awareness, teamwork, decision-making) of experienced professionals, which are a supplement to the technical skills.[253] Literature shows that many underlying causes of errors originate from non-technical aspects rather than a lack of technical expertise.[54, 115, 172, 227, 299] This is comparable to other high-risk industries such as aviation, where 70% of commercial flight accidents are caused due to communication failures among the crewmembers, rather than technical malfunctioning of the airplane.[115, 144] Part B elaborates further on this subject.

11.3.6. Protocols, checks and checklist

The use of protocols, checks and checklist would be advantageous for patient safety. Chapter 3 discusses the use of protocols and Chapters 9 and 10 focus on implementing checks, i.e. on implementing a Time Out Procedure and Debriefing procedure.

11.4. Physical ergonomics

Physical ergonomics studies the functions of the human musculoskeletal system, such as body shapes and postures, and measures movements and applied forces.

11.4.1. Physical discomfort

Maintaining good posture and limiting physical discomfort, is absolutely essential for good surgical performance and outcome.[142] Physical discomfort occurs when the team members' positions and movements differ from the ergonomically optimal positions (see Figure 11.4 [258]). This can lead to irritations or injuries.[98] Furthermore, static effort should be prevented as it restricts the blood flow to the muscles, leading to the condition of 'muscular fatigue'. In the short term, mounting discomfort may distract the surgeon from his task, leading to an increased error rate, reduced output and errors. In the long-term, pathological changes in the muscles soft tissue take over, which causes physical injury.[200] Small pauses and posture changes can prevent these physical complaints and damage. During the pauses, the muscles can relax and the blood flow can be restored, oxygen can be transported to the muscles and waste products be transported away. These pauses also allow the joint to be lubricated again.

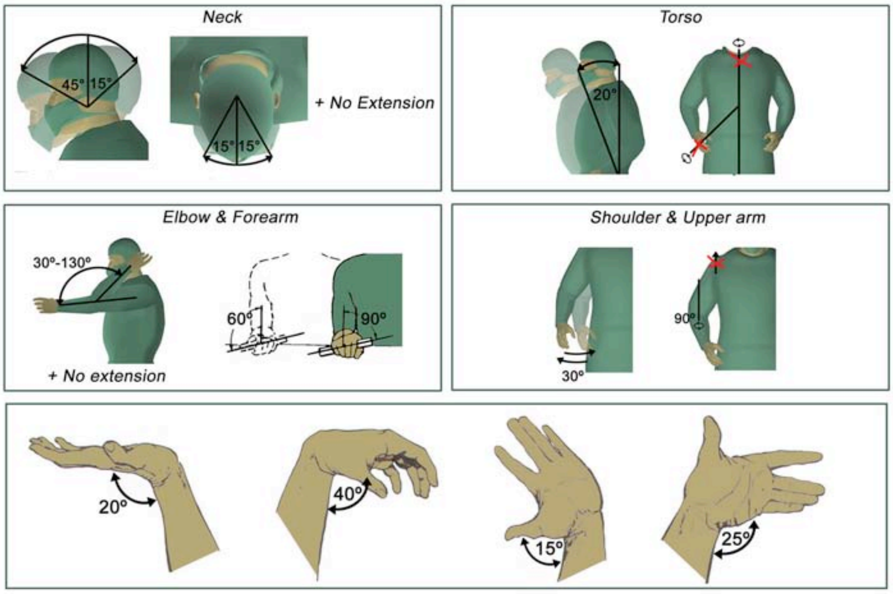


Figure 11.4. Ergonomically optimal positions

Open surgery

During open surgery the surgeon stands and sometimes sits in different postures all the time (Figure 11.5). He is constantly looking at the operating field at different angles, standing one foot or the other and / or leaning against the operating table. Occasionally, the operating field is too far away from the edge of the table, then the surgeon has to lean over or on the patient.[8] Also when the operating field is perpendicular to the edge of the table, the surgeon has to rotate and lean against the table or patient. The surgeon's posture is characterized by a head-bent and back-bent posture.[8, 22] Occasionally substantial forces on tissue have to be exerted, influencing the body posture.[18]

The assistant has to stand in awkward positions too. Flexion of the neck and abduction of the upper body occur almost all the time. However, prolonged and repetitive use of muscle groups should be avoided, because it could lead to several injuries, such as carpal tunnel syndrome, repetitive strain injury, and cumulative trauma disorder.[211]

The line of vision can be obstructed by other team members hands or bodies, leading to back and neck torsion and flexion to allow clear vision of the operating field.[97]

Although the duration of extreme postures is only short, the team members have to maintain their postures for long periods of time, which results in physical complaints, such as pain in lower back and neck, and stiffness of shoulders.[86, 131, 171]

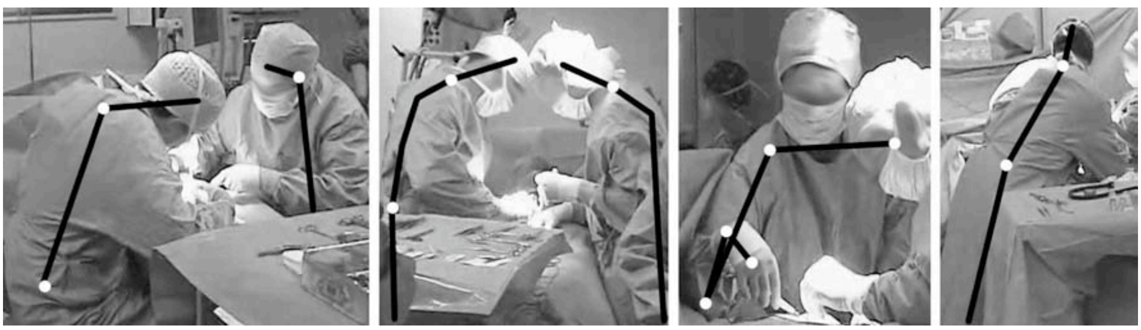


Figure 11.5. Postures during open surgery

Minimally Invasive Surgery

Most factors causing physical discomfort during MIS are: height of the operating table, position and height of the monitors, use of instruments and the use of the foot pedals. This will be elaborated below. However, there are more factors contributing to physical discomfort.

The surgeon's body posture during MIS differs from the posture during open surgery (Figure 11.6). The surgeons have a higher frequency of internal rotations of the shoulder and tend to hold their trunk very still with fewer abductions of the upper body while concentrating on the monitor.[186] Surgeons and scrub nurses exhibit repeated static postures characterized by the head bent forward (54% of the time) and the back twisted and bent (27% of the time) which they see as 'distinctly harmful' postures.[8, 18, 22] Additional discomfort with potential risks for musculoskeletal injury and muscular fatigue are pain and stiffness in neck, back, shoulders, eyestrain, wrist flexion and extension.[19, 95, 186, 199, 277] One of the injuries is the so-called 'laparoscopist's thumb' in which the nerves of the thumb and thenar are damaged.[23, 267]

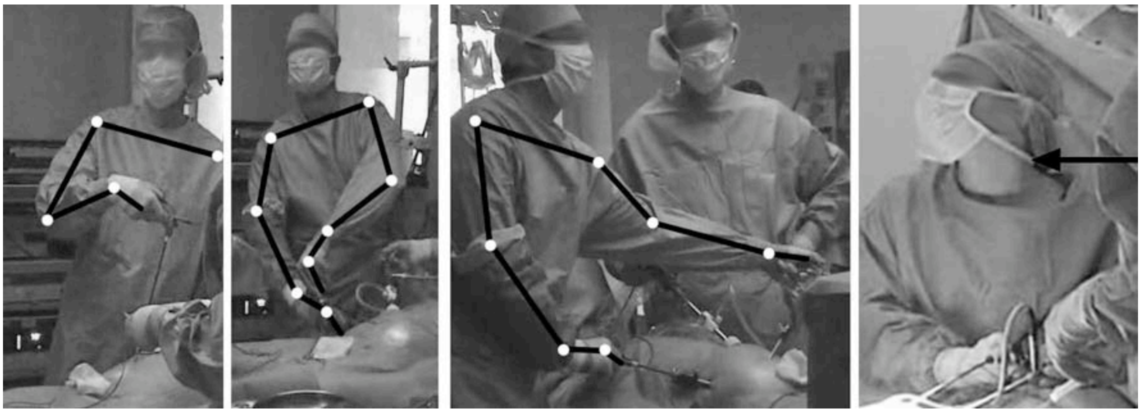


Figure 11.6. Postures during MIS

The position in Figure 11.7 is considered ideal for the MIS surgeon.[162] The arm is slightly abducted, retroverted, and rotated inward at shoulder level. The elbows are bent at about 90-120º, the wrists are slightly extended and the hands are completely relaxed. In this position the most force can be applied. The head is slightly flexed with an angle between 15-45º, or even better, different head postures between these angles.[159]

Whenever possible, MIS surgeons should strive to place their instruments and trocars at a position that minimizes extreme horizontal or vertical displacement of their hands away from a resting position of comfort.[20]

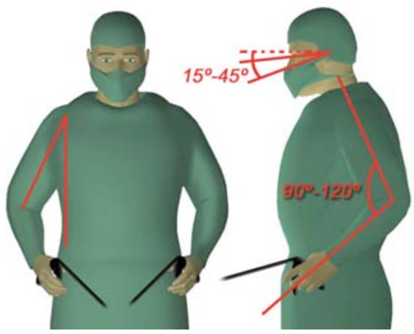


Figure 11.7. Ideal posture of the upper extremities for MIS surgeon

11.4.2. Products causing physical problems during MIS

Operating table

The operating table supports the patient during surgery. The table can be adjusted in height and can also be rotated. The operating surface height (= distance from the top of the patient to the floor) depends on different factors,[163] such as the table height, the surgeon's stature, angle of the elbow joint, instruments' handle type, working angle of the instrument in the patient's body wall, and height of the patient's (inflated) body wall. Currently available operating tables were designed for open surgery and the height range is often not adequate for MIS (mostly too high).[7, 24, 163, 260, 277] Figure 11.8 shows the optimal height range for the operating table during open surgery and MIS.[24, 159, 163, 258] During MIS the highest position should be maintained because the table and patient are raised to close the trocar sites.

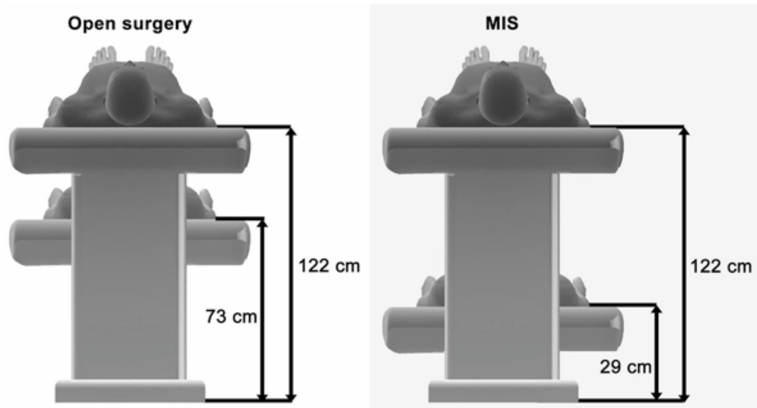


Figure 11.8. Optimal table height during open surgery and MIS

Insufficient adjustment of the table height limits freedom of movement and can therefore lead to extreme positions of the upper limb joints, causing physical discomfort in the surgeon's upper arms, neck, back, and shoulders.[22, 24, 259, 277] In addition, the table's lifting mechanism also restricts the standing area, limiting the team members to move their feet freely and causing a static posture.

Footstools can be used to level the surgical team and patient. Disadvantages are that the standing surface is small and the stools mostly have only one height, which is often not sufficient for the different body lengths. Furthermore, the stool limits the freedom of movement, leading to static postures. Finally, the pedals are difficult to be placed on.[159]

Monitor placement and height

During MIS different types of monitors are used: flat screens (LCD's and plasma), regular CRT (Cathode Ray Tube) monitors or projection of the image on a screen.[31] The CRT monitors are mostly used, and most of the monitors are currently placed on an instrument tower, restricting an adequate position and height of the monitor.[7, 277] Nevertheless, flat screen and HDTV (High-resolution Digital Television) are introduced in OT. Flat screens have some disadvantages, such as less brightness, lower resolution, limited color fidelity, and a smaller viewing angle, but the visual quality of flat screens is improving very fast.[30] Advantages of a flat screen are its thinness, lower weight, higher contrast and the possibility to place the monitor in the surgeon's line of sight. Furthermore, in a comparative study on two display systems, 92% of the subjects preferred the use of flat screens.[259] Advantages of

HDTV are higher brightness and more detailed picture compared to CRT monitors. However, its price and the incompatibility between standard and HDTV formats (making it necessary to replace all OT video systems) are major disadvantages.[237]

During the placing of the trocars, the surgeon has a higher frequency of neck flexions, because the operating field is not aligned with the monitor. This can cause physical discomfort.[186, 277] During the actual surgery, the position of the monitor is fixed and therefore the surgeon has significantly fewer lateral neck flexion movements compared to open surgery, because he only has to look straight in front, leading to a static neck posture.[186, 277]

An advantage of using a video camera and monitor is that the muscle strain and fatigue, resulting in a lower frequency of back pain for the surgeon, is considerably reduced. Furthermore, the monitor offers the opportunity for the complete surgical team to participate visually, which improves attention and training possibilities.[160]

Instruments

During MIS, four instrument groups are used besides the endoscope:[259]

1. Instruments for the active manipulation of tissue: graspers, dissectors and scissors.
2. Instruments for electro surgery.
3. Instruments for suction and irrigation.
4. Instruments for automatically suturing tissue (e.g., staplers).

The instruments used in MIS cause more physical problems than the ones used in open surgery (Table 11.1).

Table 11.1. Cause and effect (physical problems) of instruments used during MIS[17, 21, 83, 95, 162, 166, 186, 196, 234, 247]

Cause	Effect
- Limited DOF (only 5 DOF during MIS in contrast to 7 DOF in open surgery) - Instruments' length and the fixed insertion point - Changing instruments and repositioning within the abdomen - Inefficient force transmission from handle to tip	- Large envelopes of motion to direct the instrument to the desired location within the patient - Non-ergonomic motions - Increased muscle fatigue and degradation of performance - Time-consuming - Exertion of substantially higher muscle forces - Significantly greater peak and total muscle effort of the forearm and thumb - Awkward upper limb position - Awkward wrist movements (wrist supination, ulnar and radial deviations)

Handles

The handle is the interface between the surgeon and instrument. The instruments' handles have been designed with a single size for all surgeons and for multitasks. The contact surfaces, that are relatively narrow, the handles' shapes (Figure 11.9) and the movements do not correspond with anatomic hand features. As a result there is often a mismatch between the instrument-hand interface. The nature of the handle and its associated activation mechanism has an influence on joint movements, muscle recruitment, and muscle fatigue in the upper arm. In turn, these factors impact on the surgeon's comfort level, the execution speed, and the quality of task performance. Excessive pressure on sensitive areas of the palm and fingers can cause temporary nerve injuries.[17, 19, 83, 84, 258, 259]

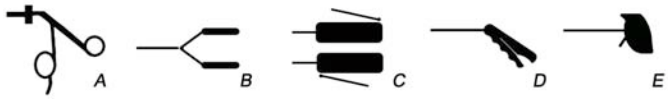


Figure 11.9. Schematic overview of types of handles: A) Angled ring handle, B) In-line handle, double action hinged, C) In-line handle, single action hinged, D) Angled handle, lever manipulated (vertical), E) Angled handle, lever manipulated (horizontal)

Foot pedals

Besides sensorial and cognitive problems, pedals also cause physical problems:[159, 162, 262, 277]

1. Flexion of one foot and the body weight on the other foot (to prevent losing contact with the right pedal). This is physically exacting and demands a high concentration level, which could lead to physical discomfort.
2. Obstruction of the surgeon's freedom of movement.

Furthermore, it is difficult for the surgeon to take position on both sides of the table. When changing, the circulating nurse has to move the pedals across the operating table.

11.4.3. Awareness and Guidelines

There are many products and even specially designed OT's available on the market to reduce physical discomfort, such as several kinds of footstools, chairs and crutches, body supports, arm supports, equipment and monitors on ceiling-mounted booms and voice controlled devices.[8, 196] However, although most team members state that ergonomics in OT are important, only few are aware of ergonomic guidelines concerning placing of the equipment and apparatus and of ergonomically correct postures (see Chapter 12).[277] This unawareness of ergonomic guidelines is a major problem that poses a tough position for the ergonomics in OT. This leads to that most of the time, equipment is used in its initial position, and although possible, it is not adjusted according to the ergonomic guidelines for better comfort. A first step is to improve the awareness. Only, then ergonomically designed product can be used to its full benefit. Figure 11.10 describes the guidelines for ergonomically optimal postures during MIS.

11.5. Environmental ergonomics

The environmental factors such as, lighting, temperature and crowding have big influence on the ergonomics in OT. Lighting is discussed in Chapter 13. This sections focuses on temperature, air condition, crowding, sound, and noise.

11.5.1. Temperature and air condition

Both ambient temperature and air condition are important in OT, as inadequate values could lead to bacteria growth, patient's hypothermia, discomfort amongst the team members, and airborne infection risk (via inhalation or settling on a susceptible area) of all people in OT.[41, 81] The ambient temperature is kept low (20-23ºC) primarily for the team's comfort. However a study of Matern and Koneczny (2007) showed that 18% of the participating surgeons experience the ambient temperature as too cold, 25% too warm and only 31% as comfortable.[161]

In order to prevent infections and contamination, high-quality ventilation, heating and air conditioning system are present in OT to guarantee and control the quality and airflow as the airborne route is the most important and consistent route of contamination of the patient's skin at the wound site (98% of bacteria in the patient's wounds after surgery came directly or indirectly from the air).[41] The features of OT airflow system for health protection are: ventilation, air distribution, room pressurization, and filtration. The higher the ventilation, the lower the concentration of airborne contaminant, which includes bacteria and anaesthetic gas.[41]

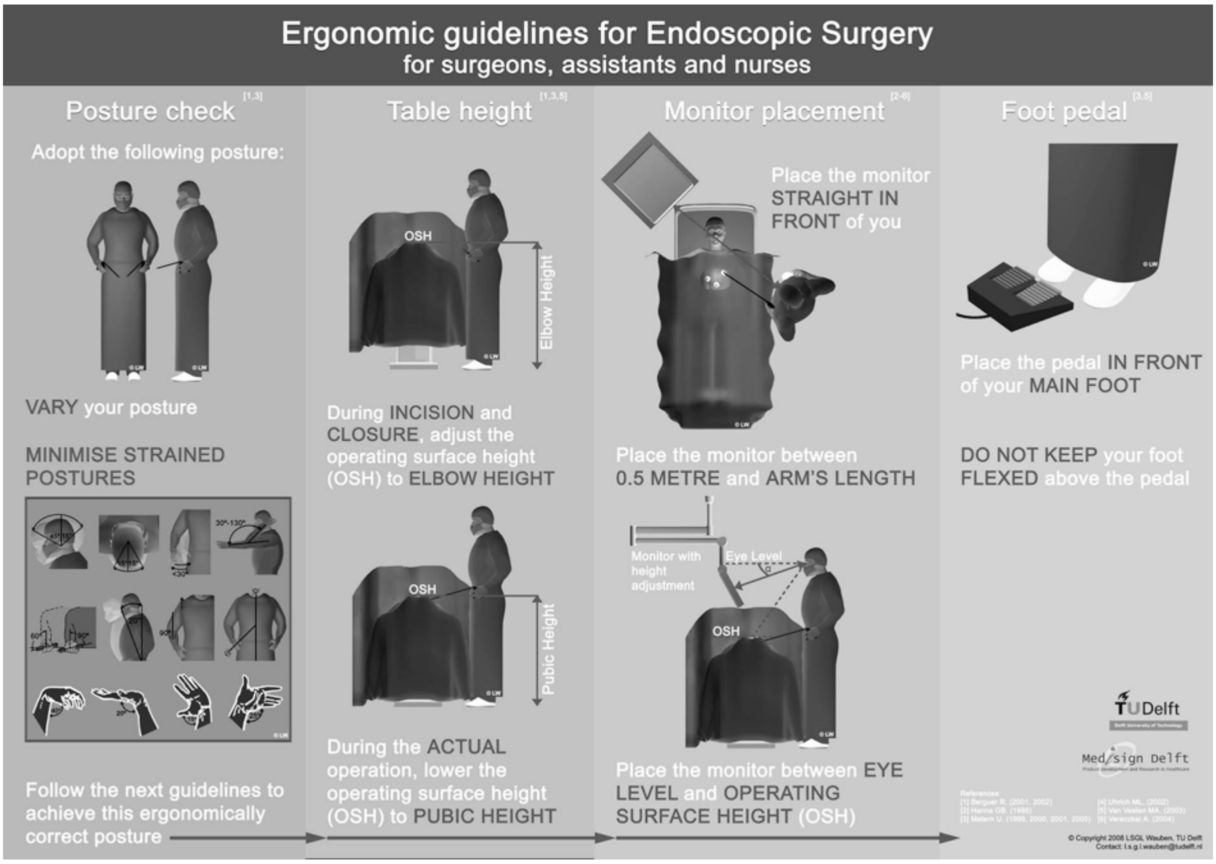


Figure 11.10. Ergonomic guidelines for MIS

11.5.2. Crowding

Operating theatres were originally designed for open surgical procedures and its lay-out has changed little over the last 100 years.[7, 95] The introduction of MIS procedures in OT has led to the proliferation of monitors, insufflators, camera control units, light sources, cables, cords, tubing, insufflators, foot controls, documentation devices and other equipment, mostly placed on wheeled instrument towers. These towers have to be wheeled into position, or even into the OT, and equipment has to individually placed and connected. In addition, extra personnel are needed. In total, this requires 10% more floor space compared to open surgery.[4] As the OTs were not designed to accommodate all these new technologies, their space is overwhelmed.[7] Adding connecting the cables, cords and tubing creates potential mechanical, electrical, biological and occupational hazards to the patient and the surgical team.[18] Also it leads to inefficiency on OT use, longer operative times, longer turnover times and greater wear and tear of the mobile equipment.[4, 116, 286]

11.5.3. Sound and noise

Staff and patients are exposed to many sounds in OT produced by apparatus and / or people.[117, 179, 203, 248] Some of these sounds are unwanted sounds, called noise, which affect both patients and team members.[117] Hodge and Thompson (1999) showed that although background noise levels were within satisfactory working environment, loud noise levels (dB A) were seen during the pre-operative phase.[117] During the intra-operative phase mainly suction and ventilators caused continuing noise levels, with sound levels higher than normal conversation (60dB). Furthermore, diathermy machines, anaesthetic alarms, and the intercom were main causes of intermittent noises.[179] Only in 1% of the whole surgery sound levels were regarded as 'moderate' noise levels. Although sound experience is objective, the effect depends on its predictable and controllable.[117, 179, 203, 248] Non-predictable and non-controllable sounds and background conversation interfere with the performance of complex tasks, and have an immediate but also a continuing effect. Finally, noise also impairs (critical) conversation.[117]

Solutions for reducing noise pollution are using background music to mask ambient OT noise.[13, 117] Music also reduces anxiety, pain levels, and sedative requirements for patients.[13, 117, 179, 248]

A questionnaire based study showed that the majority of physicians and nurses believed that music in OT makes them calmer and more efficient. Additionally, 63% of respondent believe music has a positive effect on communication between staff members.[248] However, hearing music may have a distracting effect on novice surgeons performing new task, could lead to increased levels of irritation toward these sources of distraction, and could significantly decline the task performance during laparoscopic tasks.[173, 179, 203] However, other surgeons are able to block out noise and music.[179]

11.6. Conclusion

Ergonomics is aimed to adapt the environment and its products to its users. The overview showed that there is a gap between this aim and reality in OT.

Surgery as a discipline has a proud history of science and tradition, with changes being gradual and usually with consensus. However, surgical procedures are also evolving fast to more and more complex procedures. Future research, product development, and redesign will focus on these more complex surgical procedures, which require even more advanced technology. These advanced technologies should be harnessed to optimize surgical practice by rethinking and re-applying technology that currently exist in a manner that is more systematic and better managed, and a reconsideration of who should be applying these technologies for the practice of the surgery of the 21st century.

In general, the classical ergonomic domains are: sensorial, cognitive and physical. All these domains need to be addressed in the design of products and processes, however the focus can be different in each case. When looking into the field of ergonomics in OT most scientific research and product development is conducted focussing on physical ergonomics. With the discipline OT ergonomics maturing, more difficult problems are researched. Within the domain of physical ergonomics effort is put into restoring the originally enjoyed level of surgical movement in the OT environment. However, this OT environment is changing drastically, from OTs designed for open procedures solely, to specially designed surgical suites focusing on MIS and / or robotic surgery. More and more technology is incorporated in

OT, making it a more complex and high-risk environment, comparable to environments as aviation, oil and nuclear industry. Therefore, when designing products and processes, valuable lessons can be learned and applied from these industries.

Performing MIS causes ergonomic problems, leading to higher complication rates and considerable frustration for some surgeons. Still, some surgeons have great difficulty, or are unable, to learn these skills. Ergonomics should strive to facilitate learning these skills and finally perform MIS, where it should be as intuitive as performing open surgery. In order to do so, within MIS several areas will be researched and developed: e.g., robotics, 3D vision, haptic instrument feedback, information systems, realistic training possibilities.

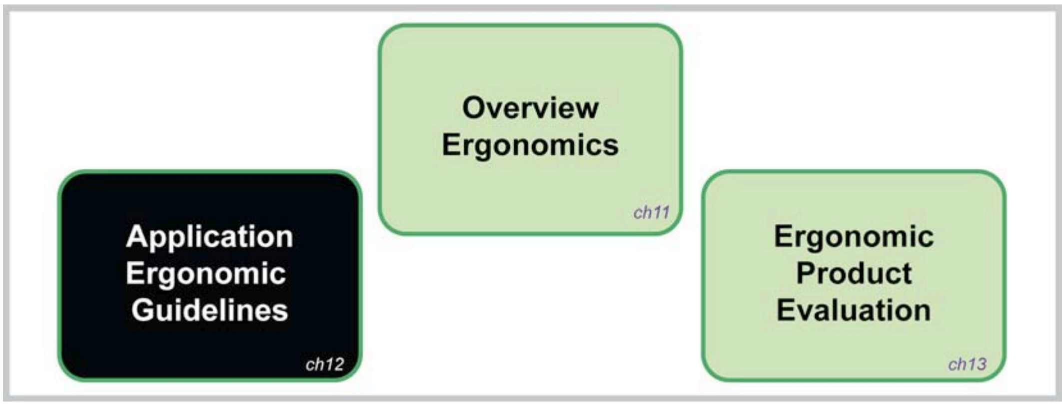
New surgical approaches as NOTES (Natural Orifice Translumenal Endoscopic Surgery) are entering the OT. This new type of surgical procedure is currently being studied at research hospitals and facilities around the world, aiming to reduce scaring and recovery time of the patient. New technologies, instruments and equipment have to be designed or redesigned, not only on the physical aspects, but also on sensorial and cognitive aspects, making products become intelligent partners of the surgical team. Also the introduction of more computers, displays, digital video equipment, storage capacity, realistic data collection, 3D motion analysis, augmented reality, etc. in OT causes a shift from physical to more sensorial and cognitive ergonomics. The latter two domains will be merged, finally leading to two domains: the physical and informational domain. The shift to informational ergonomics, focusing more on process and procedures is expected to be similar as the shift that took place in Industry in the early 60-ties.

Furthermore, a new domain is added, the environmental ergonomics. Factors as climate, lighting, colour, and noise level contribute to both the wellbeing of the medical staff and patient. In hospitals ‘healing environments’ are introduced to make the patient less nervous and stressed. These environments are quit, have natural daylight, fresh air, use of colour and convenient logistics are introduced. In OT, equipment is hanging on booms, reducing the amount of cables and wiring, special surgical lights based on Light Emitting Diode (LED) technology are introduced producing a more natural light colour, etc.

With the complexity of future products and processes increasing design teams have to be multi-disciplinary, consisting of technicians, ergonomists, philosophers, medical staff, jurists, software designers, hardware designers, user-interface specialist, end-users, etc. They all have to be included and participate in the whole design cycle: from first hunch until prototyping.

In the end, ergonomics should make sure that the advances in technology are to facilitate surgery and not to complicate it, because at the sharp end of these technologies lie patients whose wellbeing is the first priority.

Chapter 12. Ergonomic Guidelines during Minimally Invasive Surgery



Abstract

Background: This study aimed to obtain an answer for the question: Are ergonomic guidelines applied in the operating room and what are the consequences?

Methods: A total of 1,292 questionnaires were sent by email or handed out to surgeons and residents. The subjects worked mainly in Europe, performing laparoscopic and / or thoracoscopic procedures within the digestive, thoracic, urologic, gynecologic, and pediatric disciplines.

Results: In response, 22% of the questionnaires were returned. Overall, the respondents reported discomfort in the neck, shoulders, and back (almost 80%). There was not one specific cause for the physical discomfort. In addition, 89% of the 284 respondents were unaware of ergonomic guidelines, although 100% stated that they find ergonomics important.

Conclusion: The lack of ergonomic guidelines awareness is a major problem that poses a tough position for ergonomics in the operating room.

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12.1. Introduction

The advantages of minimally invasive surgery (MIS) for the patient are already well known. On the other hand, the disadvantages for the surgeon and the operating team also are becoming increasingly known.[247] Ergonomic research strives to improve the working conditions in the operating room. The word ergonomics originates from the Greek words "ergon" (labor) and "nomos" (law), which indicate knowledge concerning the law of human labor. Combined with product development and product evaluation, this leads to the working principle that the operating room designers should "adapt the environment to the workers instead of adapting the workers to their environment".[98]

Ergonomic research has led to the ergonomic guidelines presented in the literature, which deal with the placing of equipment in an ergonomic position and with ergonomic postures of the operating team to prevent discomfort.[83, 108, 159, 160, 162, 163, 258] Also during congresses, ergonomic items are introduced.

More detailed guidelines for different variables in the operating room are stated concerning the table height,[24, 159, 163, 258], the monitor placement,[159, 160, 193, 247, 258, 259] the instrument's handle design,[17, 21, 83, 162, 258] the foot pedals,[263] and the physical discomfort of the operating team.[19, 162, 186, 260, 261] Still, the question is whether these guidelines are known and used.

This study aimed to obtain an answer to the question: Are ergonomic guidelines applied in the operating room and what are the consequences? This question was divided into three sub questions:

1. To what extent are surgeons aware of ergonomic guidelines?
2. Are these guidelines being applied during MIS?
3. Do surgeons expect a relation between physical complaints and the apparatus and equipment used?

12.2. Materials and Methods

12.2.1. Inclusive criteria

The research was conducted in cooperation with the Delft University of Technology and the European Association for Endoscopic Surgery (EAES). The target group for this study included surgeons and residents who perform laparoscopic or thoracoscopic procedures within the digestive, thoracic, urologic, gynecologic, and pediatric disciplines. In addition, the subjects from the target group had to be capable of reading the English language to understand and complete the questionnaire correctly.

The survey was conducted by means of a questionnaire. Both the member database of the EAES and the database used in the research of Schoofs and Gossot[223] were used for sending the questionnaires by email. A total of 1,142 emails were sent to European surgeons and residents, 990 of who were members of the EAES at the time. The subjects received an email with an explanation of the study aim and were asked to fill out the questionnaire on the Internet. Also, 150 hard copies of the questionnaire were handed out at national and international congresses including the OR of the Future and Robotics in Leeuwarden from 31 October to 2 November 2004, the Endo Club Nord in Hamburg from 4 to 6 November 2004, and the SMIT (The Society for Medical Innovation and Technology) in Rome from 16 to 18 December 2004.

12.2.2. Questionnaire

The questionnaire included questions concerning table height, monitor position and height, use of foot pedals, physical complaints caused by the apparatus and equipment, and awareness of ergonomic guidelines. The 40 questions were arranged in separate chapters. A total of 22 questions could be answered by marking given answers.

The Internet version of the questionnaire called for the use of option buttons when only one answer could be given, and checkboxes when several answers could be given. For three questions, a category termed ''other'' was used in addition to the given answers. For example, the question ''What kind of monitors are used?'' was accompanied with the answers ''flat screen(s),'' ''regular (CRT (Cathode Ray Tube)) monitor(s),'' ''projection screen(s),'' and ''other (please describe below).'' Of the 18 open questions, 10 were preceded by the given answers ''yes'' or ''no.'' The hard copy of the questionnaire was similar to the Internet version, except that the hard copy was in black and white and all the multiple answer possibilities were preceded with bullets. Table 12.1 presents a summarized version of the questionnaire.

Table 12.1. Summarized version of the questionnaire

General
- What kind of endoscopic procedures do you perform?
- How many hours a day (mean time) do you perform endoscopic procedures?
Table height (distance from the top of the table to the floor)
- What is normally the table height during the incision and placement of the trocars?
- What is the table height during the actual operation?
- How would you rate the table height?
- Do you think the height range of the operating table is appropriate for endoscopic surgery? If your answer is no, should it be possible to lower or raise it more, or both?
Indicate your extent of agreement, from 0 (I do not agree) to 5 (I fully agree), with the next propositions.
- I experience discomfort in my neck due to a bad table height.
- I experience discomfort in my shoulders due to a bad table height.
Monitor
- How many monitors are used?
- What kind of monitors are used?
- Where are the monitors placed?
- Are you hindered by the position of the monitors? If yes, how are you hindered?
Indicate your extent of agreement, from 0 to 5, with the next propositions.
- I experience discomfort in my neck due to a bad monitor height.
- I experience discomfort in my neck due to a bad monitor position.
Foot pedal
- What do you use to activate the diathermic or the ultrasonic equipment?
- Do you find the use of the commonly used foot pedals comfortable?
- How would you prefer to control the diathermic or the ultrasonic equipment?
Indicate your extent of agreement, from 0 to 5, with the next propositions?
- I experience discomfort in my legs and foot due to use of the foot pedals.
Physical complaints
- Rate your physical discomfort, from 0 (no pain) to 5 (severe pain), in the different body areas.
Guidelines
- Are you aware of any guidelines for endoscopic surgery in the literature concerning the table height and placement of the monitor and instruments?
- Do you think that the ergonomic conditions in the operating room are important?

12.3. Results

From the 1,292 contacted subjects, 252 responded via the Internet and 32 filled out the hard copy of the questionnaire, for a total of 284 respondents and a response rate of 22%. A total of 254 surgeons and 30 residents responded. The characteristics of the respondents are presented in Table 12.2. Most of the respondents (55%) performed MIS within the discipline of digestion, followed by 22% within the thoracic discipline, 10% within the discipline of gynecology, 6% within the discipline of urology, and 7% within the discipline of pediatrics. The respondents worked mainly in Europe (n=260). Figure 12.1 shows the countries in which the largest number respondents worked. Other European countries were represented with fewer than eight respondents per country. From Figure 12.1, it can be seen that most of the respondents (n=74, 27%) worked in the Netherlands.

Table 12.2. Characteristics of the 284 respondents

Gender: 254M / 30F	Respondents	(%)
Experience (no. of procedures):	<500	29
	500-1,000	23
	1000-2000	22
	>2000	26
Mean operating time (h / day):	<1	19
	1-2	41
	2-5	33
	>5	7
Mean height (cm):	178 ± 7.5	
Mean age (years):	45 ± 9	

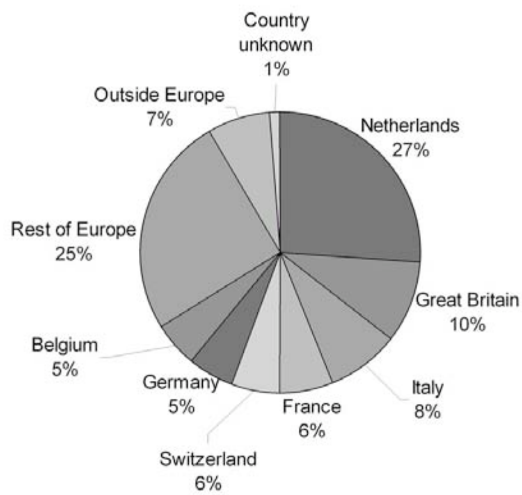


Figure 12.1. Respondents' place of work

12.3.1. Table height

During the current study, the table height was defined as the distance from the table top to the floor. This means that when the table was tilted, the table top height was measured in terms of the pubic and navel height at the standing position of the surgeon.

It can be seen from Figure 12.2a that during the incision and placement of the trocars, the height of the operating table was placed mainly at navel height (55%). During the actual operation, the table was placed mainly at pubic height (60%), as can be seen in Figure 12.2b.

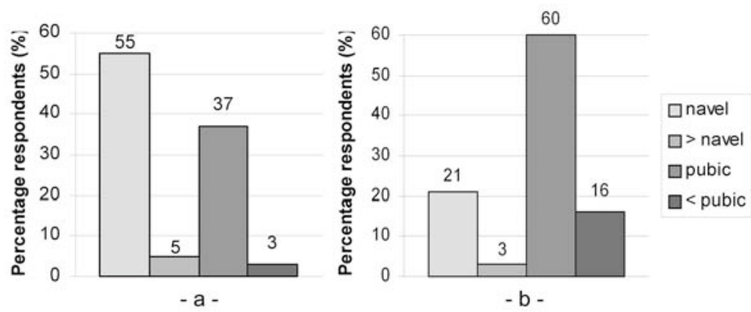


Figure 12.2. Table height during incision and placement of the trocars (a) and during the actual operation (b)

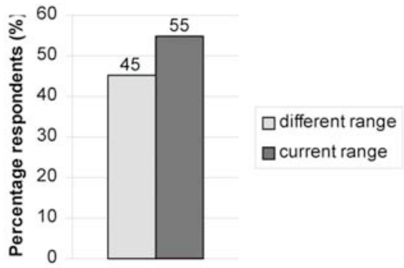


Figure 12.3. Table height preference

Figure 12.3 shows that 45% of the respondents found the height range of the operating table inadequate for endoscopic surgery and preferred a different height range. Most of the respondents (70%) wanted the table equipped to be lowered more; 4% wanted the table equipped to be raised more; and 26% wanted both.

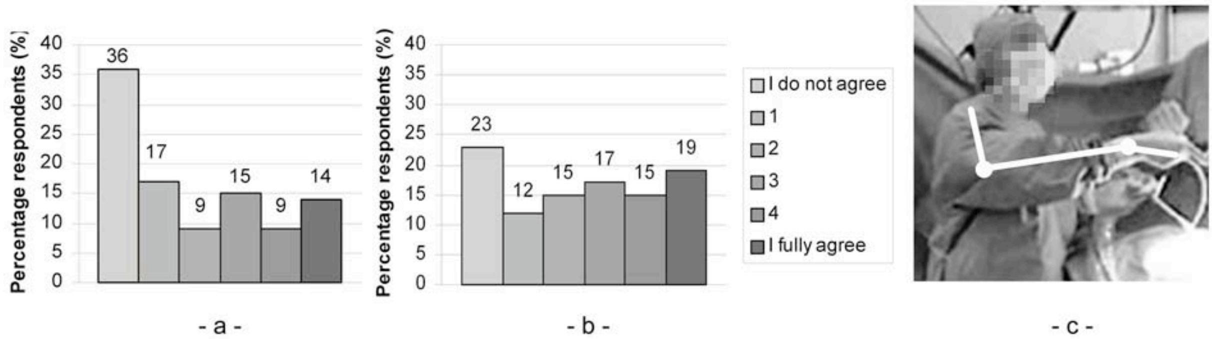


Figure 12.4. a) ''I experience discomfort in my neck due to a bad table height.'' b) ''I experience discomfort in my shoulders due to a bad table height.'' c) Raising of the shoulders to control the instrument

The respondents also were asked to indicate the extent of their agreement with the propositions concerning the table height, such as those describing discomfort in the neck and shoulders. Figure 12.4a shows that 64% of the respondents agreed, from somewhat to fully, with the proposition that a bad table height causes physical discomfort in the neck. It can be seen that 14% of the respondents even fully agreed, showing that a nonergonomic table height indeed causes neck complaints. It can be seen from Figure 12.4b that 77% agreed, from somewhat to fully, with the proposition that a bad height of the operating table causes discomfort in the shoulders. In this case, 18% of the respondents fully agreed, indicating that a nonergonomic table height causes shoulder complaints. In addition, Figure 12.4c shows a surgeon who has to raise her shoulders and arms to operate the instruments because the table is placed too high.

12.3.2. Monitor

Figure 12.5a shows that during most of the endoscopic operations, one or two monitors were used. In most cases, a regular CRT monitor was used (80%). In the remaining cases, a flat screen (19%) or a projection screen (1%) was used. Most monitors (71%) were placed on an instrument tower without height adjustment. In all other cases, the monitor was placed on a movable arm with (19%) or without (10%) height adjustment. Figure 12.5b shows that most of the respondents (77%) were not being hindered by the position of the monitor, and Figure

12.6 shows that most of the respondents (64%) were satisfied with the current position of the monitor.

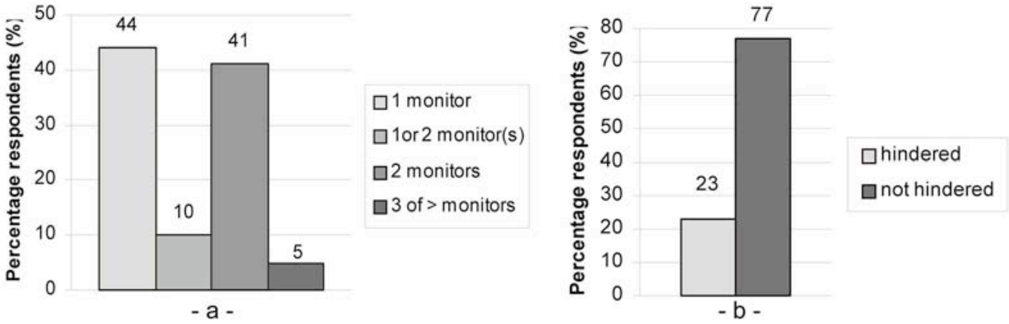


Figure 12.5. a) Number of monitors. b) Hindering of the monitor position

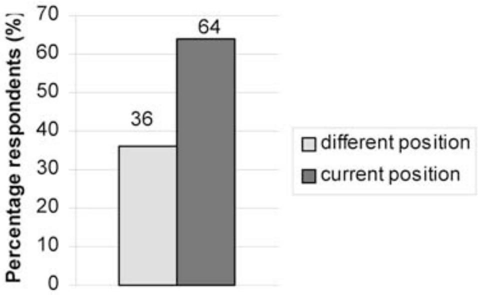


Figure 12.6. Monitor position preference

Figure 12.7. a) ‘‘I experience discomfort in my neck due to a bad monitor height.’’ b) Flexion of the neck

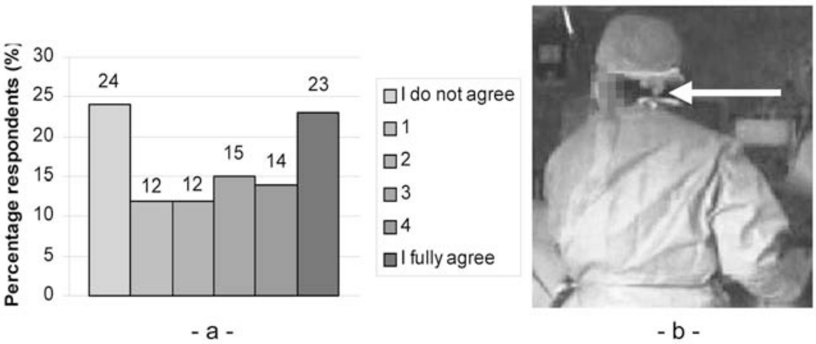


Figure 12.8. a) ‘‘I experience discomfort in my neck due to a bad monitor position.’’ b) Rotation of the neck to view the monitor

Again, the respondents were asked to indicate the extent of their agreement with propositions concerning discomfort in the neck because of bad monitor height and position. Figure 12.7a shows that 70% of the respondents agreed, from somewhat to fully, with the proposition that a bad monitor height causes discomfort in the neck, and that 16% even fully agreed, indicating that neck complaints are caused by a nonergonomic monitor height. In addition, Figure 12.7b shows that the surgeon must flex her neck to look at the monitor, which is placed too high.

Figure 12.8a shows that 74% of the respondents agreed, from somewhat to fully, with the proposition that a bad monitor position causes discomfort in the neck, and that 23% even fully agreed with the statement, implying that a nonergonomic monitor position causes discomfort in the neck. Also, Figure 12.8b shows an example of a bad monitor position causing neck complaints. The assisting surgeon must rotate his neck during the entire operation to look at the monitor placed next to him.

12.3.3. Foot pedal

Most respondents (87%) used a foot pedal to control the diathermic or ultrasonic equipment (Figure 12.9). Sometimes a hand control was used (13%). The use of the foot pedals was found to be uncomfortable by a little more than half of the respondents (53%). The following were mentioned:

1. There is no visual control over the pedal; the pedal gets lost and is hard to find beneath the table (n=64).
2. The operator has to stand on one foot, which can disturb the balance (n=30).
3. Too many pedals are used during surgery (n=13).
4. It is difficult to switch the surgeon's side of the patient during surgery (n=10).

By means of an open question, the respondents were asked how they would rather prefer controlling the diathermic or ultrasonic equipment. It can be seen from Figure 12.10 that the majority (53%) wanted to control the diathermic or the ultrasonic equipment in a different way. Of these, 72% wanted to control it by means of a hand control, 8% by voice, and 20% in an alternative way (e.g., infrared navigation, device in the shoe, more ergonomic pedals, and device attached to the foot).

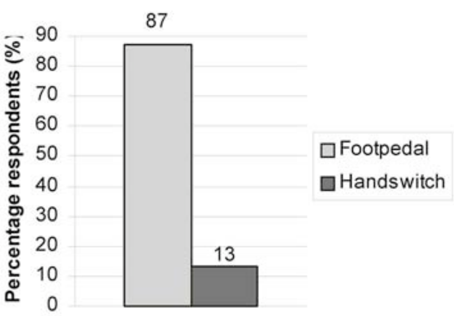


Figure 12.9. Controlling the diathermic or ultrasonic equipment

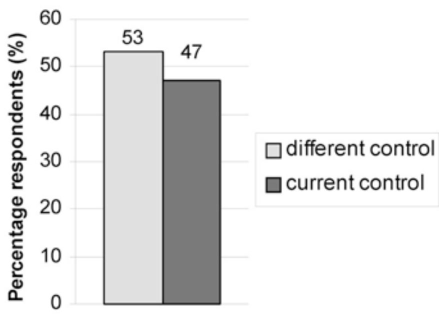


Figure 12.10. Preference for controlling the diathermic or ultrasonic equipment

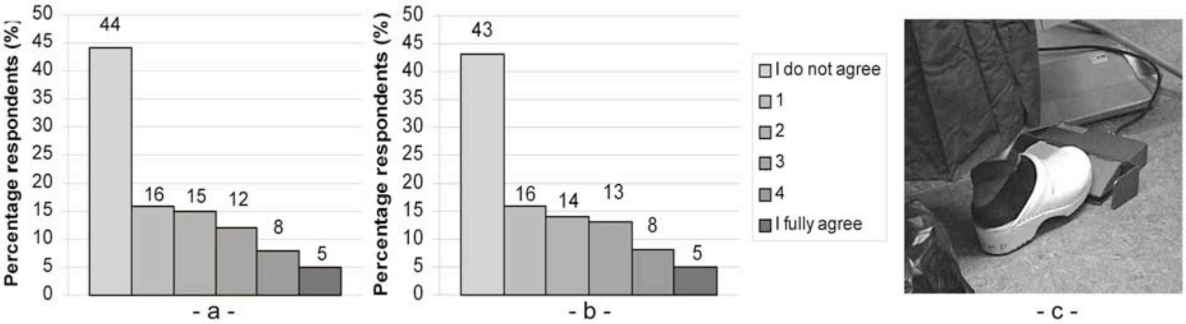


Figure 12.11. a) ''I experience discomfort in my legs due to the use of the foot pedals.'' b) ''I experience discomfort in my foot due to the use of the foot pedals.'' c) Flexion of the foot

Figure 12.11a shows that 44% of the respondents did not agree with the proposition that foot pedals cause discomfort in the legs. Figure 12.11b shows similar results. It can be seen that 43% did not agree with the statement that foot pedals cause discomfort in the foot. Both figures show that only 5% fully agreed that pedals cause discomfort in the legs and the foot. However, Figure 12.11c shows that the surgeon must flex his or her foot to control the foot pedal.

12.3.4. Physical complaints

The respondents also were asked the extent of their agreement with the following proposition: ''I experience muscle fatigue due to the static posture.'' Figure 12.12 shows that 88% agreed, from somewhat to fully, with the statement. This implies that a static posture during MIS causes muscle fatigue.

The physical discomfort in several parts of the body was rated from 0 (no pain) to 5 (severe pain). The column farthest to the left in Figure 12.13 indicates no pain, whereas the remaining columns all indicate discomfort in the particular areas. The most physical complaints concerned the neck, shoulders, and back. Figure 12.13 shows that almost 80% of the surgeons and residents experienced discomfort in these areas.

Finally, all the respondents stated that ergonomics are important in the operating room. However, only 11% of the respondents were aware of ergonomic guidelines concerning placement of the equipment and apparatus and an ergonomically correct posture (Figure 12.14).

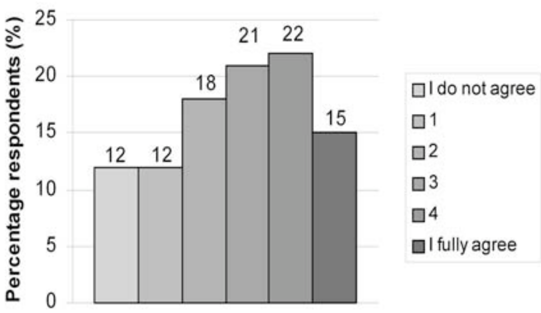


Figure 12.12. ''I experience muscle fatigue due to the static posture.''

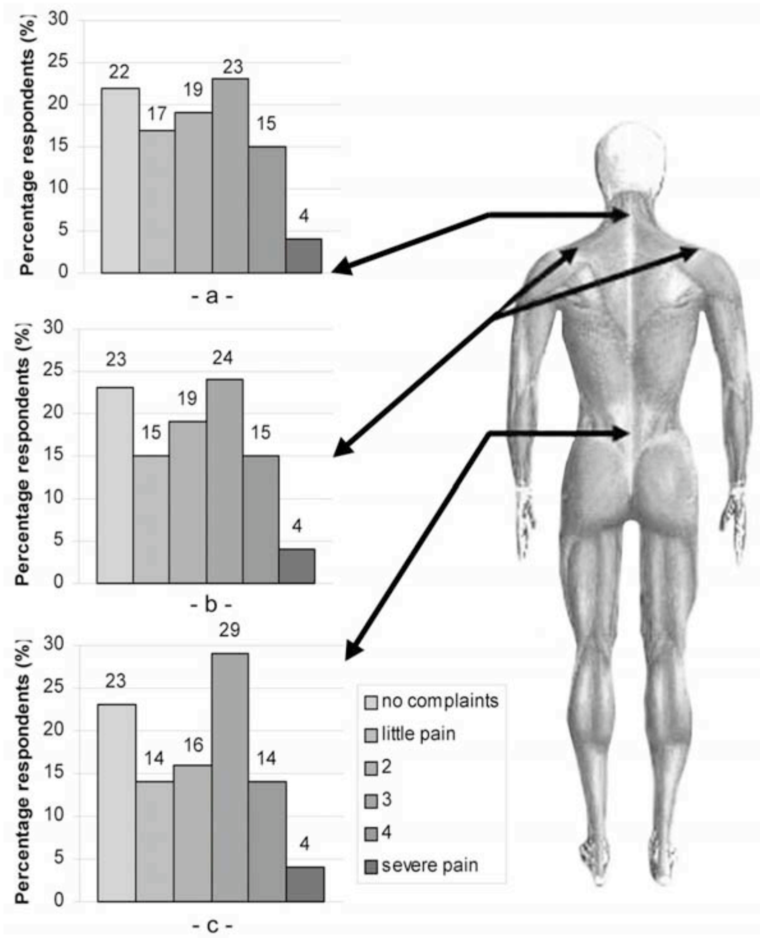


Figure 12.13. Percentage of respondents who experience pain in the neck (a), shoulders (b), and back (c)

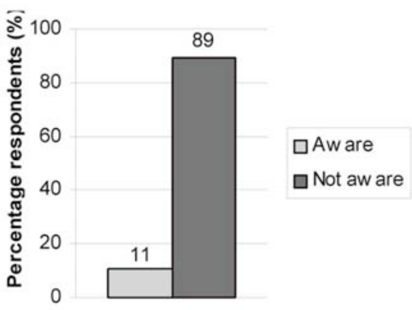


Figure 12.14. Awareness of ergonomic guidelines

12.4. Discussion

At the time of this study, the EAES had approximately 3,895 European members. Of these members, 990 registered an email address, and together with the 152 email addresses of the database of Schoofs and Gossot,[223] the questionnaires were sent. Although 284 respondents in comparison with the total of 4,047 is only 7%, the authors assume that the random survey sample still is representative for the population of surgeons in Europe. Besides, it is the largest sample survey found in the literature. This large number of respondents gives an adequate image of the problems encountered in the operating room during MIS. In addition, a total of 74 Dutch respondents filled out the questionnaire, which was 25% of the Dutch EAES members at the time. Consequently, this gives a representative image of the surgeons and their complaints in the Netherlands. It should be noted that the research was conducted mainly in Europe and thus is valid only for Europe.

Besides international differences, differences also can be found between the hospitals in each country. Many operating rooms differ in dimensions, layout, type of monitors (e.g., flat screens, CRT monitors, or projection screens), and placement of the monitors (e.g., at the side, feet, or head of the patient). All these factors, including the personal preferences of the surgeons and residents, make it difficult to compare the comfort level of the operating team during MIS.

During this study, the surgeons and residents had to rate their physical discomfort themselves. These subjective ratings (an objective study requires another approach) could have influenced the results because pain generally is seen as ''part of the job'' by surgeons and residents. Therefore, the respondents would not complain easily, which could have led to the ratings of relatively little discomfort.

Concerning the table height and the accompanying complaints, it was shown that 64% of the respondents experienced discomfort in the neck and 77% had discomfort in the shoulders. However, the operating surface height is even higher than the table height because of the patient and the inflation of the abdomen. Therefore, the physical problems are even worse because the arms and shoulders must be raised even more to control the instruments.

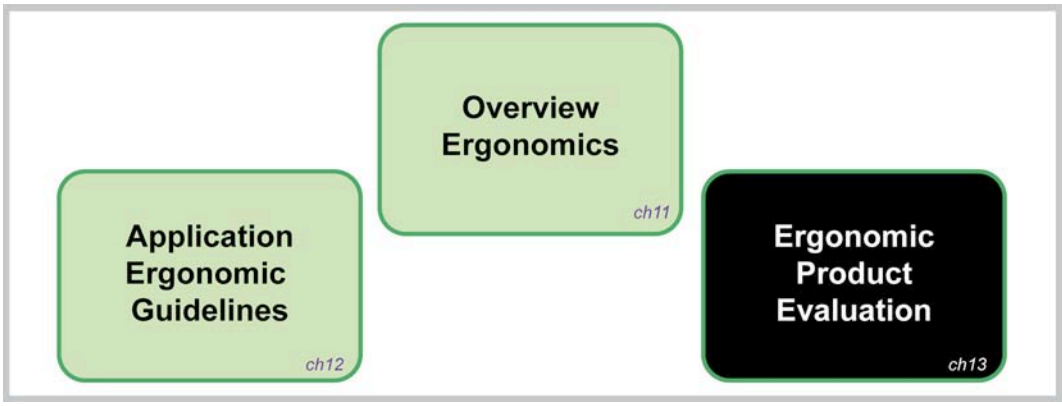
In recent years, many studies on the ergonomics in the operating room have been performed, mainly focused on minimally invasive procedures. These studies are of great importance. Although many ergonomic guidelines have been stated over the years,[24, 108, 159, 160, 162, 163, 247, 258] this study shows that only 11% of the respondents were aware of these guidelines. Considering the fact that 100% of the respondents found ergonomics to be important, it could be stated that ergonomics are inappropriately communicated to the operating team. Ergonomics should be presented as an improvement in the patient's safety. In the end, less discomfort causes less tiring, which leads to fewer mistakes, thereby benefiting the patient because less trauma is inflicted.

12.5. Conclusion

The answers to the questions stated in the introduction are as follows:

1. Notably only 11% of the 284 questioned surgeons and residents were aware of the ergonomic guidelines for placement of the equipment and ergonomic working postures, whereas 100% of the respondents stated that they find ergonomics important. It could thus be concluded that this unawareness of ergonomic guidelines is a major problem that poses a tough position for the ergonomics in the operating room.
2. Most respondents are unaware of the guidelines and therefore they are often not applied during MIS. Most of the time, the equipment is used in its initial position, and although possible, it is not adjusted according to the ergonomic guidelines for better comfort.
3. Finally, the research shows that the surgeons and residents found a relation between physical complaints and the apparatus and equipment used. The equipment indeed causes physical complaints. On the other hand, the questionnaire answers generally show relatively little discomfort in all of the researched areas, indicating that there is not one specific cause of physical discomfort.

Chapter 13. Surgical Lights: Ergonomic Product Evaluation during Open Surgery



Abstract

Introduction: In addition to the ceiling mounted lights, surgical lights are used to illuminate specific areas in the operating field. The current surgical lights are often based on xenion technology (XL: corona discharge lights). New surgical lights based on LED technology (Light Emitted Diode) are now available and have some advantages over the XL, such as uniform illuminance and shadow control. The aim of this study was to systematically evaluate both surgical lights by means of objective illuminance measurements and subjective interviews.

Materials and Methods: Surgeons and residents of different disciplines were asked to participate. Objective illuminance measurements using Xenion L+ and M+, and iLED 5 were performed using a sterile covered digital luxmeter, which was integrated in a custom made probe. The surgeon placed the probe on the measuring points in and around the operating field in random order. First measurements were performed using the XL, followed by the iLED. The wound's dimension was estimated as well. Both lights were positioned and adjusted according to all operating team members' satisfaction. Conditions were similar during both measurements. Furthermore, participants were asked to rate (1-10): the illuminance in and around the operating field, ability to see details, preference of light, and reflection using both lights.

Results: Disciplines cardio, general surgery and gynaecology participated. The objective measurements (n=11) showed that the illuminance using XL was higher during most procedures and more light dispersal was seen. Subjective measurements (n=13) showed that the illuminance in the total operating field and in a specific area was rated 8 (iLED) versus 6.5 (XL). Most participants (9/10) found the reflection non-disturbing using the iLED versus 4/10 for the XL. Compared to the XL, the illuminance of the iLED was rated better in 7 cases. The colour rendering of the iLED was found better in 9 cases. The overall view on the iLED is positive (10/11) and most participants (10/13) prefer the iLED to the XL.

Conclusion: The XL produces systematically more light dispersal and illuminance than the iLED, which can be attributed to the shading effect. The iLED produces a more uniform light due to the 184 LED's and has 'shadow control': compartments of LED's produce more or less light depending on the presence of an obstacle. The iLED was preferred to the XL. Also, overall illuminance, colour rendering, ability to see details and the absence of troublesome reflection was rated better.

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13.1. Introduction

Healthcare is one of the most dynamic and expanding areas in both western society and developing countries. The trend is discernible across the entire medical spectrum. As a result, the demand for specially trained engineers in this field is rising. At the Delft University of Technology, Faculty of Industrial Design Engineering, engineers are educated to translate the practical needs of the healthcare sector into products specially designed for medical applications in low-tech as well as high-tech applications. Industry has also been doing research into the field of design, development and production process in order to improve the quality of products, production process and human factors. The market for design and development of products for healthcare, and especially for products for the operating theatre (OT), is a multi million-dollar market with several different stakeholders and interests. Merging the interests and needs of medical professionals, industry, scientific institutions, and government legislation and regulations, can result in innovative and more appropriate ways of evaluating medical products.

This paper is meant to present the results of such evaluation where the uniqueness lies in the fact that the evaluation is performed on the spot, that is in and around the operating area during open surgery.

One of the basic necessities to perform safe surgery is good vision of the operating area and related to that the lighting conditions, especially during conventional open surgery. It is expected that each surgery require its own lighting conditions. The quality and intensity of lighting on the operating area are the main visual ergonomic considerations.[18] Matern and Koneczny (2007) showed that most of the hazards related to surgical lighting are due to insufficient illumination of the operating area, especially during dangerous situations.[161] In OT mainly two types of lights are present: 1) environmental lights, which are used for lighting the whole OT and mainly the anaesthetic area at the patient's head, and 2) surgical lights to illuminate specific areas in the operating area. Neon lighting and halogen lights mounted in the ceiling produce the environmental lights. Based on the Dutch basic quality regulations from the board of 'Hospital facilities' the nominal illuminance in OT produced by the environmental lights should be approximately 1000 lux.[46]

Most of the current surgical lights are based on xenon technology. The xenon light is based on a cutting-edge gas discharge technology, using build-in mirrors to disperse the light beam (see Figure 13.1).

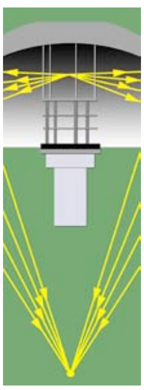

Figure 13.1. Xenon technology

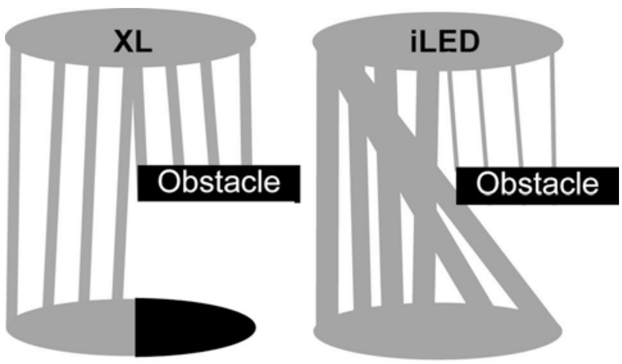

Figure 13.2. Shadow control Xenon light and iLED

New surgical lights based on LED technology (Light Emitted Diode) are now becoming available. When comparing two types of surgical lights, both produced by the company TRUMPF (Xenon Light - XL and the iLED), the iLED has a variety of technical advantages over the conventional XL, including uniform direct illuminance, shadow control (preventing shadows caused by obstacles in the light beam, see Figure 13.2), adjustable colour temperature, no start-up time, low heat generation, adjustable light characteristics, and a nearly unlimited life cycle (20,000 hours for the iLED versus 5,000 hours for the XL).[245, 246]

The aim of this study was to systematically evaluate both types of surgical lights (xenon and LED based lights) by means of objective illuminance measurements in and around the operating area during open surgery and subjective judgments of the participants through questionnaires and observations.

13.2. Materials and Methods

The research was divided into three parts: objective illuminance measurements, observations and completing a questionnaire.

13.2.1. Participants

Surgeons and residents of the disciplines cardio surgery, general surgery, gynaecology and orthopaedics, of a teaching hospital were asked to participate in the study.

13.2.2. Equipment

During the objective illuminance measurements the following surgical lights from company TRUMPF were used: 'Xenion L+' and 'Xenion M+' (XL: which were already mounted on moveable arms in the OT) and 'iLED 5' (iLED: mounted on a moveable cart with a moveable arm which was wheeled into place before measurement). The iLED consists of five panels with a multi-LED-Matrix, with each having its own convergence lens, all of them thus producing their own light field. In total 184 individual LEDs are included (blue, green, yellow and white LEDs). The main technical data of both surgical lights are shown in Table 13.1.

Table 13.1. Technical data surgical lights

Data	**iLED5**	**XL L+**	**XL M+**
Central illuminance at 1m distance [x1000 lux]	160	0.6-160	0.6- 120
Dimmable to [%]	10	50	50
Colour temp. adjustable from / to [x1000 K]	3.5 -5.0	4.3	4.3
Temperature rise in the area of the surgeon's head	<1˚C	no noticeable heat development in lamp housing / operating area	
Nominal LED / Lamp wattage [W]	184 x 1W	70/120	70
Effective life time of the light source [x1000 h]	>20	5	5
Light emitting surface [cm^2]	2.324	-	-

Besides the surgical lights a digital luxometer (Lutron LX-107), a custom-made probe for measuring illuminance in the operating area (Figure 13.3) and sterile covers for the probe (SteriVision®merete Drape) were used.

The custom made probe consisted of a bent metal 'spoon' on which a light sensor was mounted. To prevent reflection of the metal the probe was covered with a black synthetic shrink sleeve. The probe had to be held at the top in order for the light sensor to catch the light beam perpendicular (Figure 13.3).

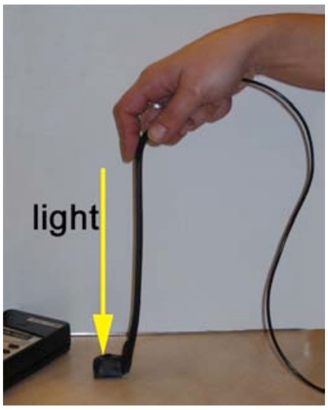

Figure 13.3. Custom made probe with light sensor

Figure 13.4. iLED in the operating theatre between XL

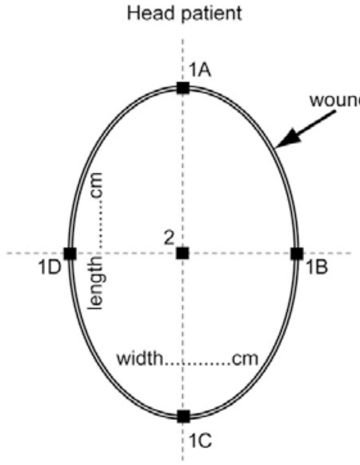

Figure 13.5. Reference points (1A-D, 2)

13.2.3. Method

The following information was recorded before surgery: date, type of surgery, surgeon's and assistant's name, surgical discipline, and OT's number.

<u>Objective illuminance measurement</u>

After the surgeon's approval to participate in the study, the iLED was wheeled into position in OT pre-operatively (Figure 13.4). During surgery the surgeon indicated when the illuminance measurements could be performed. The sterile covered probe was handed to the surgeon and randomly placed on the reference points in and around the operating area (Figure 13.5: positions 1A-D, 2) to measure the illuminance three times with the present XL. Also, the wound's dimension and depth were estimated. Subsequently, measurements were repeated using the iLED (switching the XL off or turning away). Both lights were positioned and adjusted according to all operating team members' satisfaction. Conditions were similar during both measurements (e.g., colour temperature: XL=4300K, iLED=4500K).

<u>Observations</u>

During the intra-operative phase of surgery the position and postures of the operating team and the location of the surgical lights were observed and captured by means of a digital camera.

<u>Subjective measurements</u>

One of the researchers asked the participants for their opinion about the XL and iLED immediately after surgery. See Table 13.2 for the questions posed to them.

Table 13.2. Overview of questions

1. How do you rate from 1-10:
   a. the illuminance in the total operating area?
   b. the illuminance in a specific location in the operating area?
   c. the ability to perceive details in the operating area?
   d. the colour rendering in the operating area?
2. Does the XL cause hindering reflection? (Yes / No)
3. Does the iLED cause hindering reflection? (Yes / No)
4. Compared to the XL, do you rate the illuminance of the iLED worse / same / better?
5. Compared to the XL, do you rate the colour rendering of the iLED worse / same / better?
6. Is your overall view of the iLED positive / negative?
7. Which surgical lights do you prefer, the iLED or XL?

13.3. Results

In total 11 objective and 12 subjective measurements were performed in the disciplines cardio surgery, general surgery and gynaecology (Table 13.3). No suitable surgeries were available within the discipline orthopaedics. Measurements within each discipline were performed in the same OT (reducing the possible impact of varying environmental factors). All procedures were observed and captured by means of a digital camera.

Table 13.3. Number of procedures with illuminance

Discipline	Illuminance measurements	Respondents questionnaire
Cardio	3	3
General Surgery (gs)	5	5
Gynaecology (gyn)	3	4
Total	**11**	**12**

13.3.1. Illuminance measurements

Figure 13.6, Figure 13.7, and Figure 13.8 show, per discipline, the illuminance levels measured while using the XL and iLED around the operating area (1A-D) and in the operating area (2). The ‘spots’ surround the reference points per surgery. In these figures a diagonal line is drawn to divide the figure in a segment in which the illuminance of the iLED was higher (upper left corner) and a segment in which the illuminance of the XL was higher (lower right corner).

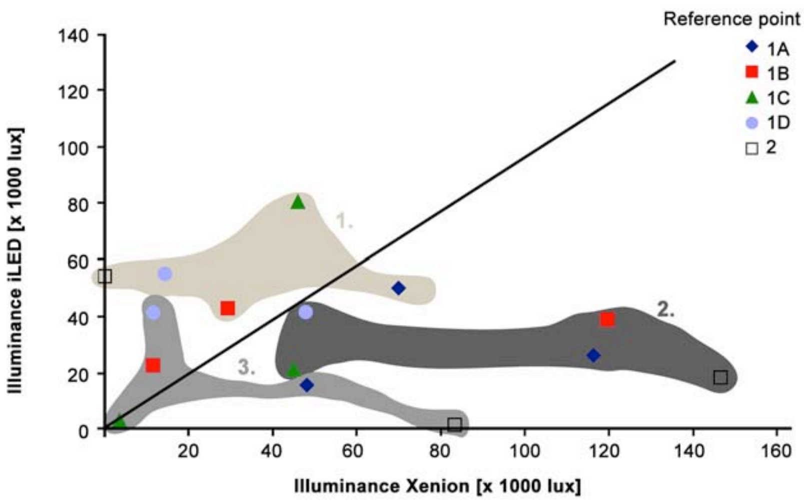

Figure 13.6. Illuminance iLED versus XL at reference points, Cardio (n=3)

Three **cardio surgeries** were performed. During surgery 1 (upper left spot in Figure 13.6) the illuminance in most reference points for the iLED was higher. During surgery 2 and 3 the XL produced more illuminance in most reference points. In addition, the XL caused systematically more light dispersal (range between the minimum and maximum illuminance) than the iLED.

Table 13.4. Illuminance in the operating area (reference point 2), Cardio

Surgery	**XL** [x1000 lux]	**iLED** [x1000 lux]
1	Missing data	54.13
2	146.53	18.22
3	83.30	1.47

Table 13.4 shows that the illuminance during surgery 2 and 3 *in* the operating area was systematically higher for the XL.

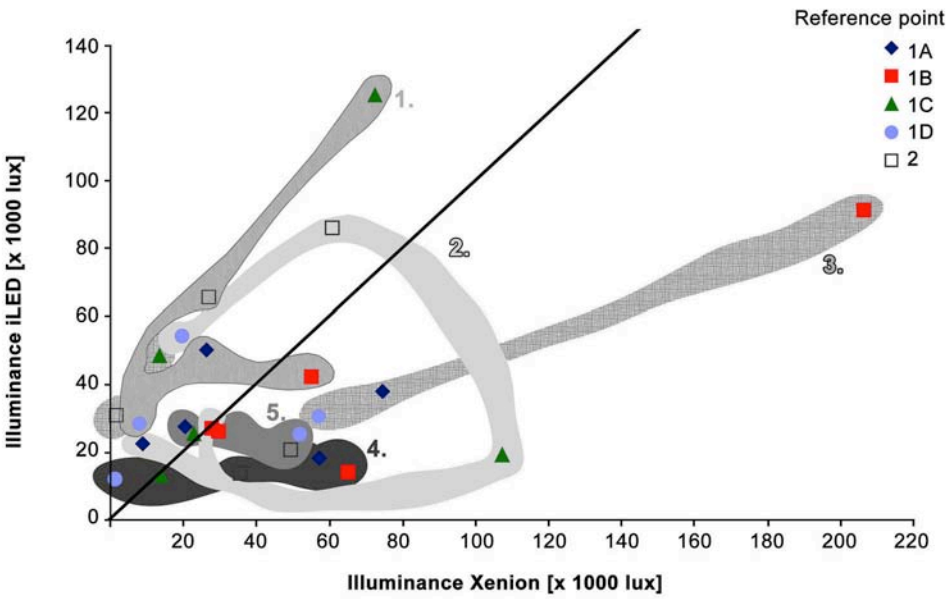

Figure 13.7. Illuminance iLED versus XL at reference points, General Surgery (n=5)

Within the discipline **general surgery** five surgeries were performed. Figure 13.7 shows that the iLED produced more illuminance in most reference points during surgery 1 and 2. Surgery 1 showed more light dispersal for the iLED (illuminance iLED at reference point 1D: 28,000 lux and at reference point 1C: 125,000 lux) than the XL (illuminance XL at reference point 1D: 7,900 lux and at reference point 1C: 72,000 lux). Surgery 2 showed little variation in light dispersal for both types of surgical lights. During surgeries 3-5 the XL produced more illuminance and also caused systematically more light dispersal than the iLED.

Table 13.5. Illuminance in the operating area (reference point 2), General Surgery

Surgery	**XL** [x1000 lux]	**iLED** [x1000 lux]
1	26.90	65.60
2	60.73	86.00
3	1.63	30.97
4	35.50	13.84
5	49.33	20.77

Table 13.5 shows that the iLED produced more illuminance in the operating area during surgeries 1-3.

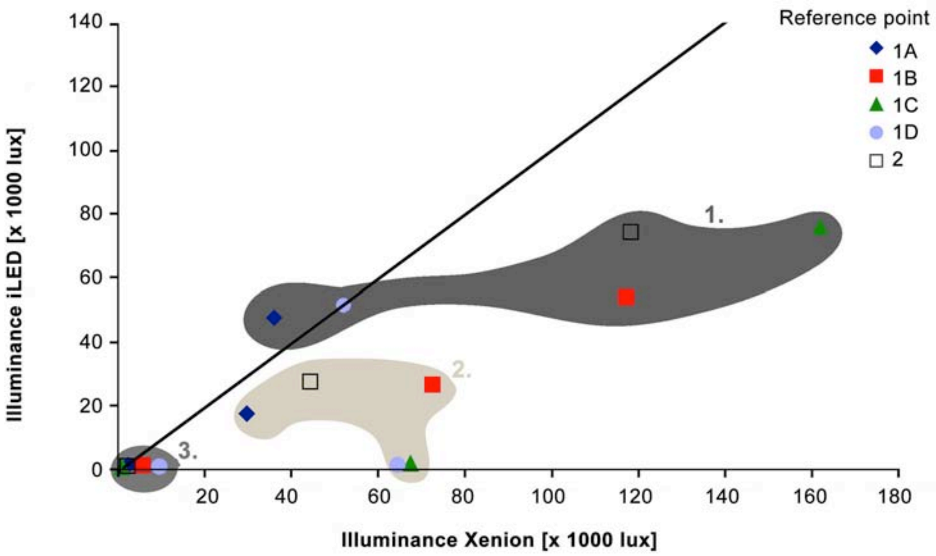

Figure 13.8. Illuminance iLED versus XL at reference points, Gynaecology (n=3)

Three **gynaecological surgeries** were performed. Figure 13.8 shows more illuminance in most reference points and systematically more light dispersal for the XL than the iLED. During surgery 3 the measured illuminance was lower than during surgeries 1 and 2. This was caused by obstruction of the light by the team members' heads.

Table 13.6. Illuminance in the operating area (reference point 2), Gynaecology

Surgery	**XL** [x1000 lux]	**iLED** [x1000 lux]
1	118.17	74.40
2	44.27	27.60
3	2.20	1.12

Table 13.6 shows that the XL produced more illuminance in the operating area during all surgeries.

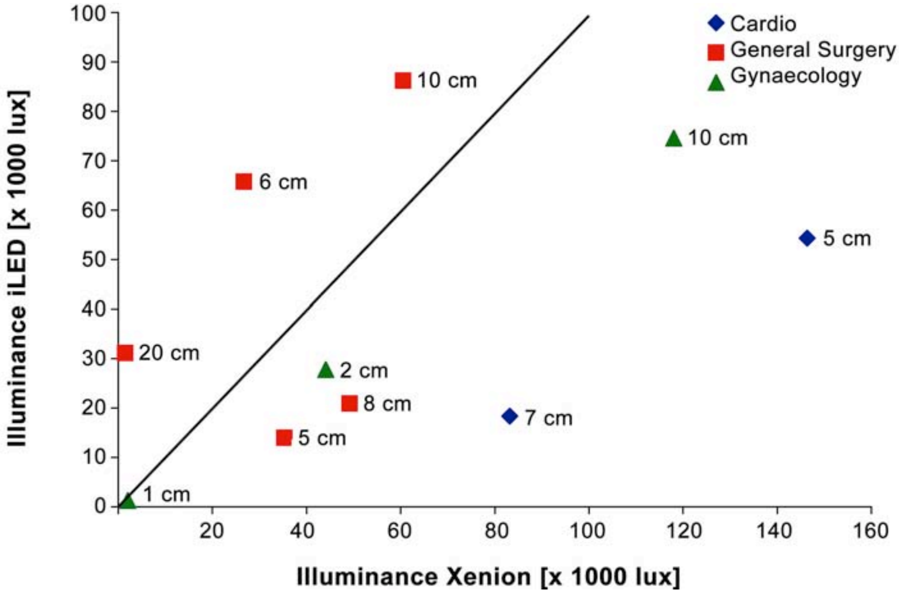

Figure 13.9. Illuminance in the wound (reference point 2) using iLED and XL (n=10)

Figure 13.9 shows the illuminance and the corresponding depth of the wound using iLED and XL. During one cardio surgery the illuminance and wound's depth were not measured. This figure was divided in similar segments as Figures 13.6-13.8. No systematic relationship seems to exist within and between the disciplines regarding the illuminance and the depth of the operating area. This holds for both surgical lights.

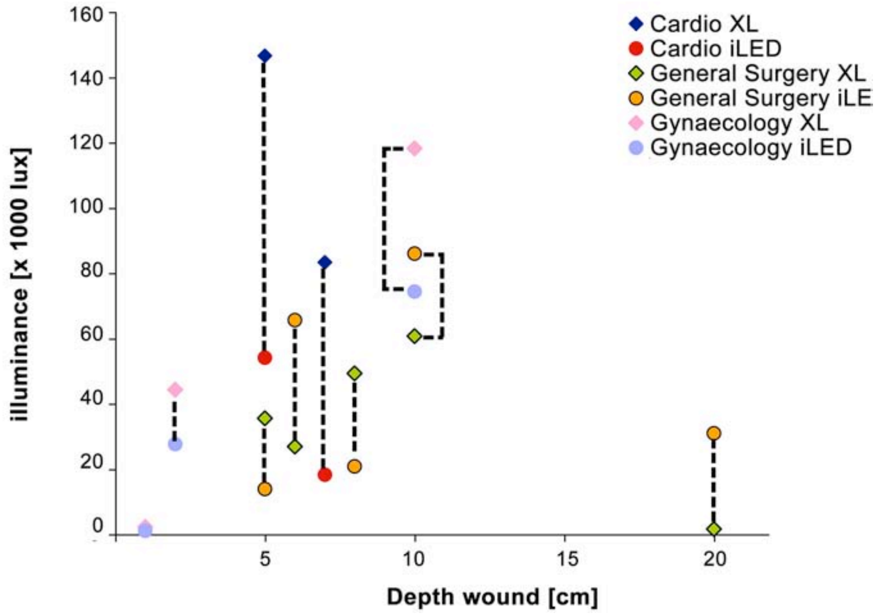

Figure 13.10. Illuminance in reference point 2 and wound's depth using iLED and XL (n=10)

Both figures 13.9 and 13.10 show that the illuminance using the XL was systematically higher than using the iLED. However, at the discipline general surgery 3 of 5 measurements show that the illuminance of the iLED is higher (procedures 1-3). In addition, the deepest wounds can be seen at this discipline.

13.3.2. Observations

The observations within the discipline cardio surgery (Figure 13.11a) indicated that the body posture of the operating team is mainly upright with a ventral flexed head. In addition to the surgical lights, a headlight is used for additional illumination of a specific location in the wound.

During general surgery and gynaecology an abducted torso and ventral flexion of the head was seen (Figure 13.11b and c). The heads are mainly above the wound, often blocking the light beam of the surgical lights.

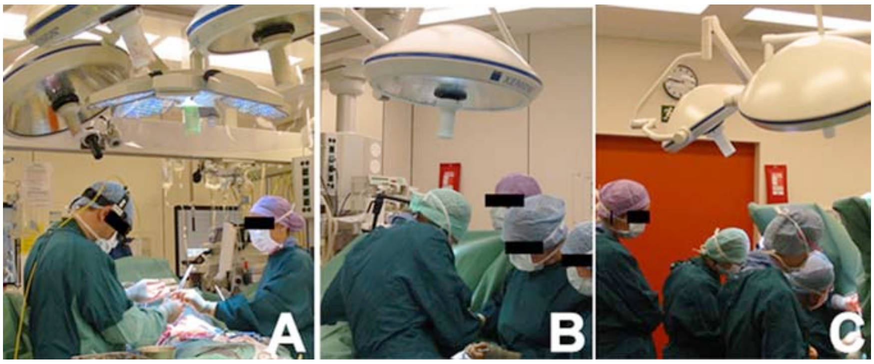

Figure 13.11. Operating team's postures during a) cardio surgery, b) general surgery and c) gynaecology

13.3.3. Subjective measurements

This section describes the results of the questionnaire.

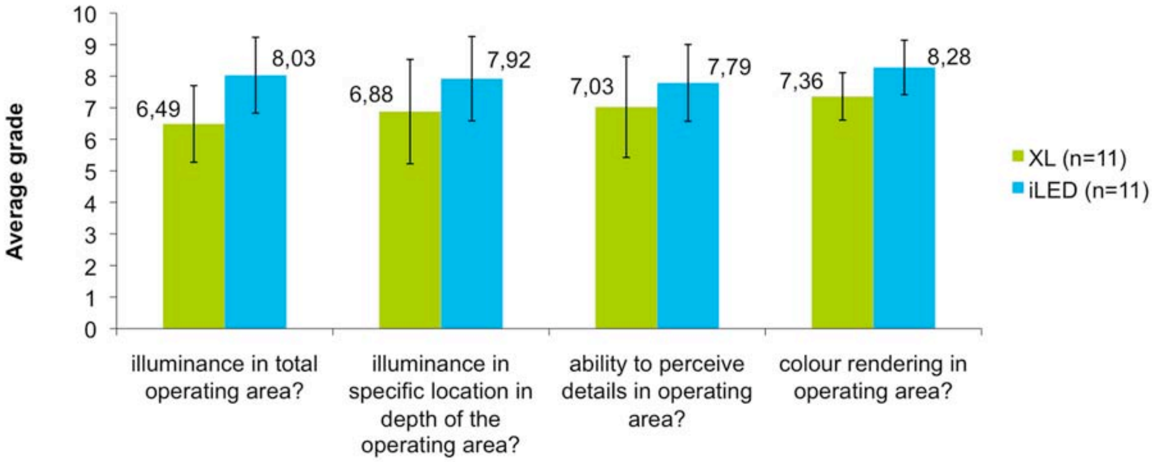

Figure 13.12. Questions: How do you rate from 1-10….?

Figure 13.12 shows that the respondents rate both the illuminance in the total operating area as well as in a specific location in the depth of the operating area better for the iLED than the XL. The ability to perceive details and the colour rendering in the operating area were also rated slightly better for the iLED.

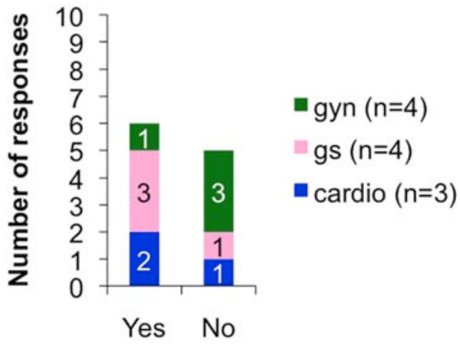

Figure 13.13. Does the XL cause hindering refection?

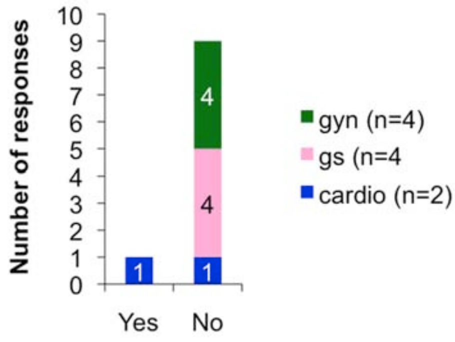

Figure 13.14. Does the iLED cause hindering refection?

Figure 13.13 and Figure 13.14 show that most participants (9/10= 90%) found the reflection non-disturbing using the iLED versus 5/11 (=45.5%) for the XL.

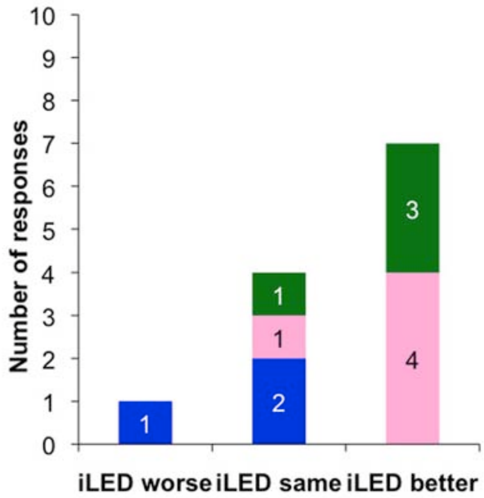

Figure 13.15. Compared to the XL, do you rate the illuminance of the iLED worse / same / better?

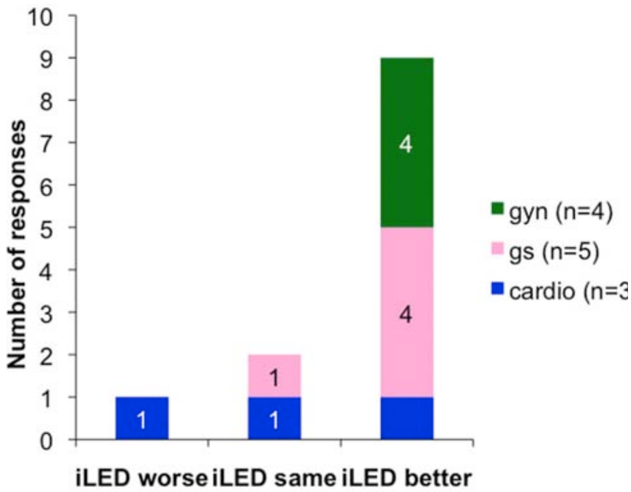

Figure 13.16. Compared to the XL, do you rate colour rendering of the iLED worse / same / better?

Figure 13.15 and Figure 13.16 show that compared to the XL, the illuminance of the iLED was rated better in 7 cases, comparable in 4 and worse in 1 case. The colour rendering of the iLED was found better in 9 cases, comparable in 2 and worse in 1 case.

The overall view on the iLED is positive (10/11) and most participants (10/13) prefer the iLED to the XL.

13.4. Conclusion

The objective illuminance measurements show that the XL produces systematically more illuminance and light dispersal than the iLED, in all disciplines. This is predominantly caused by the ‘shadow control’ option of the iLED, which produces a more uniform light with less or no shadows, but also results in less illuminance.

The questionnaires showed that the illuminance of the total operating area, as well as a specific location, is rated better in case of the iLED. In addition, the ability to see details and the colour rendering were also rated better for the iLED. Although the illuminance measurements showed a higher illuminance for the XL, the respondents did not rate it better.

The XL was perceived as blazing and dazzling, causing hindering reflection in the operating area.

Mainly the respondents within the disciplines general surgery and gynaecology preferred the iLED to the XL. Their postures caused (hindering) shadows using the XL and the iLED reduced or eliminated this shadow effect. Within the discipline cardio surgery the team's postures were more upright and usually an additional headlight was used to light specific areas, so hindering shadows were already reduced or absent.

No comparative scientific literature was found on illuminance measurements during the intra-operative phase of surgery in the actual operating area. This study provides unique and important realistic data of the illuminance in the operating area compared to a simulated environment. A disadvantage of this realistic setting is that it is difficult to keep the environmental factors constant. Factor that had an influence on the illuminance measurements were the angle of incidence, positions of obstacles and position and posture of the operating team. The researchers in OT have maintained these environmental factors as comparable as possible by means of good communication and instruction.

The additional features of the iLED, such as variation in colour temperature, switching different compartments on and off and a special 'Endo-light' option (to be used during minimally invasive surgery) were not objectively studied. In addition, the effect of colour temperature on the surgeon's concentration and fatigue should be studied. During this study some participants only tested a limited set of features at the end of the surgery. For an overall evaluation of the product these aspects have to be included as well, because these can add value to the conventional surgical lights.

13.5. Acknowledgements

The authors would like to acknowledge the contribution of the company TRUMP for providing the moveable iLED surgical light.

Chapter 14. Conclusions, General Discussion and Recommendations

Abstract

This chapter recapitulates all research findings and discusses these in a broader scope. Issues that are relevant for preventing errors are discussed and a model for research and reliable design in healthcare is presented. Furthermore, clinical implications of the initiatives studied are shortly discussed, followed by ideas for future development and research.

14.1. Recapitulation and general conclusions

The overall aim of this thesis was to answer the question: How to improve patient safety in the operating theatre during surgery? In order to answer this question, it was split into three parts referred to as Blackbox, TOP*plus* and Ergonomics.

14.1.1. Part A – BlackBox

A first step to improve patient safety is to study the processes concerning 'planning, acting and recording' surgical procedures. The key questions / topics of Part A were: 1) Gain insight in the current method for reporting surgical procedures and how these operative notes are used, 2) Study the disadvantages of current operative notes, and 3) Define initiatives to improve the quality of current operative notes. Answers to these questions can support and improve the design of objective recording systems. In turn, these recording systems can contribute to more objective operative notes, better postoperative detection of errors leading to more appropriate and faster treatment of the patient, education of medical professionals and students, and postoperative explanation to patients.

All studies conducted within this part focused on the minimally invasive procedure laparoscopic cholecystectomy (LC). The advantage of minimally invasive surgery (MIS) is that procedures are relatively easy to record as an image is already generated in order to perform the procedure. LC was chosen as this procedure is the most performed minimally invasive procedure and is the method of choice for gallbladder disease.

Procedure protocols aim to improve the quality and safety of the procedure. However, currently no protocol uniformity exists (Chapter 3). Although most operative notes are still dictated postoperatively, a trend towards template based and database based operative notes exists (Chapter 4). Applying these methods seems to improve the completeness and accuracy of the information in the notes. However, current operative notes are unable to serve all intended functions, such as research, education / training, medicolegal, and billing purposes. One of the factors causing this limited applicability is that operative notes are sometimes not written according to the guidelines for operative note writing (Chapter 5). In up to 30% of studied cases the operative notes did not comply. A second factor is that the notes are subjective (Chapter 6). Especially information concerning complications or deviations in the procedure was underreported (slightly more by surgeons than residents). Finally, current operative notes do not fully correspond to the actual events observed in the video recordings of that particular LC (Chapter 7). Video recordings could significantly support the quality of operative notes and could also improve its use for other purposes.

14.1.2. Part B – TOPplus

The second step to improve patient safety is by evaluating and improving the communication and teamwork in the operating theatre (OT). The key questions of Part B were: 1) What is the perception of communication and teamwork by the OT team members and what are considered weak points? and 2) How can the communication and teamwork be improved?

The first study showed that operating team members hold different perceptions of communication, teamwork and situation awareness (Chapter 8). Most significant differences were observed between surgeons and the other team members. Almost all team members also rated routine team briefings and debriefings as inadequate. In order to support communication and teamwork in OT and reduce errors, a Time Out Procedure *plus*

Debriefing (TOP*plus)* was designed by means of participatory design and implemented (Chapter 9). The Time Out Procedure is a double-check performed with the whole team and focuses on patient and procedure related details. The postoperative Debriefing reflects on the surgery that was performed by asking the question: Are there any details to be registered related to: surgery, anaesthesiology, materials and instruments, and communication and teamwork? During both procedures all team members played an active role by asking and answering role specific questions. After a pilot phase of approximately a week each hospital was encouraged to re-design the TOP*plus* poster according to their local context (Chapter 10). This user-centred participatory design approach, in combination with the context-specific design principles, proved advantageous for implementing the procedures and acted as a catalyst for initiatives to check the pre- and postoperative phase by means of checklists.

14.1.3. Part C – Ergonomics

The third step was to study ergonomics in OT, as a mismatch between the environment and persons could lead to errors. Improving ergonomics affects the operating team directly. In addition, it also improves patient safety indirectly, as the working conditions for the operating team improve, leading to less 'distractions' and thus resulting in safe care. The key questions of Part C were: 1) What is the current state of application of ergonomics in OT? and 2) What are the main points of attention in order to improve ergonomics in OT?

All ergonomic domains (sensorial, cognitive and physical) play an important role in OT (Chapter 11). Furthermore, the new domain 'environmental ergonomics' also plays an important role, as the OT environment is changing drastically into specially designed, technology-dependent surgical suites focussing on MIS and / or robotic surgery. Surgeons performing MIS experience physical discomfort in mainly neck, shoulder, and back (Chapter 12). Although no specific cause was found for this discomfort, applying ergonomic guidelines for positioning and placing apparatus and equipment is expected to improve comfort. In general, the importance of ergonomics was recognised, but only few surgeons were aware of general ergonomic guidelines to improve their working conditions. This poses a though position for ergonomics in OT. Finally, new products are designed to improve performance and safety of patients and team members. The surgical lights' product evaluation showed discrepancies between data and perception (Chapter 13). Although the Xenion light produced more intense light (lux), the subjective ratings showed a preference for the LED based surgical lights.

14.2. General Discussion

During the last centuries patient care has become safer. Many new treatments have been developed to improve both quantity and quality of live of people that suffer from disease. Technology has played and will continue to play an important role in improving this safety. Current OT's are highly complex and high-tech environments. Some of the technology applied has led to a decrease of physical discomfort for the operating team, such as the use of robotics. Other developments have led to an increase of discomfort for the team, such as MIS, as OT layout, apparatus, and equipment have not yet chanced accordingly. But from a patient's perspective the advantages are considerable. In combination with developments in anaesthesia, patients experience less postoperative pain and scars and can return to their daily activities much sooner.

All healthcare professionals want to provide safe patient care, but they are only human. Errors are expected to occur when humans interact with each other, instruments and equipment.[134, 207] Rasmussen (2003)[207] described that human behaviour in relation to work performance is governed by two boundaries of constraints: the individual boundary (e.g., tools available, competences, information about state of affair, processing capacity) and the environmental boundary which is given by the control requirements posed by the system (i.e. acceptable work strategies, available means of work) (Figure 14.1). These boundaries specify the 'space' in which the human can navigate freely without errors: the acceptable work performance. Violation of the constraints will be considered human error or task violation. In order to reach a specific goal, different functions with corresponding tools, physical and mental processes will be implemented. During each task the acceptable work performance differs, but humans try to keep this space of acceptable size. In case the environment will not provide an acceptable work performance (e.g., unavailable equipment, hampered coordination, time constraints) the individual will compensate by addressing his or her individual resources. An example:

> *During elective minimally invasive surgery the surgical team always includes an experienced camera assistant. However, during emergency surgery at 4 o'clock in the morning no experienced camera assistant is available, resulting into unsteady images. This means the environmental boundary in Figure 14.1 will shift to the right, reducing the surgeon's acceptable work performance. However, in order to restore the original space, the surgeon will try to address his mental capacities more to compensate for the movement. When this is not accurate enough the individual boundary will be crossed which may result in human error. Experienced surgeons cross this boundary less often than residents, as they are better trained in dealing with unfamiliar, new situations, and unexpected events as their human behaviour is more knowledge based.*[282]

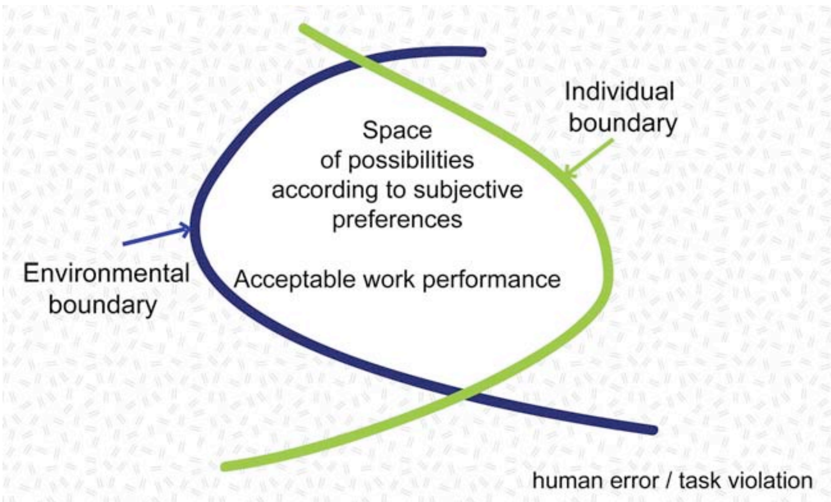

Figure 14.1. Acceptable work performance (adapted from Rasmussen 2003 [207])

The report 'To Err is Human' was one of the first publications openly acknowledging the human limitations in care.[134] As a result, many countries repeated the study in their own country.[57] The main results of all studies were similar: many errors occur, of which at least half could have been prevented.[54, 57, 134, 256] Often these errors are not caused by the individual care professional solely (persons approach), but are also the result of a mismatch between the design of a system and the production process (systems approach).[26, 134, 207, 232] This mismatch includes latent failures embedded in the system. In order to reduce the chance of latent errors leading to adverse event, the system has to be improved by shifting the environmental boundaries. This requires a re-design of the system with e.g., better technical facilities and equipment, better organisational structure, reasonable work schedules, good organisational culture, sensible redundancy, the use of protocols, and a good transfer of knowledge. Besides latent errors, active errors can also result in adverse events. The system should provide defence systems so these errors cannot happen, or happen safely and controllably. In order to reduce active errors, staff should e.g., follow training courses on technical skills and also on non-technical skills.

The task of the industrial design engineer (IDE) is to extend the ‘acceptable work performance’ by improving both the environmental and individual conditions, thereby expanding the boundaries of acceptable work performance. In addition, the IDE has to convince people of the relative ease of this change by giving examples of successful implementations and also by supporting the start-up phase. The TOP*plus* project is a good example of a product (poster) that was implemented successfully to improve the current situation. However, in some cases evidence based research is needed first before products and processes can be designed and implemented. This was the case for the blackbox project (Part A).

In order for products and processes to achieve their intended purpose, knowledge of the limitations and strengths of human performance and actions, and the complex setting of a healthcare organisation is vital. A human-centred approach is adequate for this purpose and requires insight on different levels. Kim Vicente (2006) describes the Human-tech approach in which five levels can be distinguished: Political, Organisational, Team, Physical, Psychological (see Figure 14.2).[269] In order to design products and processes for improved patient safety by means of a human-centred approach, input from all five levels is needed. This requires bridging the medical and technical fields by incorporating different methodologies that originate from design approaches and include multidisciplinary teams (e.g., technicians and medical professionals).

Before generating solutions and re-designing the system, research has to be conducted within all levels to gain insight in the needs, wishes and constraints. The type of research depends on the level. Gaining insight in the ‘political’ and ‘organisational’ level mainly requires document review, literature review and studying e.g., guidelines of associations, government, inspectorate, and rules and regulations. In the ‘team’, ‘psychological’ and ‘physical’ level mainly field studies have to be conducted (e.g., interviews, observations, questionnaires)(Figure 14.2).[5] Furthermore, research into causes of current errors from a systems perspective has to be performed as well, because ‘*there is no control without measurement of state, since controls are applied to reduce that state discrepancy (p.384)’.*[232] Priority has to be given to reducing unacceptable acts.

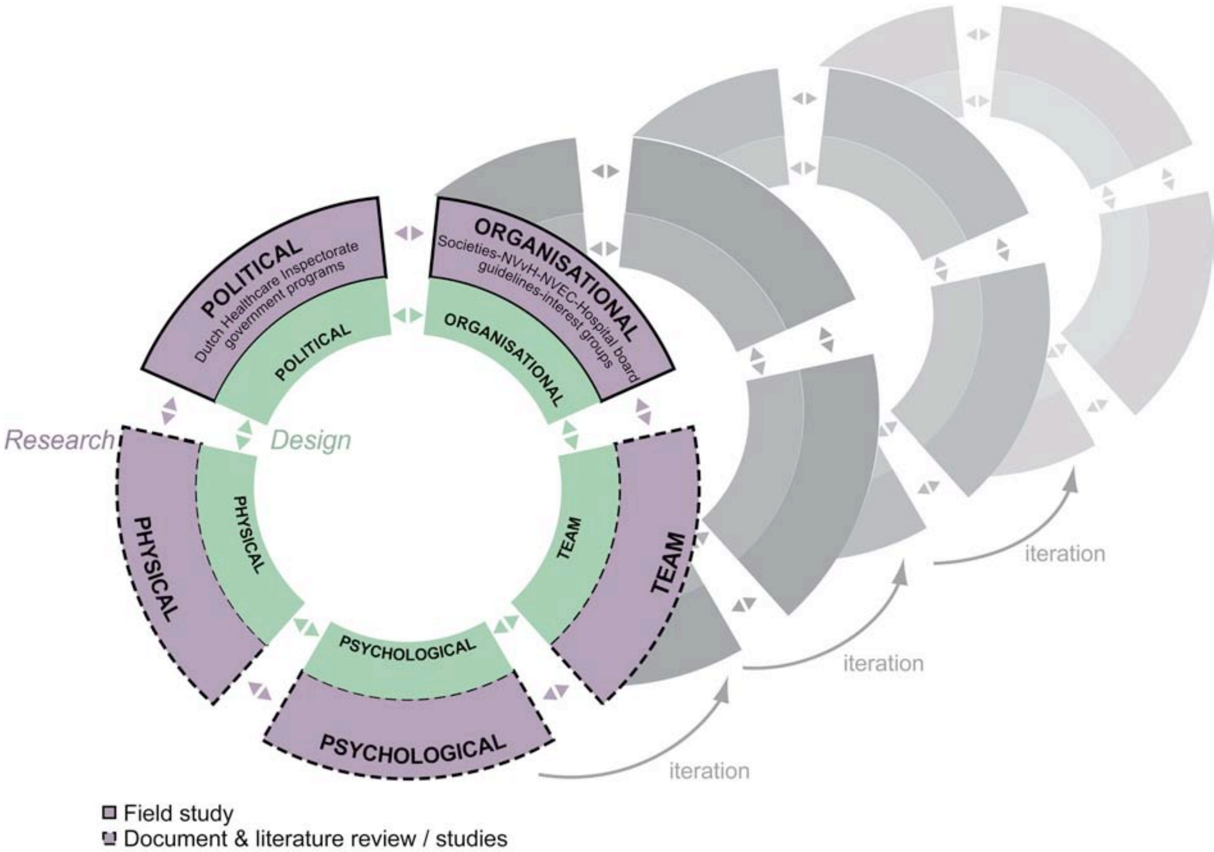

Figure 14.2. Levels to be included and actively involved during research and design

After performing research, a first version of the design (which could be a tangible product, but also a process or virtual tool) has to be generated by means of user-centred participatory design. In this process the people associated with each level have to be involved. Some people will be involved continuously, while others only play a role intermittently.[9] This first version has to be implemented by the people of the team working in OT, with support of the local organisation. The latter has to provide the necessary resources (e.g., money, staff, facilities). This bottom-up approach, in contrast to the often-used top-down approach, improves the chance of adoption and acceptance. However, early adopters (believers) are needed to start up the process.[114]

Designs for healthcare need to be reliable. Reliability in healthcare can be defined as: *'The measurable ability of a health-related process, procedure, or service to perform its intended function in the required time under commonly occurring conditions'*.[122] In order to achieve reliable designs, the first version of a solution (Design 1, Figure 14.3) should prevent initial failure or solve the initial problem with an 80-90% success rate (10^{-1} level of performance). For the design of *processes* this mainly includes standardization of processes.[122] In the second iteration, the failures of the first design, the remaining 10-20%, are identified and the design is modified, again with the intent of achieving 10^{-1} level of performance. The second iteration mainly includes two steps: identifying the defects caused by human factors (e.g., usability, intuitiveness), and designing *sensible* redundancy. In relation to the redundancy a measurement tool has to be set up as well, to determine the frequency of use of the redundancy. A rarely used redundancy will erode over time, will not be dependable, and will be perceived as 'waste'.[122] In contrary, redundancy used too frequently shows the design requires redesign.[122] The total outcome of the first two cycles results in a 10^{-2} level of performance.[122]

In the third and successive cycles, the defects of the previous cycles are prioritized and again modified. This iterative process leaves space for the team working with the design to adapt it to their local context. User-centred participatory and context-specific design should support the worker in such a way that the final design is the one costing the least effort, as humans will prefer to use as little effort as possible.[207, 232]

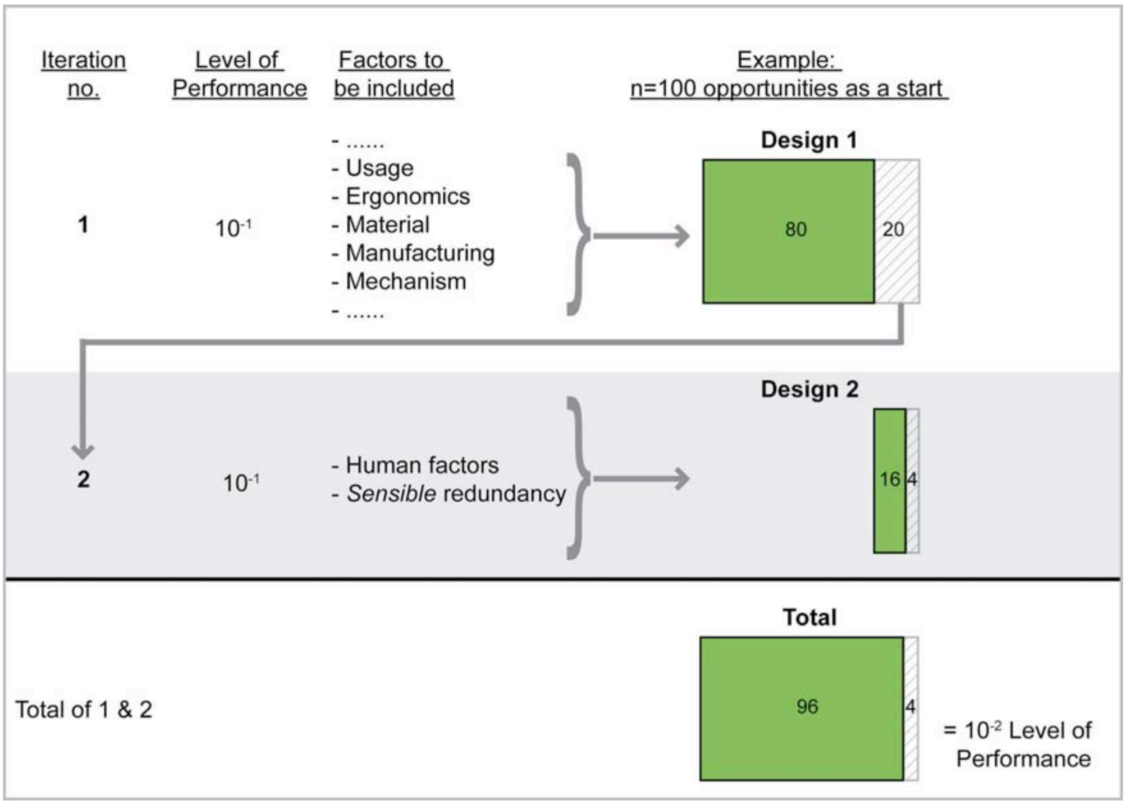

Figure 14.3. Level of performance when 100 opportunities are taken as a start [122]

In consumer goods, context specific features are very common, as many of today's products are customizable (e.g., covers for phones, PC settings, extra's on a car). This will improve the 'owning' of the product by its consumer. In the end, its intended users should like the design and they should feel as if *they* designed it themselves. Owning the product also makes it more likely that its users will keep on developing the product and will adapt it to the ever-changing circumstances (both environmental and individual).[207, 232] This is especially important in surgery, as patients, teams, and knowledge levels within the team are variable and changes in one aspect of the healthcare system can have an impact on the other aspects.[26]

The Dutch Healthcare Inspectorate published three reports covering the whole surgical trajectory.[71-73] Results showed that besides the lacking safety of equipment and apparatus, non-technical skills, i.e. communication within and between teams, and the information transfer were inadequate. These non-technical skills have to improve, as they are important contributors to patient safety. The most important non-technical skills are: Situation awareness and Vigilance, Leadership and Management, Teamwork and Cooperation, Problem solving, Decision making, and Communication and Interaction.[2, 106, 146, 172, 175, 226, 242, 249] Several systems can be used for assessing and training these skills.[172, 226, 250, 252, 253] However, improving non-technical skills has to be incorporated in daily routines (e.g., time out, debriefing, cross-checks). One of the projects focussing on non-technical skills is the 'The Hearts and Mind program' of the Energy Institute. This program focuses on progressing up the Health, Safety and Environment (HSE) Culture ladder by means of technology and standards, HSE management systems, and improving culture.[114] In order to promote behavioural and cultural change, personal responsibility, individual consequences, and pro-active interventions are necessary.[114] Other Dutch initiatives to reduce the number of 'preventable errors' with 50% before 2012 are 1) the projects within 'Sneller Beter' aiming to stimulate benchmarking, transparency, efficiency and quality in curative care, and 2) the national introduction of the VMS systems in hospitals ('veiligheidsmanagement systeem' - safety management system).[271] VMS provides a system for hospitals to *continually* point out risks, make corrections, and establish, evaluate and adjust policy.[271]

14.3. Clinical implications

The TOP*plus* project had the largest clinical implications, as this project was mainly an implementation study. Preliminary results show that more synergy was created in the perception on communication, teamwork and situation awareness, which should lead to more effective collaboration, better establishment of common goals for improving team performance, and ensuring patient safety. Although wrong side surgeries have a low incidence rate, they have far-reaching consequences for the patient. During the course of the TOP*plus* project some wrong side surgeries were prevented. Other small defects were sorted out (e.g., patient identification, administration of antibiotics).

TOP*plus* aimed to introduce a double-check in OT first, although in some hospitals a first check was absent, before introducing checks throughout the whole surgical trajectory. In contrast, the SURPASS (SURgical PAtient Safety System)[62] checklist implemented all checks (from the clinical ward to OT and back) at once. For some hospitals, joining the TOP*plus* project at a later stage, this full implementation was not feasible. The combination of the user-centred participatory design and context-specific design principles used in the TOP*plus* project appealed to many people, e.g., managers, boards, nurses, surgeons, and anaesthetists. Although the initial research started with three hospitals, already 15 (out of the 100 Dutch) hospitals perform TOP*plus* during all their procedures. The best response heard was: *'without performing TOP, I feel unsafe'.* Furthermore, there is a great demand for the TOP*plus* posters and our expertise. Medirisk (large liability insurance organisation) also showed interest in the project. In addition, TOP*plus* acted as a catalyst for interventions set up by the people on the work floor aiming to improve the pre- and postoperative phase. Finally, TOP*plus* convinced many people of the importance of double-checks and non-technical skills in OT.

Currently, data reported on surgical procedures are subjective and not standardized. Although the actual blackbox was not designed and implemented yet, the studies performed in Part A show the *need* for a new method for recording surgical procedures. During the course of this research, the participating hospitals experienced that recording procedures is relatively easy with today's video recording equipment in OT. These recordings are a mean for generating operative notes, but also a mean for research, possibly medicolegal cases, training, and quality assurance. Although the blackbox is not part of the operative note yet, residents started recording their procedures for training purposes. One hospital recorded their procedures on an external hard disk as a safeguard if the operative note could not be written immediately after surgery. During the study presented in Chapter 7 a bile duct injury was inflicted. This DVD was reclaimed in order to study the cause(s) leading to this complication. Furthermore, in the Erasmus MC the recording of procedures was facilitated by means of recording on a personal memory stick. One participating hospital already recorded each procedure on their server based on a 'first in first out' principle. Unfortunately, this opportunity could not been followed up with a systematic approach yet. As Part A provides the necessary data to convince the importance of video recording, a first step has been made to expedite the development of the surgical blackbox for MIS to improve clinical outcome.

14.4. Future development and research

Future research should focus on interventions and designs that aim at broadening the acceptable work performance (Figure 14.1). Firstly, improve the environmental conditions by e.g., providing ergonomically sound products, reducing the administrative workload by using a blackbox. Secondly, improve the individual conditions. The Time Out Procedure and Debriefing are a first step in introducing double-checks in OT. However, intra-operative checks should also be included. This is a relatively new principle in healthcare that should be explored further. Historically doctors and specialists, like surgeons, are trained as individual, autonomous, healthcare workers with traditional legitimacy with regard to taking crucial decisions, denying the human factors-reality as such.[122] Like in other high-risk technically complex industries the introduction of defined decision moments during therapies, like operations, with cross-checking of all team members should be seriously considered. This cross-checking aims to establish important procedure related factors (e.g., CVS reached before transection of cystic artery and duct) and aims to improve the knowledge level and involvement of the OT team members. However, in order for designs to fulfil their aim, the direct effect on patient safety has to be established.

Based on the results of Part A, the necessary data are available for a first design of the surgical blackbox. As the necessary technology is already available too, a prototype could be introduced. However, the staff has to be convinced that all recordings are safe for both patients and teams and are not used for malpractice cases. This requires defining explicit rules and regulation for (video) recordings that in the end should lead to a statutory regulation.[69] Some of the questions to be answered are: what should be recorded?, what should be saved?, who may and who may not look into the recordings?, and will it substitute the written report or be an appendix? Furthermore, in order to reduce the amount of protocols and guidelines and improve communication between healthcare professionals, future research should study the link between procedures' protocols, performing surgery, and recording the surgery. In other words, if the procedure protocol requires e.g., reaching CVS and cross-checking CVS, it is only logical that this is recorded as well. Additional research is also needed for the recording of open procedures. Preliminary results of recording colorectal anastomosis (joining together two parts of the colon) showed that results from the LC studies are not fully applicable for other procedures. Challenges lie in the field of the unavailability of an official national guideline on critical moments, the absence of a camera as part of the standard equipment, recording the anastomosis all-round, and not interrupting the flow of the operation too much. Finally, further research and development is needed for generating operative notes based on image and video.

Based on the TOP*plus* project many initiatives have been started by the hospitals. With the Time Out Procedure and Debriefing being part of the Crew Resource Management principle, the next step will be to implement this training and so further improving the team's non-technical skills.

Although many medical professionals acknowledge the importance of ergonomics in the workplace, it seems that this receives only limited attention. Although many hospitals acquire new OT's, with e.g., monitors on moveable arms, these functions will not be used to its full advantage if healthcare professionals are not aware of the guidelines. Future research and development should focus on the importance of all ergonomic domains in relations to all team members (not just the surgeon). Including ergonomic positioning of equipment in the Time Out Procedure might improve awareness. Additionally, engineers and manufacturers should consider ergonomic aspects equally important as technological aspects. Furthermore, although patients do not have an active role during the operation, they experience discomfort postoperatively from badly designed products, mainly a hard and too narrow operating table. When arm-, and leg supports are used additional unacceptable levels of pressure can be applied. The straps and bandages used to fix the patient to table and to the supports can also cause discomfort. Finally, the connection between ergonomics, operating team, patient, and patient safety has to be established.

In conclusion, putting *patient-centred* care plans into action and making the *patient* the centre of interest requires merging the medical and technical domain.

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Summary

In 2008 approximately 3.7 million people visited a hospital in the Netherlands. Half of them had to undergo surgery. Surgery involves activities between humans, and between humans and specialized medical equipment in a specialized room, the operating theatre (or operating room). During surgery several persons (e.g., surgeons, residents, anaesthetist, nurses) are involved, each with her or his own profession, tasks and responsibilities.

This thesis focuses on the intra-operative phase of the most performed types of surgery: conventional open surgery and Minimally Invasive Surgery (MIS; surgery performed through small incisions in the skin or through the natural openings of the human body, at which the surgical field is projected on a monitor).

Human performance introduces errors in the operating theatre (OT). The advances in high-tech technology in OT and the increased complexity of surgical procedures, contribute to the increase in medical errors rates. Errors may or may not have consequences for the patient. These consequences range from minor harm to death, and also contribute to a rise in healthcare costs. A way to reduce these errors is by standardising the surgical environment as well as the processes and activities that take place in OT (human-product and human-human interaction).

The main question of this thesis is: *How to improve patient safety in the operating theatre during surgery?*

The literature overview presented in **Chapter 2** shows that although the cockpit of an airplane and OT are comparable, they are not similar. Main differences exist in patient's variance and in the existing culture, especially in acknowledging human error and human fallibility. Furthermore, differences exist in reporting errors, using standardisation by means of procedural checklists, and the training of technical and non-technical skills. By analogy with other high-risk industries, the proposed solutions can be categorised into: 1) transparency: gaining insight in the process leading to errors (e.g., patient safety reporting systems), 2) culture (e.g., open non-punitive culture, horizontal hierarchy), 3) standardisation (e.g., checklists, cross-checks), and 4) training (e.g., of non-technical and technical skills).

In order to answer the main question, this thesis has been split up into three parts.

Part A | Blackbox focuses on one of the conditions improving patient safety directly: the processes concerning 'planning, acting / performing and recording' surgical procedures.

Surgical procedures are described in protocols. One of the most performed minimally invasive procedures is laparoscopic cholecystectomy (LC), and its most common complication is iatrogenic bile duct injury. **Chapter 3** studies the uniformity of LC protocols ('planning') by comparing the described steps ('acting') written in existing protocols from various Dutch hospitals. The results show that many differences exist and that present protocols differ too much to define a universal procedure among surgeons in the Netherlands. Major differences can be found for the concept of 'critical view of safety (CVS)' and the order of clipping and cutting the cystic artery and duct. Descriptions of instruments

and apparatus are also inconsistent. With regard to unambiguous language, it can be concluded that different terminology is used and that the steps differ in their level of detail.

Chapter 4 provides an inventory of the different methods for writing operative notes ('recording'), its use, and relevance. Most operative notes are still narrative reports, often dictated or handwritten. However, a trend towards template- and database-based notes can be observed, which is expected to improve record keeping. Occasionally, images and / or video are added. This review shows that, at present, there is a lack of uniform and structured standards for operative notes, and although notes are used for e.g., safe patient care, follow-up, research, education / training, medicolegal, and billing purposes, they often are unsuitable to serve all these functions.

In **chapter 5** the compliance with the Dutch guidelines for writing operative notes concerning LC is assessed. Current operative notes do not fully comply with these standards, which could influence adjuvant and future patient treatment and make the notes less suitable for other purposes. Descriptions of the patient's posture, bandage, blood loss, name of the scrub nurse, postoperative conclusions, and postoperative instructions are often lacking.

Chapter 6 studies the subjectivity of operative notes by evaluating the current routine of operative note writing for LC and by looking at the differences between notes on the same surgery written by surgeons and residents. The current routine of note writing shows that both surgeons and residents describe 60% of the general items analysed. On average the residents include an additional two to three general items compared to the surgeons.

Chapter 7 compares the video recordings of LC with the corresponding operative notes. Today's operative notes in the Netherlands do not fully correspond to the actual events observed in the recordings. Main differences can be found for introducing trocars under vision, gallbladder's status, CVS, and removing trocars under vision. Contrarily, iatrogenic gallbladder perforation is described in most notes.

Part B | TOP*plus* focuses on a second set of conditions improving patient safety directly, namely the implementation of a Time Out Procedure *plus* Debriefing (TOP*plus*). During the Time Out Procedure, just before surgery, the surgical team members will check surgical details, anaesthetic details, and patient information. The aim is to prevent wrong side, wrong procedure, wrong person and wrong doses of medication. During the Debriefing, immediately after surgery, the surgery performed is evaluated with the whole team.

Chapter 8 describes the differences in perception of the non-technical skills communication, teamwork, and situation awareness between surgeons, anaesthetists, nurse anaesthetists and nurses. This study shows discrepancies in perception within communication, particularly between surgeons and all other team members. For teamwork differences between all team members can be observed. For situation awareness most differences can be observed between surgeons and other team members, and between OT nurses compared to anaesthetists and nurse anaesthetists. Additionally, most team members rate routine team briefings and debriefings as inadequate.

Chapter 9 describes the basic design of TOP*plus* by means of participatory design (PD), its implementation, and evaluation. Designing TOP*plus* with a multidisciplinary design-expert-team and adapting it to its local context with the hospital-expert-teams is valuable, fast, easy, and much appreciated by most professionals. However, resistance to chance is not reduced in all hospitals. TOP*plus* starts the dialogue between all OT team members and acts as a catalyst for improving the whole care process.

Chapter 10 investigates the feasibility of context-specific design principles in addition to user-centred PD (UPC-Design method) in order to improve implementation and sustainability of initiatives to improve patient care in hospitals. Here TOP*plus* is taken as a case. Using the UPC-design method improves team discussion and active participation of all team members. UPC-Design also improves adapting the procedure to the needs of the local context, which in turn improves implementation of the project hospital-wide. The UPC-Design method is of value for patient safety initiatives.

Part C | Ergonomics in the Operating Theatre focuses on conditions improving patient safety indirectly by improving the working conditions of the operating team.

Chapter 11 provides an overview of ergonomics for both open and MIS in OT. The three main domains of specialization in ergonomics are related to sensorial, cognitive and physical ergonomics. Problems encountered in the sensorial domain are mainly observed during MIS and are related to vision, instruments' haptics, and the use of pedals. Problems encountered in the cognitive domain during MIS are related to indirect vision, behaviour, inadequate and lacking training of technical and non-technical skills, and the use of protocols, checklist, briefings and debriefings. In the physical domain, problems encountered during MIS are caused by the height of the operating table, monitor position and height, instrument handles, pedals, and posture. Furthermore, an extra domain is added, the environmental ergonomics. Factors such as lighting, temperature, air condition, sound, noise, and crowding contribute to both the wellbeing of the medical staff and patient.

Chapter 12 studies whether ergonomic guidelines are applied in OT and what the consequences are. European surgeons and residents performing laparoscopic and / or thoracoscopic procedures state that they experience discomfort in their necks, shoulders, and backs. However, not one specific cause is provided. Although all respondents state that they find ergonomics important, only few are aware of ergonomic guidelines. Most of the time, the equipment is used in its initial position and, although possible, it is not adjusted according to the ergonomic guidelines for better comfort. This lack of ergonomic guidelines awareness is a major problem that poses a tough position for ergonomics in OT.

Chapter 13 systematically evaluates two types of surgical lights (i.e. Xenion, iLED) by means of objective illuminance measurements during open surgery and interviews. The objective measurements show that the Xenion light produces more light dispersal and illuminance than the iLED. The interviews show that the iLED is preferred to the Xenion light (due to less troublesome reflection and hindering shadows, better illuminance and colour rendering).

Finally, **Chapter 14** recapitulates all research findings and discusses these in a broader scope. Issues that are relevant for preventing errors are discussed and a model for research and reliable design in healthcare is presented. Furthermore, clinical implications of the initiatives studied are shortly discussed, followed by ideas for future development and research.

Samenvatting

In 2008 bezochten circa 3,7 miljoen Nederlanders het ziekenhuis. Jaarlijks ondergaat de helft van deze patiënten een operatie. Opereren betreft activiteiten tussen mensen en activiteiten tussen mensen en gespecialiseerd medisch instrumentarium en apparatuur in een speciale ruimte, de operatiekamer (OK). Bij een operatie zijn verschillende professionals betrokken (o.a. chirurgen, chirurgen in opleiding (AIOS), anesthesiologen, anesthesiologen in opleiding (AIOS) en ok-assistenten) ieder met zijn / haar eigen takenpakket en verantwoordelijkheden.

Dit proefschrift richt zich op de peroperative fase van de meest uigevoerde typen operaties, namelijk conventionele, open chirurgie en Minimaal Invasieve Chirurgie (MIC; operaties uitgevoerd via kleine incisies in de huid of via de natuurlijk openingen van het lichaam, waarbij het operatiegebied geprojecteerd wordt op een monitor).

Menselijk handelen gaat gepaard met fouten. De toenemende high-tech technologie in de OK en een toenemende complexiteit van chirurgische ingrepen dragen bij aan toename van het aantal medische fouten in de OK. Fouten hebben al dan niet consequenties voor de patiënt (van klein letsel tot overlijden), hetgeen ook gepaard gaat met hogere kosten voor de gezondheidszorg. Een mogelijke invalshoek om fouten te reduceren is om zowel de chirurgische omgeving, als de processen die daarin plaatsvinden (mens-product en mens-mens interactie), zoveel mogelijk te standaardiseren.

De hoofdvraag van dit proefschrift luidt: *Hoe kan patiëntveiligheid in de operatiekamer verbeterd worden?*

Het literatuuroverzicht in **hoofdstuk 2** laat zien dat, hoewel de cockpit van een vliegtuig vergelijkbaar is met de OK, er ook grote verschillen zijn. De grootste verschillen zijn te vinden in de variatie in patiënteigenschappen en de werkcultuur, met name in het erkennen van menselijke fouten en feilbaarheid. Bovendien zijn er verschillen te vinden in het melden en rapporteren van fouten, in de standaardisatie door middel van procedurele checklists en in de training van technische en niet-technische vaardigheden. Mogelijke oplossingen vanuit vergelijkbare risicovolle, technisch-complexe industrieën zijn in te delen in vier categorieën: 1) Transparantie: het verkrijgen van inzicht in de processen die tot fouten leiden (o.a. meldingssystemen voor patiëntveiligheid), 2) Cultuur (o.a. open, niet-straffende cultuur, horizontale hiërarchie), 3) Standaardisatie (o.a. checklists, cross-checks) en 4) Training (o.a. trainen van niet-technische en technische vaardigheden).

Om de hoofdvraag te kunnen beantwoorden is dit proefschrift opgedeeld in drie delen.

Deel A | Blackbox focust op één van de condities die patiëntveiligheid direct beïnvloeden: het proces van 'plannen, uitvoeren en verslagleggen' van operaties.

De meest uitgevoerde minimaal invasieve operatie is de laparoscopische cholecystectomie (lap chol), met als ernstigste complicatie iatrogeen galwegletsel.

Hoofdstuk 3 bestudeert de uniformiteit van lap chol protocollen ('plannen') door middel van een vergelijking van de beschreven stappen ('uitvoeren') in bestaande protocollen van verschillende Nederlandse ziekenhuizen. De resultaten laten zien dat huidige protocollen te veel van elkaar verschillen om één universele procedure onder Nederlandse chirurgen op te stellen. De grootste verschillen zijn te vinden in het concept 'critical view of safety (CVS)' en de volgorde van clippen en klieven van de arteria cystica en de ductus cysticus. Beschrijvingen over het gebruik van specifiek instrumentarium en apparatuur is ook inconsistent. Bovendien kan geconcludeerd worden dat verschillende terminologie wordt gebruikt en dat de beschrijving van de stappen verschilt in mate van detail.

Hoofdstuk 4 beschrijft een inventarisatie van verschillende methodes voor verslaglegging van operaties ('verslagleggen'), alsook het gebruik en de relevantie ervan. De meeste operatieverslagen zijn beschrijvend en worden vaak gedicteerd of met de hand geschreven. Wel is er een trend naar templates en database-gegenereerde operatieverslagen (waardoor de verslaglegging verbetert). Soms wordt foto- en / of videomateriaal toegevoegd aan het verslag. Dit literatuuroverzicht toont aan dat er momenteel geen uniform gestructureerde standaard is voor operatieverslagen. Hoewel operatieverslagen gebruikt worden voor o.a. veilige patiëntenzorg, nazorg, onderzoek, educatie / training, medicolegale en financiële doeleinden, zijn deze momenteel dus ongeschikt voor al deze doeleinden.

Hoofdstuk 5 beschrijft de naleving van de Nederlandse richtlijn voor verslaglegging van operaties met betrekking tot de lap chol. Huidige operatieverslagen voldoen niet volledig aan de richtlijnen. De items: houding van de patiënt, het gebruik van verband, bloedverlies, naam van de instrumenterende, postoperatieve conclusies en postoperatieve instructies worden vaak ondergerapporteerd. Dit kan de vervolgbehandeling en toekomstige behandeling van de patiënt beïnvloeden. Tevens beperkt dit het gebruik van operatieverslagen voor overige doeleinden.

Hoofdstuk 6 bestudeert de subjectiviteit van operatieverslagen in vergelijking met de huidige routine van verslaglegging en de verschillen in operatieverslagen geschreven door chirurgen en AIOS. De huidige routine van verslaglegging laat zien dat zowel de chirurgen als de AIOS 60% van de algemene geanalyseerde items beschrijven. Gemiddeld beschrijven de AIOS twee à drie algemene items meer dan de chirurgen.

Hoofdstuk 7 vergelijkt de video opnames van lap chol ingrepen met de bijbehorende operatieverslagen. Huidige Nederlandse operatieverslagen corresponderen niet volledig met de uitgevoerde handelingen zoals die in de video opnames te zien zijn. De grootste verschillen zijn te vinden in het introduceren van de trocars onder zicht, de pathologie van de galblaas, CVS en het verwijderen van de trocars onder zicht. Iatrogene galblaasperforaties worden wel beschreven in de meeste operatieverslagen.

Deel B | TOP*plus* focust op een tweede groep initiatieven om de patiëntveiligheid direct te verbeteren: de implementatie van een Time Out Procedure (preoperatieve briefing) *plus* Debriefing (TOP*plus*). Tijdens de Time Out Procedure, vlak voor de operatie, controleert het operatieteam chirurgische aandachtspunten, anesthesiologische aandachtspunten en patiënt informatie met als doel het voorkomen van operaties aan de verkeerde kant, aan de verkeerde persoon en het voorkomen van verkeerde operaties en verkeerde dosis medicatie. Tijdens de Debriefing, direct na de operatie, wordt de operatie geëvalueerd met het hele team.

Hoofdstuk 8 beschrijft de verschillen in perceptie van de niet-technische vaardigheden 'communicatie', 'teamwerk' en 'situation awareness' tussen de operatieteamleden. Met betrekking tot 'communicatie' zijn er met name verschillen tussen de chirurgen en de overige teamleden. Met betrekking tot het 'teamwerk' tussen alle teamleden en met betrekking tot 'situation awareness' zijn de grootste verschillen te vinden tussen de chirurgen en de overige teamleden en tussen de operatie-assistenten en de anesthesiologen / anesthesiemedewerkers. Tevens vinden de meeste teamleden de huidige briefings en debriefings inadequaat.

Hoofdstuk 9 beschrijft het basisontwerp van TOP*plus*, ontworpen door middel van 'Participatory Design (PD)', en de implementatie en evaluatie van deze aanpak. Het ontwerpen van TOP*plus* met een multidisciplinair design-expert-team en het aanpassen aan de locale context met de ziekenhuis-expert-teams is nuttig, snel en gemakkelijk en wordt door de meeste professionals erg gewaardeerd. Desondanks is de weerstand tot verandering niet in ieder ziekenhuis gereduceerd. TOP*plus* start de dialoog tussen alle teamleden en dient als katalysator ter verbetering van het hele zorgproces.

Hoofdstuk 10 onderzoekt de haalbaarheid van context-specific ontwerpen ter aanvulling van de 'user-centred PD' aanpak (UPC-Design methode), met als doel het bevorderen van de implementatie en 'sustainability' van initiatieven ter verbetering van de patiëntenzorg in ziekenhuizen. Het TOP*plus*-project wordt hierbij als case behandeld. De UPC-Design methode verbetert de discussie in het team en bevordert de actieve participatie van alle teamleden. UPC-Design ondersteund ook de aanpassingen die noodzakelijk zijn om de procedure aan te passen aan de behoefte van de locale context, wat vervolgens de ziekenhuisbrede implementatie bevordert. De UPC-Design methode blijkt nuttig voor patiëntveiligheid-initiatieven.

Deel C | Ergonomie in de operatiekamer focust op de condities die patiëntveiligheid indirect beïnvloeden, namelijk de werkomstandigheden van het operatieteam.

Hoofdstuk 11 geeft een overzicht van de ergonomie, toegepast op zowel open als MIC. De drie hoofddomeinen binnen de ergonomie zijn de sensorische, cognitieve en fysieke ergonomie. Problemen binnen het sensorische domein zijn met name te vinden tijdens MIC en hebben betrekking op het geprojecteerde beeld, de haptiek van de instrumenten en het gebruik van pedalen. Problemen binnen het cognitieve domein tijdens MIC hebben betrekking op het indirect zicht, menselijk gedrag, onvoldoende training van technische en niet-technische vaardigheden en het gebruik van protocollen, checklists, briefings en debriefings. Binnen het fysieke domein worden problemen veroorzaakt door de hoogte van de operatietafel, de positie en hoogte van de monitor, de handgrepen van de instrumenten, de pedalen en de lichaamshoudingen van de teamleden. Bovendien is een extra domein, de omgevingsergonomie, toegevoegd omdat ook factoren zoals licht, temperatuur, luchtkwaliteit, het gebrek aan werkruimte, geluid en lawaai het welzijn van zowel de teamleden als de patiënt beïnvloeden.

Hoofdstuk 12 bestudeert of ergonomische richtlijnen worden toegepast in de OK en wat de consequenties daarvan zijn. Europese chirurgen en AIOS die laparoscopische dan wel thoracoscopische ingrepen uitvoeren geven aan dat zij discomfort ervaren in hun nek, schouders en rug. Voor dit discomfort wordt geen specifieke oorzaak gegeven. Ondanks het feit dat alle respondenten ergonomie belangrijk vinden, zijn slecht enkele op de hoogte van ergonomische richtlijnen. Meestal wordt apparatuur gebruikt zonder deze in te stellen conform de ergonomische richtlijnen. Dit gebrek aan kennis is een groot probleem dat de ergonomie in de OK bemoeilijkt.

Hoofdstuk 13 evalueert twee typen OK lampen (Xenion en iLED) door middel van objectieve lichtintensiteitsmetingen tijdens open chirurgie en interviews. De lichtmetingen tonen aan dat de Xenion lampen systematisch een hogere lichtintensiteit geven in de wond dan de iLED. De lichtverstrooiing is ook groter voor de Xenion lamp. Bij de interviews geven de respondenten aan dat zij de iLED prefereren boven de Xenion lamp (minder hinderlijke reflectie en schaduwen, betere lichtintensiteit en kleur temperatuur).

Tenslotte, worden in **Hoofdstuk 14** de onderzoeksresultaten kort samengevat en bediscussieerd. Relevante uitkomsten ter voorkoming van fouten worden behandeld en een model voor onderzoek aan 'reliable' design voor de gezondheidszorg wordt beschreven. Tevens worden de klinische implicaties van de bestudeerde initiatieven kort besproken, gevolgd door ideeën voor verder onderzoek en ontwikkeling.

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Dear Armaĝan and Mark, my ushers, colleagues from Delft and Rotterdam, but most of all, my dearest friends. One engineer, one doctor, comparable to the fundaments of this thesis. Thank you for all your mental support, for you laughter, feedback, and philosophic discussions about our work and lives, and thanks for putting up with me.

Dear Connie, you are my ‘partner in crime’ for the TOP*plus* project. You also are a TOP colleague and friend. Thanks you for having an open ear for everything and for all the effort and long evenings you had to spend with me, finishing and submitting our articles. From now on I am completely at your service for all graphics and other professional or personal issues. I hope I will be able to assist you in finishing your thesis.

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TU Delft – *Erasmus MC* – **Delft Design Institute** – **Medisign**
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Curriculum Vitae

Linda Wauben was born in Heerlen, the Netherlands on 3 September 1980. After finishing her VWO in 1998, she moved to Delft to study Industrial Design Engineering at the Delft University of Technology. In March 2005, she graduated at this faculty on the subject 'Ergonomics in the Operating Theatre during Minimally Invasive Surgery'. The study was conducted in cooperation with the European Association of Endoscopic Surgery.

Being inspired by her many visits to the operating theatres, she was fortunate to start her PhD focussing on patient safety in surgery in September 2005. This project was conducted in close cooperation with the Department of Surgery of the Erasmus University Medical Center Rotterdam. During her PhD project she was invited to present parts of her work at various national and international conferences.

Currently, Linda is continuing her research as post-doc within the faculty of Industrial Design Engineering. She is also applying for grants to continue research on these subjects in the future.

Publications

Journal articles

Wauben LSGL, Goossens RHM, Lange JF. (in press). *Evaluation of Operative Notes concerning Laparoscopic Cholecystectomy - Are standards being met?* World Journal of Surgery. DOI: 10.1007/s00268-010-0422-7.

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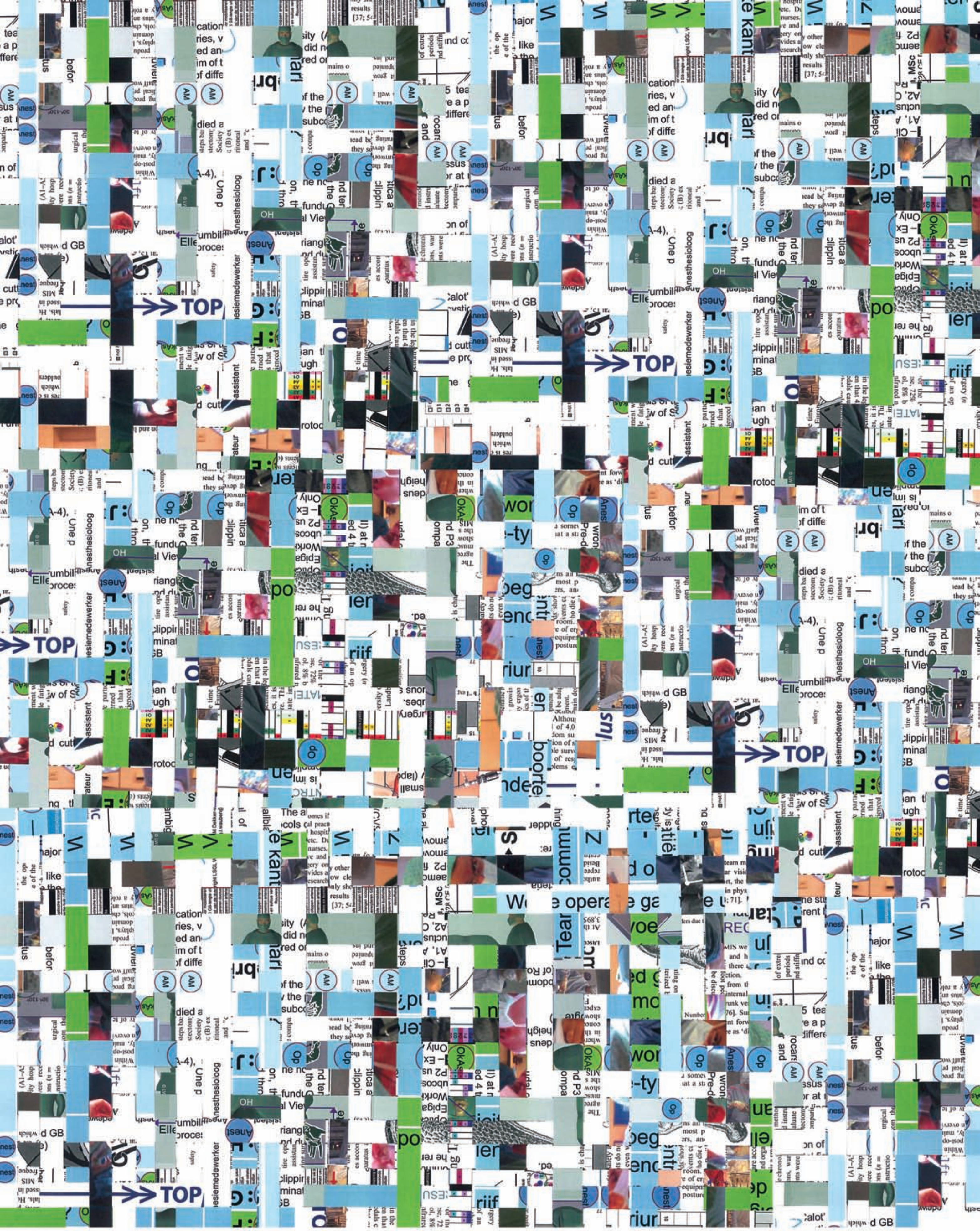

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