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DIGITAL
OPERATING
ROOM
ASSISTANT

ANNETJE GUEDON

DIGITAL OPERATING ROOM ASSISTANT

Annetje Christina Paule GUEDON

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DIGITAL OPERATING ROOM ASSISTANT

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Technische Universiteit Delft,
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CHAPTER 1: INTRODUCTION

PATIENT SAFETY AND EFFICIENCY IN THE OPERATING ROOM

Providing the best possible care to patients is the main focus of healthcare. Years of developments in care delivery have resulted in many improvements. More diseases can be treated and life expectancy is higher than ever. However, patient safety is still a recognized issue and area of research in healthcare [1, 2]. The number of medical errors that could be prevented is considered too high. In the Netherlands, it is estimated that 30,000 errors could be prevented each year [3]. With 60% of hospital patients being treated in the Operating Room (OR), it is estimated that more than half of these errors occur in the OR [4, 5]. This makes the OR an area of high interest in efforts to improve patient safety.

Increasing process efficiency is an approach to improve quality of care [6, 7]. Efficient processes are well-considered and less sensitive for errors. They leave room for professionals to focus on their primary tasks and to act consciously in unexpected situations. At a hospital level, studies have been performed to improve the flow of goods, such as pharmaceuticals and sterile goods, and patient logistics [6, 8]. For the OR in particular, scheduling and resources capacity planning have been the subject of various studies [4, 9-14]. The growing attention for supply chain management in the healthcare sector aims to increase safety as well as to reduce costs [6, 8, 15]. However, this field is rather inexperienced compared to supply chain management in the industrial sector. The complexity of hospitals' environment, especially in the OR, hinders straightforward application of supply chain management principles as applied in the industrial sector [6].

COMPLEXITY OF OPERATING ROOM PROCESSES

The OR is a complex dynamic environment due to the large variety of patients and diseases that can be treated, as well as the number of unexpected events (such as emergency surgeries and unexpected progress of procedures). Moreover, the increasing use of technology in the OR, such as information technology, monitoring and surgical devices to assist surgical procedures, presents obvious benefits but also contributes to complexity by adding more parameters and possibilities of action, making the situation harder to oversee [5, 16, 17].

The complexity of OR processes can be illustrated by thinking of the various requirements for safe and efficient surgery. Patients have to be prepared for surgery at the preoperative area and have to be transported timely to the OR. An entire surgical team have to be scheduled, consisting of one or more surgeons, OR nurses, nurse anaesthetists and possibly personnel in training, and with the appropriate training and competences for a specific procedure. The room itself has to be ready for use as well. The OR needs to be cleaned, the air pressure kept at the

required level, and the technical equipment ready to use. That means that the required surgical devices have to be present, correctly maintained and checked for well-functioning. Additionally, a complete and sterile set of surgical instruments has to be delivered and prepared for use. Last but not least, information about patients, progress and outcome of procedures have to be exchanged (digitally) across different departments of the hospital.

CURRENT ISSUES REGARDING OPERATING ROOM PROCESSES

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Many issues that reflect suboptimal OR processes have been reported in scientific literature. Equipment-related incidents, such as unavailability or failure of devices or instruments, occur in 15% of the surgical procedures [18]. Missing equipment results in an average of 12 minutes of extra work and 5 minutes of delay per surgical procedure [18]. These types of issues have also shown to affect the workload of the OR team [19] and increase the stress of surgeons [20]. Stress can diminish human performances and thereby increase the potential for errors in the OR [20, 21]. As communicated by Dutch institutions, focussing on adequate equipment management is needed to improve patient safety [22-24].

Scheduling of ORs is currently not optimal. Accurate prediction of surgery duration, which is essential for OR scheduling, is lacking [9, 25]. The accuracy of the predictions influences many processes. If a surgical procedure is taking longer than scheduled, the subsequent procedures will be postponed or even cancelled. This causes undesirable longer waiting times for patients



Figure 1.1: An operating room during a surgical procedure

and an overload of the preoperative holding area [26]. On the other hand, if a surgical procedure finishes earlier than expected, the next patient may not be ready yet for surgery. The OR then remains unnecessarily vacant and an entire OR team have to wait for the next patient [9]. Information on the progress of procedures to adjust the planning and keep it optimal throughout the day is currently exchanged by means of phone calls between the OR team and the OR scheduler or by entering the OR to discuss it. Both ways are disrupting the surgical process and are therefore not desirable [19, 27, 28].

Another prominent issue is related to information exchange. As identified by Leape et al. [29], hospitals were never 'designed' as a whole but just grew. That is why many processes in hospitals have not been well thought out. Problems with information exchange lead to delays or extra work for the staff and focussing on these issues is recommended to improve patient safety [30]. This issue is particularly apparent in OR practices. Not only are many different information systems and means of information exchange in use but structured information exchange processes are also lacking [31]. From a supply chain management point of view, information exchange, especially centralising information to increase the availability and ease of access for different parties, is an important factor to improve quality [32, 33].

TECHNOLOGY TO SUPPORT OPERATING ROOM PROCESSES

Considering the complex circumstances of the OR, systems to support the staff in improving patient safety and efficiency are very welcome. Technology can play a key role in the development of such systems. It can be used to support or even automate certain processes and therefore decrease the workload of the professionals and lower the risk of errors.

Technology is already used intensively to support OR processes. Many devices are used to support surgical procedures. For instance, the field of anaesthesia relies on anaesthetic equipment, for the controlled administration of drugs and breathing of patients, and on monitoring equipment, for retrieving information on physiological state and depth of anaesthesia of the patient. Technology is also extensively used in surgery, especially in laparoscopic surgery, in which devices are used to enable to perform a procedure through small incisions while watching a video monitor [16, 34]. Even robotic systems are used to improve complex procedures in challenging anatomical locations [35, 36]. Moreover, information technology is used in many support systems such as electronic health records and OR scheduling system. Another example is the application of real time locations systems to track and trace equipment, supplies and people in real-time and provide this information to the concerned personnel [37, 38].

However, it has been observed that the adoption of technology by the OR staff is limited and many systems are not implemented successfully, mainly because they are not suitable for the complex processes and the multiple user groups [37, 39, 40]. The systems can be too rigid with respect to the complexity of the OR and also too time consuming [41]. The consequence can be the proliferation of workarounds that can compromise safety, such as deviations, improvisation and shortcuts of these systems, as observed in the behaviour of nurses [41].

GOAL OF THIS THESIS:

Technology should make surgical practice easier, not harder. This brings us to the main objective of this thesis, which is to develop technology to support healthcare professionals in improving patient safety and efficiency in the OR.

APPROACH AND OUTLINE THESIS

The title of this thesis 'Digital Operating Room Assistant' represents the reasoning behind support systems in the OR. In practice, OR assistants have to be aware of the environment, understand the situation at hand, make sure that the required equipment is available and well-functioning, and also make sure the patients are ready for surgery in time. In short, OR assistants support OR processes as well as they can. Support systems in the OR should strive to support OR processes in the same way OR assistants do it, though digitally.

This thesis consists of four main parts. In the first part, an approach on how to improve patient safety is presented. Each of the following three parts presents one topic that have been selected to test our approach in practice: OR devices, surgical instruments and OR scheduling.

PART I - APPROACHES TO IMPROVE PATIENT SAFETY

This part consists of **chapter 2**, which presents two current approaches to deal with complexity in the OR in order to improve patient safety. The first is applying standardization to decrease complexity for the OR staff. The other is embracing complexity by being flexible. We propose a new approach, called adaptive support, which supports the staff in dealing with complexity in the OR by striking a balance between standardization and flexibility, according to the situation at hand. The key role of technology is highlighted in recording and analysing data to gain a deep understanding of OR processes, in real-time recognition of a situation and in designing adaptive support systems.

PART II - MONITORING SAFETY OF OPERATING ROOM DEVICES

This part consists of two chapters that describe how technology can support the safe use of OR devices.

In **chapter 3**, a monitoring system is presented that provides information on the safety status of OR devices present in the OR and facilitate the notification of defects. Therefore, the work processes and required information for the different professionals involved in the safe use of OR devices were analysed, a monitoring system was developed based on track and trace technology, and a well-suited interface was designed to communicate with the OR staff. The monitoring system was implemented in four ORs and was tested during six months for technical functioning and usability.

As introducing new systems in ORs is a challenging task (because of the complexity of processes and the diversity of staff), an approach to design and implement monitoring systems is presented in **chapter 4**. This approach is based on participatory design, which takes into account the complexity of processes and the various user groups.

PART III - DELIVERY PROCESS FOR SURGICAL INSTRUMENTS

This part consists of two chapters that describe how information technology (IT) can support the timely availability of surgical instruments.

The relevant processes to be supported need to be deeply understood. As it was not the case for the delivery of surgical instruments, the current process and an analysis of the risks involved are presented in **chapter 5**. Besides, the importance of centralised information and IT support is highlighted.

In **chapter 6**, the potential benefits of applying just-in-time principles (a well-known method for supply chain management in the industrial sector) to the delivery of surgical instruments are investigated. A process design and an analysis of the risks involved are presented. Moreover, requirements for IT systems to support this process are defined.

PART IV - OPERATING ROOM SCHEDULING

This part consists of two chapters that describe how technology can support the monitoring of the progress of surgical procedures, which is essential to achieve efficient operating room scheduling.

In **chapter 7** describes how the progress of surgical procedures can be monitored automatically by recording the use of one single piece of equipment, the electrosurgical device. A prediction system for the remaining surgical procedure duration was trained based on these recordings and its performance was assessed.

In **chapter 8**, the prediction system was incorporated in a real-time prediction system that communicated to the OR staff when it was time to start preparing the next patient for surgery. The real-time prediction system was tested in practice for accuracy and usability for the OR staff during 21 procedures.

Finally, the work presented in this thesis is discussed in chapter 9. The ways the developed systems provide adaptive support are considered, the impact on patient safety and efficiency is discussed, and the importance of collaborating with multiple disciplines and testing systems in living labs is highlighted.

REFERENCES

1. Hollnagel E, Wears RL, Braithwaite J (2015) From Safety-I to Safety-II: A White Paper. The Resilient Health Care Net: Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.
2. Staender S (2015) Safety-II and resilience: the way ahead in patient safety in anaesthesiology. *Current opinion in anaesthesiology* 28:735-739
3. de Bruijne MC, Zegers M, Hoonhout LHF, Wagner C (2007) Unintended harm in Dutch hospitals. Dossier study of hospital admissions in 2004. [Onbedoelde schade in nederlandse ziekenhuizen. Dossieronderzoek van Ziekenhuisopnames in 2004].
4. Ayca Erdogan S, Denton BT (2011) Surgery planning and scheduling. *Wiley Encyclopedia of Operations Research and Management Science*
5. Cuschieri A (2006) Nature of human error - Implications for surgical practice. *Ann Surg* 244:642-648
6. de Vries J, Huijsman R (2011) Supply chain management in health services: an overview. *Supply Chain Manag*:159-165
7. Gupta AK (2012) JIT in Healthcare: An Integrated Approach. *International Journal of Advances in Management and Economics* 1:20-27
8. Dobrzykowski D, Deilami VS, Hong P, Kim SC (2014) A structured analysis of operations and supply chain management research in healthcare (1982-2011). *Int J Prod Econ* 147:514-530
9. Eijkemans MJ, van Houdenhoven M, Nguyen T, Boersma E, Steyerberg EW, Kazemier G (2010) Predicting the unpredictable: a new prediction model for operating room times using individual characteristics and the surgeon's estimate. *Anesthesiology* 112:41-49
10. Dexter F, Epstein RH, Traub RD, Xiao Y (2004) Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453
11. Guinet A, Chaabane S (2003) Operating theatre planning. *Int J Prod Econ* 85:69-81

12. Jebali A, Alouane ABH, Ladet P (2006) Operating rooms scheduling. *Int J Prod Econ* 99:52-62
13. Wright PD, Bretthauer KM, Cote MJ (2006) Reexamining the Nurse Scheduling Problem: Staffing Ratios and Nursing Shortages. *Decision Sciences* 37:39-70
14. Pasin F, Jobin M-H, Cordeau J-F (2002) An application of simulation to analyse resource sharing among health-care organisations. *International Journal of Operations & Production Management* 22:381-393
15. Rais A, Viana A (2010) Operations Research in Healthcare: a survey. *International Transactions in Operational Research* 18:1-31
16. Verdaasdonk EGG, Stassen LPS, van der Elst M, Karsten TM, Dankelman J (2007) Problems with technical equipment during laparoscopic surgery - An observational study. *Surgical Endoscopy and Other Interventional Techniques* 21:275-279
17. Aggarwal R, Mytton OT, Greaves F, Vincent C (2010) Technology as applied to patient safety: an overview. *Quality & safety in health care* 19 Suppl 2:i3-8
18. Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH (2010) Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Quality & safety in health care* 19
19. Weigl M, Antoniadis S, Chiapponi C, Bruns C, Sevdalis N (2015) The impact of intra-operative interruptions on surgeons' perceived workload: an observational study in elective general and orthopedic surgery. *Surgical endoscopy* 29:145-153
20. Arora S, Hull L, Sevdalis N, Tierney T, Nestel D, Woloshynowych M, Darzi A, Kneebone R (2010) Factors compromising safety in surgery: stressful events in the operating room. *Am J Surg* 199:60-65
21. Tucker AL (2004) The impact of operational failures on hospital nurses and their patients. *J Oper Manag* 22:151-169
22. Dutch Healthcare Inspectorate (IGZ) (2008) Risico's van medische technologie onderschat.
23. Dutch association of medical specialists (Orde van medisch specialisten) (2008) Leidraad: Verantwoordelijkheid medisch specialist bij onderhoud en beheer van medische apparatuur.
24. Dutch association of hospitals (NVZ) and Dutch association of university hospitals (NFU) (2011) Convenant veilige toepassing van medische technologie in het ziekenhuis.
25. Dexter F, Epstein RH, Lee JD, Ledolter J (2009) Automatic updating of times remaining in surgical cases using bayesian analysis of historical case duration data and "instant messaging" updates from anesthesia providers. *Anesthesia and analgesia* 108:929-940
26. Wauben LSG, Guedon ACP, De Korne DF, van den Dobbelen JJ (2015) Tracking surgical day care patients using RFID technology. *BMJ Innovations*:1-8
27. Healey AN, Sevdalis N, Vincent CA (2006) Measuring intra-operative interference from distraction and interruption observed in the operating theatre. *Ergonomics* 49:589-604

28. Healey AN, Primus CP, Koutantji M (2007) Quantifying distraction and interruption in urological surgery. *Quality & safety in health care* 16:135-139
29. Leape LL (1997) A systems analysis approach to medical error. *Journal of evaluation in clinical practice* 3:213-222
30. Christian CK, Gustafson ML, Roth EM, Sheridan TB, Gandhi TK, Dwyer K, Zinner MJ, Dierks MM (2006) A prospective study of patient safety in the operating room. *Surgery* 139:159-173
31. Guedon ACP, Wauben LSG, Van der Eijk AC, Vernooij ASN, Meeuwse FC, van der Elst M, Hoeijmans V, Dankelman J, Van den Dobbels JJ (2015) Where are my instruments? Hazards in delivery of surgical instruments. *Surgical endoscopy*
32. Claassen MJT, van Weele AF, van Raaij EM (2008) Performance outcomes and success factors of vendor managed inventory (VMI). *Supply Chain Manag* 13:406-414
33. Simchi-Levi D, Kaminsky P, Simchi-Levi E (2003) *Designing and Managing the Supply Chain*, McGraw-Hill, New York, NY
34. van Hove PD, van Wijk R, Verdaasdonk EGG, Stassen LPS, Dankelman J (2013) Training and assessment of equipment-related competence. Comparison of a petrochemical company and a hospital. *Health and Technology* 3:221-226
35. Szold A, Bergamaschi R, Broeders I, Dankelman J, Forgione A, Lango T, Melzer A, Mintz Y, Morales-Conde S, Rhodes M, Satava R, Tang CN, Vilallonga R, European Association of Endoscopic S (2015) European Association of Endoscopic Surgeons (EAES) consensus statement on the use of robotics in general surgery. *Surgical endoscopy* 29:253-288
36. Lalys F, Jannin P (2014) Surgical process modelling: a review. *International Journal of Computer Assisted Radiology and Surgery* 9:495-511
37. Fisher JA, Monahan T (2012) Evaluation of real-time location systems in their hospital contexts. *Int J Med Inform* 81:705-712
38. Kamel Boulos MN, Berry G (2012) Real-time locating systems (RTLS) in healthcare: a condensed primer. *International Journal of Health Geographics*
39. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O (2004) Diffusion of innovations in service organizations: systematic review and recommendations. *The Milbank quarterly* 82:581-629
40. Fisher JA, Monahan T (2008) Tracking the social dimensions of RFID systems in hospitals. *Int J Med Inform* 77:176-183
41. Debono DS, Greenfield D, Travaglia JF, Long JC, Black D, Johnson J, Braithwaite J (2013) Nurses' workarounds in acute healthcare settings: a scoping review. *BMC health services research* 13:175

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APPROACHES TO IMPROVE PATIENT SAFETY

PART I

CHAPTER 2: A DELICATE BALANCE: ADAPTIVE SUPPORT TO IMPROVE PATIENT SAFETY

CH 2
P 22

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ABSTRACT

The complexity of operating room (OR) processes is increasingly recognized as a potential threat to patient safety. Standardisation of processes as an attempt to reduce complexity is a popular approach to improve safety. However, this may lead to unsafe and stressful situations when standardised processes are not well suited to deal with unexpected events. The goal of this study is to reconcile standardisation and flexibility to both reap the benefits of standardisation and maintain the ability to anticipate unexpected events.

We propose adaptive support as a way to strike a balance between the seemingly contradicting demands of standardization and flexibility, i.e. standardisation that is adaptive to the particularities of a situation, while increasing the abilities of medical professionals to respond to varying and unexpected situations. We propose a three-step approach to provide adaptive support, which involves: 1) high-level understanding of OR processes, 2) real-time recognition of the situation that is at hand, and 3) providing technological support accordingly. Technology plays a key role in gaining understanding of OR processes and enabling systems to automatically adapt to day-to-day variability in the OR.

Adaptive support helps to ensure patient safety by supporting OR staff through automation and standardisation where possible, and by providing them flexibility and autonomy when needed.

INTRODUCTION

Patient safety increasingly depends on health professionals' ability to deal with the technological, organisational and social complexity of their working environment [1]. The Operating Room (OR) is such a complex dynamic environment, not only because of the increasing use of technology, such as information technology, monitoring and surgical devices to assist surgical procedures [3, 7], but also because of less obvious factors, such as an increasing number of co-morbidities per patient [1] and the pressure to increase productivity and efficiency [2, 3]. Although over the years many efforts have been made to improve patient safety in the OR, considerable avoidable harm to patients still occurs in the operative process [2-6].

This paper starts from the assumption that supporting medical staff to deal with the increasing complexity of day-to-day OR practices will increase patient safety. This paper provides an overview of the current discussions on standardisation on the one hand, and flexibility on the other hand, as approaches to deal with complexity in the OR (section 2). We argue that a balance must be struck between standardisation and flexibility to ensure patient safety. More specifically, we propose to develop technological support systems based on an approach (section 3) in which standardisation and flexibility are reconciled to both reap the benefits of standardisation and maintain the ability to anticipate unexpected events. We call this *adaptive support*. Then, we propose a stepwise approach to provide adaptive support (section 4) by: 1) ensuring high-level understanding of OR processes, 2) real-time recognition of the situation that is at hand, and 3) providing technological support accordingly. We describe how technology already provides some ways to make systems that adapt to day-to-day variability in the OR, but conclude that more work is needed to make adaptive support possible.

STANDARDISATION AND FLEXIBILITY: DIFFERENT APPROACHES TO IMPROVE PATIENT SAFETY

Many studies have recognized the tension between the complexity of medical practice and ensuring patient safety. This section depicts two common approaches to ensure patient safety with regard to the increasing complexity of medical practices; one intends to reduce complexity through standardisation, the other to embrace complexity by stimulating flexible policies, behaviour and technologies. Note that it is not merely complexity that poses a problem for patient safety. A process or situation can be complex in terms of factors and elements that feed into it, but still be perfectly manageable (for instance through automation). In our view, complexity poses problems once it leads to medical staff being presented with multiple options for action that are hard to oversee or prioritize because of similar emergent character. Then, managing all the different elements of the complex system becomes a too demanding task.

THE PRINCIPLE OF STANDARDISATION

In the field of patient safety, systems thinking aims at improving patient safety by creating robust and reliable systems. This often implies a form of standardisation; an attempt to reduce variability and to make the system as a whole less complex. For instance, the introduction of standards and guidelines has remarkably benefitted safety in anaesthesia [4-6]. The added value of standardising processes have also been recognized in clinical oncology in which time-outs, quality and safety checks were implemented strategically to increase the ability to detect and respond to failure, and thus reduce the propagation of errors [7]. Moreover, surgical checklists have shown to decrease the amount of surgical complications and mortality [8, 9] as well as the amount of incidents per procedure related to surgical equipment [10]. Guidelines on hand hygiene have also been introduced to reduce healthcare associated infections [11, 12]. Thus, a systems approach has definitely contributed to the provision of safe care.

Despite many benefits of standardisation, it may also result in unsafe practices due to a mismatch with existing working practices [5]. Disadvantages, such as the time-consuming aspect and the rigidity of the processes have been recognized in previous studies [10, 13]. These disadvantages can be well illustrated with the low rate of adherence of surgical checklists [14, 15] and hand hygiene protocols [12, 16]. They do not seem to be apt as patients sometimes arrive with several different checklists in the OR, which causes bureaucracy, time pressure, and leads to frustration of the OR team and thus devaluates the safety aspects of applying standardisation. Another example of rigid systems can be observed in OR scheduling. In general, average durations for each type of procedure are used to set up OR schedules. These schedules are often unreliable as they are not adaptable to unplanned changes in the progress of the procedures [17, 18]. The consequence of employing rigid and time-consuming systems can be the proliferation of workarounds such as deviations, improvisation and shortcuts of these systems [19]. Workarounds can compromise safety as they may result in situations being less safe than without using the systems. Meticulous attention to the actual use of systems in situ is required to implement standardised processes while reducing the chance for workarounds [20].

THE PRINCIPLE OF FLEXIBILITY

Several studies acknowledged the complexity of healthcare systems and the non-validity of simple cause and effect assumption [6, 21-23]. Standards and guidelines are designed to match stable and predictable situations, which is not the actual situation in many healthcare settings [6, 22]. As stated by Patterson, 'imposing a simple standard on a complex process does not result in simplicity' [21]. This has recently led to a new approach to safety called Safety-II, which claims, amongst others, that in complex healthcare systems, individual health professionals are often the ones ensuring safety by providing flexibility to the system. Through mindfully adapting to unexpected events, medical staff can balance the physical, social, and technical demands they are confronted with in the OR [6]. Safety-II, therefore, encourages to study the functioning of systems under varying conditions [6, 22], and particularly the role of the individual in dealing with unexpected events [22, 23].

The importance of individual and team capacity in patient safety is widely recognized [24]. Training of medical teams focussed on communication, situational awareness, leadership and situation monitoring [24]. These aspects increase the ability of a team to function under varying conditions, and therefore matches the Safety-II approach. An example to illustrate the key role of professionals in OR processes is OR scheduling. Despite research performed to improve OR scheduling [25], the role of the OR scheduler in practice is still essential to deal with all the complexities of aligning the OR processes. One striking example of this is that even an OR manager game has been developed to give insights in the difficulties of this task [26]. Despite the extensive training of medical professionals, it is impossible to prepare for each possible unexpected event. Medical staff is trained for both planned and acute emergency procedures, but sometimes things go wrong in busy OR departments. There is a limit to the ability of professionals to oversee all OR processes and possible course of actions.

The view emerges that standardisation targets elements of the system (such as procedures or protocols) to simplify OR processes. Flexibility, on the other hand, targets professionals in the sense that it gives them the opportunity to deal with the complexity of OR processes. There is a clear difference in mind-set (reduce complexity vs. embrace complexity) and in targets (systems vs. professionals). In practice, a combination of both is needed; it is clear some autonomy is needed for the professionals to manage complexity. At the same time, some form of standardisation is needed to ensure a constant level of quality and make OR practices more efficient and less demanding for medical staff.

STRIKING A BALANCE THROUGH ADAPTIVE SUPPORT

Knowing what level of standardisation or flexibility is desirable in a certain situation is key in adequately dealing with complexity. However, the two ways of dealing with complexity do not rule each other out. Therefore it has been argued that a balance between, or rather an integration of standardisation and flexibility is needed [6, 21]. We propose adaptive support as a way to reconcile standardisation and flexibility; i.e. standardisation that is adaptive to the particularities of a situation, while increasing the abilities of medical professionals to respond to varying and unexpected situations. Instead of creating rigid standardised systems in which professionals are forced to find 'workarounds', creating adaptive systems can incorporate standardisation in a flexible way. For example, adaptive checklists would entail a high level of standardisation, and at the same time, introduce flexibility by helping medical professionals make decision on the on-going procedure. Adaptive support could help professionals with monitoring processes, situation awareness and automating certain tasks. This provides support for professionals without the disadvantages of rigidity.

Support systems need to be well-designed to respond to the situation at hand, and the interaction with the OR staff needs to be carefully studied. In order to do this a high-level understanding of OR processes is required. This is obviously not an easy task considering the complexity of the environment. Insights in this complexity, which is essential to deeply understand the OR processes, is often lacking. Much of the friction and hazards that happen with systems based on standardised practices can be considered a knowledge problem. Such systems may not sufficiently take the particularities of the situations they were developed for into account. To develop adaptive support systems, we need firstly high-level understanding about the range of possible OR processes, secondly, to be able to recognize the situation that is at hand, and thirdly, to provide support accordingly.

THE WAY TO PROVIDE ADAPTIVE SUPPORT

The implementation of adaptive support is challenging at various levels; therefore, this section discusses a stepwise approach for how to achieve adaptive support. The approach is represented schematically in Figure 2.1. For each step, we give practical examples of how technology may help achieve adaptive support. We also identify opportunities and challenges in doing this.

STEP 1: GENERATING HIGH-LEVEL UNDERSTANDING OF OR PROCESSES

In order to gain insight into OR processes, information needs to be systematically recorded in the OR. Various solutions to gather data intraoperatively are available, such as audio and video recording, or using endoscopic images and vital parameters of the patient [27-29]. Additionally, the usage of instruments and devices can be monitored [29-32] and data can be retrieved from electronic health records and OR scheduling systems. These studies revealed many opportunities of (automated) data recording, but are not performed on a large scale (yet). In order to record and store these many data sources, a robust and integrated IT infrastructure is required. A recent study showed the potential of IT infrastructures for structured recording of intraoperative data and expressed a wish for further integration of data acquisition technologies [31].

Next, we can start to study the complexity of OR processes and achieve high-level understanding of OR processes through data analysis. There are several data-analysis tools available that can help assess and predict the variability medical staff is confronted with [33]. Various studies worked on modelling of surgical procedures to analyse and evaluate procedures [34-38]. For example, there are seemingly unpredictable events, such as surgical procedure durations, that turn out to be predictable once sufficient data is gathered [17, 18]. Another example is unexpected difference among surgeons in handling surgical devices during relatively

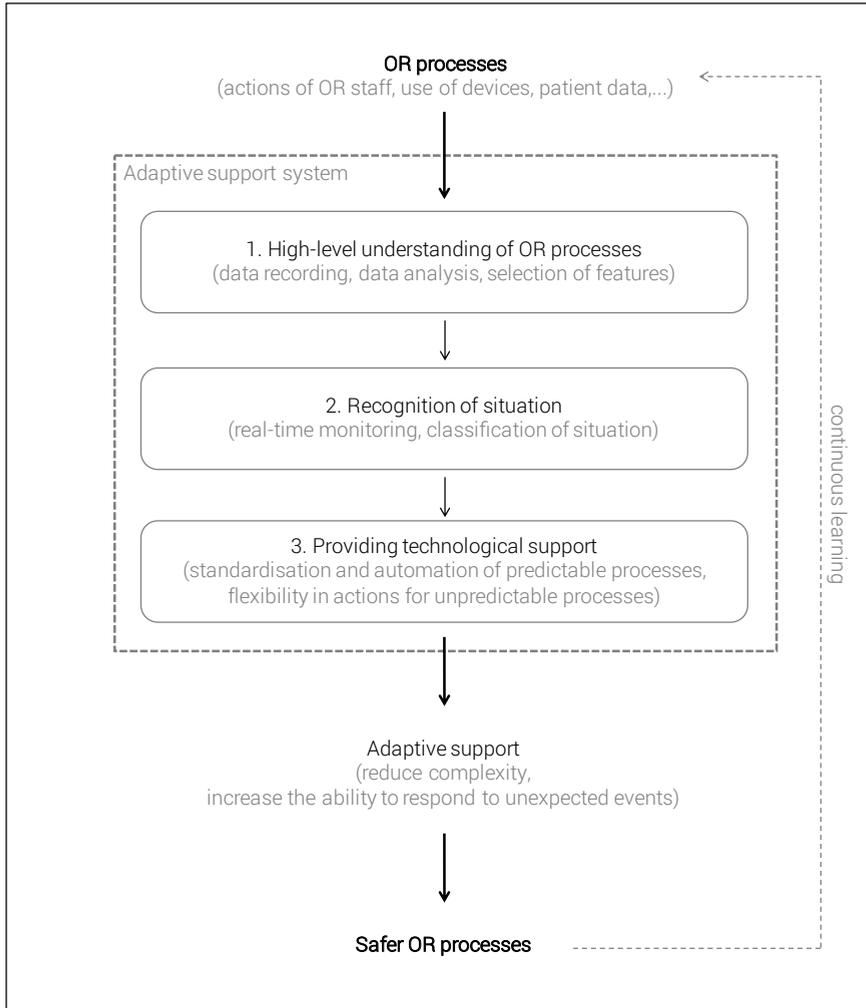


Figure 2.1: Schematic representation of adaptive support

standardised procedures [39]. Data analysis can bring interesting insights in OR processes and help recognize hazardous situations. However, much of the data analysis still requires manual steps, such as the identification of use of instrument from endoscopic images [29, 40, 41] and interpretation and coding of text in electronic health records, which is time-consuming.

Through high-level understanding we can select relevant features that influence the variability and predictability of OR processes. These features allow to distinguish differences in progression of procedures, which is essential in providing adaptive support. Note, however, that the choice of data that have been recorded influences the selection of features to monitor for

adaptive support purposes. There is a risk that too much attention is paid to specific features as opposed to others that may be overlooked by the initial choice of data gathering. This reflects the limitations of patterns/models that are constructed through data-analysis.

STEP 2: REAL-TIME RECOGNITION OF THE SITUATION

In order to make adaptive systems, OR processes need to be recognised automatically. Real-time monitoring of the identified relevant features, is needed to classify the situation at hand. The information and models that are developed in step 1 will feed into this classification process. The accuracy of the real-time recognition is dependent on the data gathered previously. . Although it is not an easy task to automatically perform, various studies have presented promising results on real-time recognition of the surgical process [29, 41-43]. They monitored specific activities, such as equipment usage and different states of the patients. Not only is the recognition of the situation at hand necessary, but also the predictability of the remainder of the situation matters. There may be situations that are complex but still present recognizable patterns, and therefore become predictable. On the other hand, there are situations that are inherently unpredictable. Once the situation is recognized, systems can be adapted accordingly.

STEP 3: PROVIDING TECHNOLOGICAL SUPPORT

At this stage, the question arises how to proceed once a situation is automatically recognized. We propose that technological support should depend on the predictability of the progression of the processes. The balance between standardisation and flexibility relies on the classification of the situation, i.e. how much is known about the next steps in the OR processes.

On one side of the spectrum we find predictable processes, for which tasks can be fully automated or standardised. For example, OR devices can be configured automatically according to the type and stage of procedures [44]. Other examples are track and trace systems that automate the searching for the location of assets in the hospitals [45] or the check for correct maintenance dates of OR devices [46]. Such processes, that do not require interventions by medical professionals, can be automated but should still be transparent, as we believe it is important to still provide information on the automated task to the OR staff. Processes that do require interventions by medical professionals, such as checklists, can be adapted to the specific situation and thereby provide standardisation that take the situation into account.

Some processes are *not completely predictable*, but still occur within a certain range of reliability. In such processes, e.g. the planning of procedures and patient flow, technology can support information availability and exchange between medical staff. For example, patients can be tracked in order to streamline the patient flow to reduce intermittent communication between nursing department and OR [47]. Another example is a system supporting updates from estimated surgical procedure duration by the anaesthesia staff in the OR [17]. In these cases,

gaining information about patients is automated, but the decision on how to proceed remains with the medical staff. On the other end of the spectrum, there are unpredictable processes, for example, when an OR device is unexpectedly malfunctioning, or unexpected complications occur during surgery. It is important that unpredictable situations do not become the object of rigid standardisation, as this will most likely have adverse effects. However, some form of support is still possible. For example, by supporting easy exchange and centralize information about unexpected events, such as malfunctions of devices [46]. Moreover, systems can be used to increase situation awareness, to support staff in dealing with information overload and keep track of the different processes under stressful conditions. For example, a task information system could be used that is personalized for the different OR staff members [48] or other systems that provide essential information on the activity of the OR staff, the anatomical structures and technical equipment [49]. The feedback that these systems provide to medical staff will help them to be situation aware and make intelligent adjustments of their working processes to the demands of the situation.

OUTCOME FOR THE OR STAFF

The outcome of this approach is a technological system that take the complexity of day-to-day OR practices into account. The automation or standardisation of predictable OR processes reduces complexity for health professionals, by taking over processes or providing support to the professionals, and thereby reducing their workload. Providing information about unpredictable OR processes increases situation awareness and leaves flexibility for actions of medical professionals. Thereby, it increases the ability of professionals to respond to unpredictable events. Adaptive support systems help in the recognition of the predictability of situations. This helps professionals to decide what processes need more attention at that moment, for example in the case of hazardous situations, and ensures that the system allows them to flexibly operate when needed.

Adaptive support is a dynamic process that facilitates continuous learning. Adaptive support systems do not only provide information about the current situation at hand, but also enable high-level understanding of the complexity of OR processes, which may lead to the identification of unnecessary standardisation, redundancies that can be reduced, and steps that are essential in providing safe care [50]. Integrating adaptive support systems in the OR may lead to redesign of work processes and new interactions between technology and OR staff, which will provide input for new cycles of adaptive support. It is essential that medical teams are actively involved in this learning and (re)design process [51]. Systematic evaluation of processes in structured non-hierarchical and blame-free team meetings would benefit outcome of care. This will encourage the OR staff to adopt the adaptive systems as well as to jointly take responsibility for patient safety.

CONCLUSION

Adaptive support systems can help ensure patient safety and team performance in the OR by enabling learning about the complexity of OR practices. By gaining knowledge through data gathering and analysis of OR practices, support systems can recognize situations in real-time. This allows systems to provide support that is adapted to the day-to-day variability in the OR, by automating and standardising processes where possible, and providing information and flexibility to professionals when needed. However, much work is needed to meet the challenges and grasp the opportunities in building adaptive support systems. Particularly the development of technologies for real-time recognition and real-time adaptable technological support systems will be key to achieve adaptive support.

REFERENCES

1. Pittet V, Perret C, Moret V, Despond O, Burnand B, Group ADSS (2013) Evolution of anaesthesia care and related events between 1996 and 2010 in Switzerland. *Acta anaesthesiologica Scandinavica* 57:1275-1286
2. de Vries J, Huijsman R (2011) Supply chain management in health services: an overview. *Supply Chain Manag*:159-165
3. Dobrzykowski D, Deilami VS, Hong P, Kim SC (2014) A structured analysis of operations and supply chain management research in healthcare (1982-2011). *Int J Prod Econ* 147:514-530
4. Gaba DM (2000) Anaesthesiology as a model for patient safety in health care. *Brit Med J* 320:785-788
5. Klein J (2008) Multimodal multidisciplinary standardization of perioperative care: still a long way to go. *Curr Opin Anesthesio* 21:187-190
6. Staender S (2015) Safety-II and resilience: the way ahead in patient safety in anaesthesiology. *Current opinion in anaesthesiology* 28:735-739
7. Chera BS, Mazur L, Buchanan I, Kim HJ, Rockwell J, Milowsky MI, Marks LB (2015) Improving Patient Safety in Clinical Oncology: Applying Lessons From Normal Accident Theory. *JAMA oncology* 1:958-964
8. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA, Group SC (2010) Effect of a comprehensive surgical safety system on patient outcomes. *The New England journal of medicine* 363:1928-1937
9. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA, Safe Surgery Saves Lives Study G (2009) A surgical safety checklist to reduce morbidity and mortality in a global population. *The New England journal of medicine* 360:491-499

10. Verdaasdonk EG, Stassen LP, Hoffmann WF, van der Elst M, Dankelman J (2008) Can a structured checklist prevent problems with laparoscopic equipment? *Surgical endoscopy* 22:2238-2243
11. Organization WH (2009) WHO Guidelines on Hand Hygiene in Health Care. In: Press W (ed), Geneva, Switzerland
12. Erasmus V, Daha TJ, Brug H, Richardus JH, Behrendt MD, Vos MC, van Beeck EF (2010) Systematic review of studies on compliance with hand hygiene guidelines in hospital care. *Infection control and hospital epidemiology* 31:283-294
13. Wauben LS, Dekker-van Doorn CM, Klein J, Lange JF, Goossens RH (2011) Participatory design: implementation of time out and debriefing in the operating theatre *Journal of Design Research* 9:220-240
14. Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN (2014) Introduction of surgical safety checklists in Ontario, Canada. *The New England journal of medicine* 370:1029-1038
15. van Klei WA, Hoff RG, van Aarnhem EE, Simmermacher RK, Regli LP, Kappen TH, van Wolfswinkel L, Kalkman CJ, Buhre WF, Peelen LM (2012) Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. *Ann Surg* 255:44-49
16. Kingston L, O'Connell NH, Dunne CP (2015) Hand hygiene-related clinical trials reported since 2010: a systematic review. *The Journal of hospital infection*
17. Dexter F, Epstein RH, Lee JD, Ledolter J (2009) Automatic updating of times remaining in surgical cases using bayesian analysis of historical case duration data and "instant messaging" updates from anesthesia providers. *Anesthesia and analgesia* 108:929-940
18. Eijkemans MJ, van Houdenhoven M, Nguyen T, Boersma E, Steyerberg EW, Kazemier G (2010) Predicting the unpredictable: a new prediction model for operating room times using individual characteristics and the surgeon's estimate. *Anesthesiology* 112:41-49
19. Debono DS, Greenfield D, Travaglia JF, Long JC, Black D, Johnson J, Braithwaite J (2013) Nurses' workarounds in acute healthcare settings: a scoping review. *BMC health services research* 13:175
20. Koppel R, Wetterneck T, Telles JL, Karsh BT (2008) Workarounds to barcode medication administration systems: their occurrences, causes, and threats to patient safety. *J Am Med Inform Assoc* 15:408-423
21. Patterson ES (2008) Structuring flexibility: the potential good, bad and ugly in standardisation of handovers. *Quality & safety in health care* 17:4-5
22. Hollnagel E, Wears RL, Braithwaite J (2015) From Safety-I to Safety-II: A White Paper. *The Resilient Health Care Net: Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.*
23. The Health Foundation (2010) Evidence scan: Complex adaptive systems.
24. Weaver SJ, Dy SM, Rosen MA (2014) Team-training in healthcare: a narrative synthesis of the literature. *BMJ quality & safety* 23:359-372

25. Cardoen B, Demeulemeester E, Beliën J (2010) Operating room planning and scheduling: A literature review. *European Journal of Operational Research* 201:921-932
26. Hans EW, Nieberg T (2007) Operating Room Manager Game. *INFORMS Transactions on Education* 8:25-36
27. Cone SW, Leung A, Mora F, Rafiq A, Merrell RC (2006) Multimedia data capture and management for surgical events: Evaluation of a system. *Telemed J E-Health* 12:351-358
28. Guerlain S, Adams RB, Turrentine FB, Shin T, Guo H, Collins SR, Calland JF (2005) Assessing team performance in the operating room: Development and use of a "Black-Box" recorder and other tools for the intraoperative environment. *J Am Coll Surgeons* 200:29-37
29. Padoy N, Blum T, Feussner H, Berger M-O, Navab N (2008) On-line Recognition of Surgical Activity for Monitoring in the Operating Room. *AAAI*, pp 1718-1724
30. Guédon ACP, Paalvast M, Meeuwse FC, Tax DMJ, van Dijke AP, Wauben LSG, Van der Elst M, Dankelman J, Van den Dobbelsteen JJ (2015) Real-time estimation of surgical procedure duration. *IEEE Healthcom*. 1st International Workshop on Intelligent Operating rooms, Boston, USA
31. Rockstroh M, Franke S, Neumuth T (2014) Requirements for the structured recording of surgical device data in the digital operating room. *International Journal of Computer Assisted Radiology and Surgery* 9:49-57
32. Kranzfelder M, Schneider A, Fiolka A, Schwan E, Gillen S, Wilhelm D, Schirren R, Reiser S, Jensen B, Feussner H (2013) Real-time instrument detection in minimally invasive surgery using radiofrequency identification technology. *The Journal of surgical research* 185:704-710
33. Lallys F, Jannin P (2014) Surgical process modelling: a review. *International Journal of Computer Assisted Radiology and Surgery* 9:495-511
34. Mackenzie CF, Ibbotson JA, Cao CGL, Lomax AJ (2001) Hierarchical decomposition of laparoscopic surgery: a human factors approach to investigating the operating room environment. *Min Invas Ther & Allied Technol* 10:121-127
35. Meng F, D'Avolio LW, Chen AA, Taira RK, Kangaroo H (2005) Generating models of surgical procedures using UMLS concepts and multiple sequence alignment. *Am Med Inform Assoc Annu Symp*
36. Neumuth T, Jannin P, Strauss G, Meixensberger J, Burgert O (2009) Validation of knowledge acquisition for surgical process models. *J Am Med Inform Assoc* 16:72-80
37. Neumuth T, Durstewitz N, Fischer M, Strauss G, Dietz A, Meixensberger J, Jannin P, Cleary K, Lemke HU, Burgert O (2006) Structured recording of intraoperative surgical workflows. *SPIE Medical Imaging: PACS and Imaging Informatics*
38. Neumann J, Neumuth T (2015) Towards a framework for standardized semantic workflow modeling and management in the surgical domain. *Current Directions in Biomedical Engineering*:172-175

39. Meeuwssen FC, Guedon A, Van Dijke AP, wauben LSGL, Klein J, Van der Elst M, Dankelman J, Van den Dobbelsteen JJ (2015) Real-time monitoring of electrosurgical applications for excellent training and performance evaluation. IEEE Healthcom. 1st International Workshop on Intelligent Operating rooms, Boston, USA
40. Bouarfa L, Jonker PP, Dankelman J (2011) Discovery of high-level tasks in the operating room. *J Biomed Inform* 44:455-462
41. Padoy N, Blum T, Ahmadi S-A, Feussner H, Berger M-O, Navab N (2012) Statistical modeling and recognition of surgical workflow. *Medical Image Analysis* 16:632-641
42. Blum T, Padoy N, Feußner H, Navab N (2008) Modeling and online recognition of surgical phases using hidden markov models. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2008*, Springer, pp 627-635
43. Franke S, Meixensberger J, Neumuth T (2015) Multi-perspective workflow modeling for online surgical situation models. *J Biomed Inform* 54:158-166
44. Franke S, Neumuth T (2015) Rule-based medical device adaptation for the digital operating room. EMBC, Milano, Italy
45. Yao W, Chu CH, Li Z (2012) The Adoption and Implementation of RFID Technologies in Healthcare: A Literature Review. *J Med Syst* 36:3507-3525
46. Guedon AC, Wauben LS, Overvelde M, Blok JH, van der Elst M, Dankelman J, van den Dobbelsteen JJ (2014) Safety status system for operating room devices. *Technol Health Care* 22:795-803
47. Wauben LSGL, Guedon ACP, De Korne DF, van den Dobbelsteen JJ (2015) Tracking surgical day care patients using RFID technology. *BMJ Innovations*:1-8
48. Burgert O, Fink E, Wiemuth M, Thies C (2014) A model-guided peri-operative information systems approach. 7th International Biomedical Engineering Conference, Cairo, Egypt
49. Franke S, Schreiber E, Neumuth T (2012) A time and resource management support system for the digital operating room based on surgical process models. *Int J Comput Assist Radiol Surg* 7(S1):507-508
50. Mesman J (2012) Resources of Strength: an exnovation of hidden competences to preserve patient safety. In: Rowley E, Waring J (eds) *A socio-Cultural Perspective on Patient Safety*, Ashgate Publishing Ltd, Aldershot
51. Guedon AC, Wauben LS, de Korne DF, Overvelde M, Dankelman J, van den Dobbelsteen JJ (2015) A RFID specific participatory design approach to support design and implementation of real-time location systems in the operating room. *J Med Syst* 39:168

MONITORING SAFETY OF OPERATING ROOM DEVICES

PART II

CHAPTER 3: SAFETY STATUS SYSTEM FOR OPERATING ROOM DEVICES

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ABSTRACT

Since the increase of the number of technological aids in the operating room (OR), equipment-related incidents have come to be a common kind of adverse events. This underlines the importance of adequate equipment management to improve the safety in the OR. A system was developed to monitor the safety status (periodic maintenance and registered malfunctions) of OR devices and to facilitate the notification of malfunctions. The objective was to assess whether the system is suitable for use in an busy OR setting and to analyse its effect on the notification of malfunctions.

The system checks automatically the safety status of OR devices through constant communication with the technical facility management system, informs the OR staff real-time and facilitates notification of malfunctions. The system was tested for a pilot period of six months in four ORs of a Dutch teaching hospital and 17 users were interviewed on the usability of the system.

The users provided positive feedback on the usability. For 86.6% of total time, the localisation of OR devices was accurate. 62 malfunctions of OR devices were reported, an increase of 12 notifications compared to the previous year.

The safety status system was suitable for an OR complex, both from a usability and technical point of view, and an increase of reported malfunctions was observed. The system eases monitoring the safety status of equipment and is a promising tool to improve the safety related to OR devices.

INTRODUCTION

Patient safety has become a more prominent topic in the health care sector since the publication of *To Err is Human* [1]. Multiple studies focussed on patient safety in the operating room (OR), which has been recognised as a common site for adverse events [2-6]. Furthermore, the strongly increasing use of sophisticated high-tech equipment (i.e. instruments and devices), especially during minimal invasive surgery, has made the OR environment more complex and susceptible to errors [3, 7]. Wubben et al. have found that equipment-related incidents in the OR occurred in 15.9 % of the surgical procedures; 93% of these incidents were categorized as equipment unavailability or failure [5]. Dutch institutions underlined the importance of adequate equipment management to improve patient safety [8-10], and the responsibility of the medical specialists for the management and maintenance of OR devices [9]. However, not only the medical specialists but also other staff members of the hospital play an important role in the safety of OR devices. The department of Clinical Physics is responsible for the maintenance and the repair of the devices, the OR team leaders consider the availability of devices for the OR planning and the nurse anaesthetists and OR nurses perform the daily preparation and testing of the devices prior to the surgery. Having insight in the periodic maintenance and the defects of devices is crucial for the different OR staff members to improve the safety related to OR devices, but is currently limited to information on stickers and through verbal communication. The nurses are responsible for notifying a malfunction verbally to the department of Clinical Physics and to mark the device as defect, but no real-time feedback on the safety status of OR devices is provided in the OR.

The use of information technology may substantially contribute to overcome the safety challenges in health care in general and in equipment management in particular [11]. In order to provide insights into the maintenance and malfunctions of devices (i.e. the safety status) to the OR staff, information about which devices are present in a specific OR is also needed. Real-time location systems are often used for localisation purposes in hospitals [12, 13]. One of the commonly used technologies for real-time location systems is Radio Frequency Identification (RFID). According to recent reviews of Wamba and Yao et al. on RFID in health care, RFID technology has been used to track and to manage the allocation of OR devices [14, 15]. Although these applications were suited to improve the availability of the OR devices, they did not contribute to gain insight into the safety status of OR devices and to improve the exchange of information between the different users in the OR and the department of Clinical Physics.

In this work, a system was developed to monitor the presence and the safety status (periodic maintenance and registered malfunctions) of OR devices, to ease access to this information for OR staff and to facilitate the notification of malfunctions. The aim of this study is to research if such a system is suitable for an OR complex, from a usability and technical point of view, and to analyse the effect of the system on the number and the way of notifying malfunctions of OR devices.

METHODS

The safety status system was implemented in four ORs of a Dutch teaching hospital. For this study a selection of 94 OR devices used for laparoscopic procedures (34 anaesthesia and 60 surgery devices) was made from the devices that presented the most malfunctions in the previous three years; such as anaesthetic machines, infusion pumps, patient warmers, cell savers, laparoscopic tower devices, electrosurgical devices, surgical motor units, displays and mobile C-arms.

The system was composed of four tablets (iPad3, Apple Inc., USA) interfacing with the OR staff, 94 active RFID tags (869.3 MHz, 10 mW) equipped with a button and a LED, ten readers for detecting and localizing the RFID tags that were mounted on the OR devices, one gateway and one server. The server of the safety status system communicated through a common Microsoft SQL Server database with Ultimo (Ultimo Maintenance Management Version 8.49.00.0403, Ultimo Software Solutions, the Netherlands), the hospital's technical facility

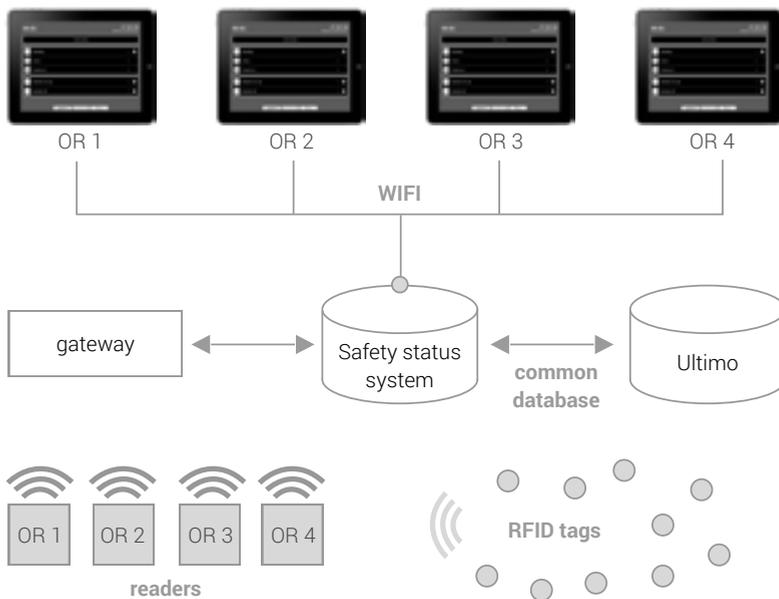


Figure 3.1. Schematic overview of the safety status system

management system. Information gathered by the system and by Ultimo was both continuously updated through this database. The web application shown on the tablet (made in Django by DoubleSense B.V., the Netherlands) communicated with the server through the internal network of the hospital. Figure 3.1 shows a schematic overview of the system.

The location of the tags was determined by the strength of the signal detected by the readers. The placement of the readers within the OR complex and the type of walls between the rooms are shown in Figure 3.2. The tags were equipped with a movement sensor that enabled two

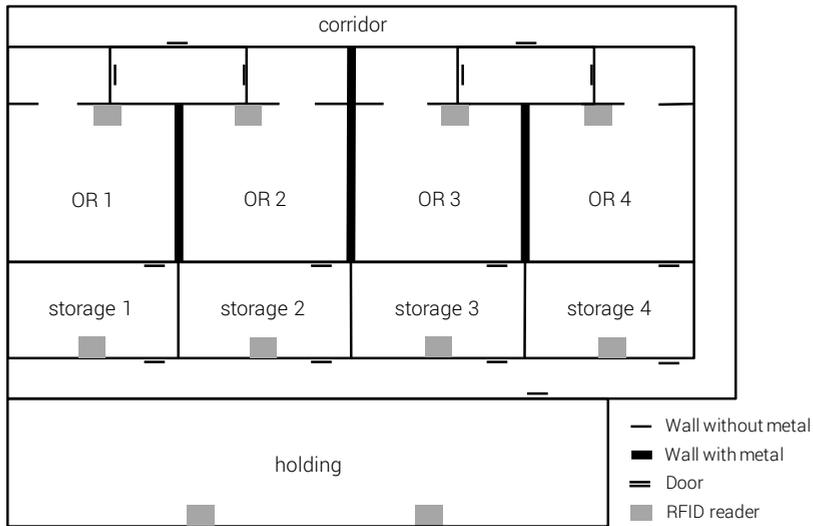


Figure 3.2. Placement of the RFID readers in the OR complex

settings, 'movement' and 'rest'. When a tag moved a signal was send every five seconds and when a tag was at rest a signal was send every minute in order to safe battery life. Prior to the implementation of the safety status system in the OR, interference tests with OR devices were performed on all tagged devices by placing a RFID tag on the device during two minutes. No interference was noticed for any of the devices that were included in this study.

The location and safety status of the 94 OR devices were instantly determined by the system. The screen of the tablet portrayed the safety status and the presence of the devices. A green screen on the tablet indicated a correct safety status of the devices that were present in the corresponding OR; the maintenance was-up-to date and the devices were tested to work properly. A red screen indicated that maintenance was overdue or a malfunction had been reported. Detailed information about the safety status of a particular device (date of the malfunction, name of the person who notified it, explanation of what happened, and feedback of the department of Clinical Physics) could be found by clicking through the web page.

Moreover, the system allowed to notify malfunctions of OR devices. The OR staff could report a malfunction by pushing the button of the RFID tag placed on the malfunctioning device. Automatically, a new page opened on the tablet asking for more information (name of the user and explanation of the malfunction) about the specific device. The screen turned red and all the information provided by the user was send automatically to the department of Clinical Physics and registered automatically in Ultimo. Once the device was repaired and its status updated in Ultimo by the technicians, the information was transmitted to the system and the screen of the tablet turned green. Figure 3.3 shows the tablet and the RFID tags in the OR.

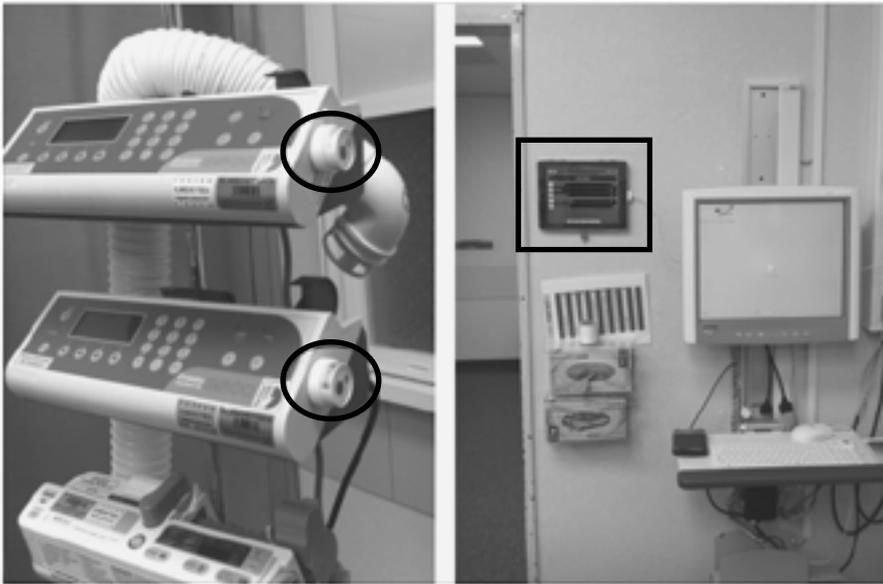


Figure 3.3: RFID tags placed on pumps (left) and tablet in the OR (right)

For the OR staff, the system enabled them to check the safety status of the devices and to notify malfunctions. For the staff of the Clinical Physics department, the system helped to get information about the malfunctions automatically in Ultimo and to get information about the location of the different devices.

DATA COLLECTION

The safety status system was tested during a pilot period of six months (1 October 2012- 31 March 2013). The feasibility of this system in an OR complex was studied by evaluating the usability through interviewing users of the system and by determining the accuracy of the location of the tags. The effect on the number and the way of notifying malfunctions was studied as well.

Semi-structured interviews were performed at the end of the pilot with the users of the safety status system. OR staff members were interviewed about if and when they used the tablet, what they did when the screen was red, and if they used a particular OR device when it was marked unsafe. Questions about the ease of use of notifying malfunctions and the wish to continue using this system in the future were asked to the users of the OR and the department of Clinical Physics. The latter were also asked about the time needed to search for devices in the hospital.

Secondly, the location of all the tags was followed and classified in terms of stability and certainty to determine the localisation accuracy of the system. When a signal sent by a RFID tag was detected by more than one reader, the room of the reader that detected the strongest signal was chosen as the location. However, it happened that the location detected by the system changed within 15 minutes. In this case, the location was considered as unstable. When the signal of a RFID tag was detected at about the same strength by the readers of two different rooms, the location was considered as uncertain between those two rooms. In this study, a difference was made between an uncertain location between two rooms side by side (e.g. OR 1 or storage 1) and an uncertain location between two rooms not side by side (e.g. OR 1 or OR 3). Table 3.1 gives an overview of the different possibilities in terms of stability and certainty, and which measurements were considered as accurate.

Table 3.1. Accuracy of the location determined by the system in terms of certainty and stability.

Location	Stable	Unstable
Certain (e.g. OR 1)	✓	
Uncertain between two rooms side by side (e.g. OR 1 or storage 1)	✓	X
Uncertain between two room not side by side (e.g. OR 1 or OR 3)	X	

Finally, the effect of the system on notifying malfunctions was analysed by the number of registered malfunctions for the 94 OR devices and by the way the notifications were performed by the OR staff. The OR staff was instructed to notify malfunctions by pressing the button of the RFID tag. However, the common way of notification (by calling the department of Clinical Physics, marking the device with a defect sticker, and filling out a log book) was still in use and both means were used during the pilot. The number of registered malfunctions in Ultimo during the pilot period (1 October 2012- 31 March 2013) was compared to the number of registered malfunctions on the same devices during the same period one year earlier (1 October 2011- 31 March 2012).

RESULTS

USABILITY

Seventeen users were interviewed on the usability of the system: 13 OR staff members (three medical specialists, four nurse anaesthetists, five OR nurses and one OR team leader) and four staff members of the department of Clinical Physics. Six out of the 13 OR staff members mentioned that everybody in the OR looked at the tablet, six mentioned that all nurses looked at it, and one did not know. All OR staff members said they looked at the tablet at least once a day. When the screen of the tablet was red, the reaction of the nurses and the medical specialists differed. Eight out of nine nurses looked further on the tablet for more information and one nurse did not take any action. None of the medical specialists looked further on the tablet, but consulted the nurses about it. 11 out of 13 OR staff members mentioned that the decision to use the OR device in question depended on the type of malfunction and two OR staff members did not experience a malfunction during their recent working hours.

Regarding the notification system, eight out of the 13 OR staff members and three out of the four members of the department of Clinical Physics found it easy to use. Five OR staff members did not use it during the pilot period so could not give any feedback. Finally, all four members of the department of Clinical Physics would like to continue using this system in the future, as well as ten out of 13 OR staff members. The other three OR staff members did not have an opinion on the possible future use.

The members of the department of Clinical Physics did not notice a difference in time to search for devices in the hospital during the pilot, but mentioned that the periodic maintenance (when the search for devices can be time consuming) did not take place during the pilot period.

TECHNICAL RELIABILITY

The percentage of the total time for the different types of locations are presented in Table 3.2. For 86.6% of the total time, the location was considered accurate.

Table 3.2. Percentage of total time for the different types of locations.

Location	Stable	Unstable
Certain (e.g. OR 1)	48.8%	
Uncertain between two rooms side by side (e.g. OR 1 or storage 1)	37.8%	10.3%
Uncertain between two room not side by side (e.g. OR 1 or OR 3)	3.1%	

NOTIFICATION OF MALFUNCTIONS

62 malfunctions were reported during the pilot period and 50 malfunctions in the previous year. An increase of 12 reported malfunctions was observed. Furthermore, the way of notification was registered. 21 notifications were done by using the button of the RFID tag on the malfunctioning OR device and 41 notifications were done by calling the OR team leader or the department of Clinical Physics and by marking the device as defect, which was the common way of notifying malfunctions already in use in the hospital.

DISCUSSION

A safety status system for OR devices was developed and tested in a Dutch teaching hospital. The system monitored the presence and the safety status (periodic maintenance and malfunction) of 94 OR devices. Moreover, the system allowed to notify malfunctions of OR devices. The usability and the technical reliability of the system were assessed as well as the effect on notifying malfunctions.

First, the overall feedback on the usability of the system was positive as most of the interviewed users looked at the tablet at least once a day, looked for more information when the screen was red, and wanted to keep this system in the future. After the pilot, the hospital decided to acquire this safety status system in this OR complex and to install it in the future building of the hospital which is in process at the time of writing this paper. Previous studies have shown that the level of use of many RFID based equipment tracking systems implemented in health care was low [12, 14, 15]. In contrast to those studies, the level of use of the safety status system tested in this study was high. Although this system combined tracking and monitoring of the safety status of OR device, and therefore provided more advantages for the users than a tracking system only, the long term success of the system needs to be followed in the future.

The second aim of this study was to research if the safety status system for OR devices was suitable for an OR complex from a technical point of view. The results showed that for 86.6% of the total time the localisation was considered accurate. A probable reason for the occasionally erroneous localisation of the devices is the architecture of the OR complex. The walls between the ORs and the storages, as well as between the storages, were without metal and the signals of the tags were able to reach readers at the other side of the wall of the room they were in. For 97.2% of the time that the registration of the location was stable but uncertain between two locations side by side (37.8% of the total time), the uncertainty was between an OR and its storage or between two storages. For only 2.8% the uncertainty was between two ORs that were separated by walls containing stainless steel. Every wall separating two ORs contains a window that probably let some of the signals through to the other room. This can explain the small but remaining amount of uncertainty between two ORs. The surrounding environment of the tags

and readers has a large influence on the RFID signal due to reflecting and absorbing effects of the present materials [16]. As metal is a factor that reduces reading distance, the reliability of the localisation system in an OR complex with metal walls would probably be improved. In literature, different real-time location systems (such as WIFI, RFID, infrared, ultrasound, GPS) were evaluated in health care contexts and the accuracy of the location system was often lower than expected [12, 13]. The reliability of the location system could be improved by combining technologies such as RFID and infrared [13]. An improvement of the localisation is needed in the future if such a system will be used as a strict go-no go system prior to surgeries.

The last aim of this work was to study the effect of this safety status system on the notification of malfunctions of OR devices. The results showed an increase of 12 registered malfunctions compared to the previous year. This can be explained by the increased OR staff's awareness of the safety of the devices due to the constant presence of the tablet in the OR and the possibility to read the feedback of the technicians of the department of Clinical Physics. Automatic detection of defects through a self-check system of OR devices would be desired in the future. Nevertheless, keeping the staff actively involved in decisions is important as the process of reporting and receiving feedback is known to raise the awareness of patient safety and sense of responsibility for reporting [17-19].

More notifications were done in the traditional way than by using the button on the RFID tag of the malfunctioning devices. Although much effort was invested in repetitively instructing the OR staff about the use of the system, most staff members indicated the need for more instructions and training. The OR staff of the hospital counted about 180 employees, with a circulating working schedule between 12 ORs. The system was installed in only four ORs, in the eight other ORs communication by phone was the only mean for notifying malfunctions. With 62 registered malfunction in six months, it was difficult for the OR staff to get used to the new method of notifying malfunctions.

An important limitation of this study is the lack of indicators of the effect on safety in the OR. The difficulty to assess the effect of safety systems on patient safety and adverse events was often mentioned in literature [20-22]. More specific indicators of error and harm need to be monitored and targeted to provide a reliable measurement of safety and quality [22]. However, the users mentioned that the safety status system presented in this work provided a better overview and information facility, an easier and faster notification system and a faster detection of problems. So although not objectively measured by set indicators, the users were convinced that the system contributed to an improvement of the safety related to OR devices.

Checklists can improve the safety related to OR equipment [23] but increasing staff's workload is one of the important reason for the low adoption of checklists in health care [12, 24]. The safety status system can be seen as a step towards the implementation of automatic checklists in the OR, without asking more time or work from the users. The safety status system can be extended to sterilisable instruments and disposables in order to cover all equipment in the

OR. Therefore, the system should be adapted to match the large quantities of equipment to be tagged (e.g. using both passive and active RFID). This extended safety status system should also allow automatic registration and communication with the sterilization department, similar to the present communication with the department of Clinical Physics, to enable follow up of defects of equipment or disposables. Also, the system can be easily linked to the Time Out safety procedures that are already institutionalized in Dutch hospitals, thereby further promoting adherence to safety procedures. In conclusion, this study shows that the technology is present and ready to be used in such applications and that this system presents a great potential for an improvement of the safety in the OR.

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson MS (2000) To err is human: building a safer health system, National Academy Press, Washington DC
2. Leape LL (1994) Error in medicine. *JAMA: the journal of the American Medical Association* 272:1851-1857
3. Cuschieri A (2006) Nature of human error - Implications for surgical practice. *Ann Surg* 244:642-648
4. Baines RJ, Langelaan M, de Bruijne MC, Asscheman H, Spreeuwenberg P, van de Steeg L, Siemerink KM, van Rosse F, Broekens M, Wagner C (2013) Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ quality & safety*
5. Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH (2010) Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Quality & safety in health care* 19
6. Greenberg CC (2009) Learning from adverse events and near misses. *Journal of gastrointestinal surgery: official journal of the Society for Surgery of the Alimentary Tract* 13:3-5
7. Verdaasdonk EGG, Stassen LPS, van der Elst M, Karsten TM, Dankelman J (2007) Problems with technical equipment during laparoscopic surgery - An observational study. *Surgical Endoscopy and Other Interventional Techniques* 21:275-279
8. Dutch Healthcare Inspectorate (IGZ) (2008) Risico's van medische technologie onderschat.
9. Dutch association of medical specialists (Orde van medisch specialisten) (2008) Leidraad: Verantwoordelijkheid medisch specialist bij onderhoud en beheer van medische apparatuur.
10. Dutch association of hospitals (NVZ) and Dutch association of university hospitals (NFU) (2011) Convenant veilige toepassing van medische technologie in het ziekenhuis.
11. Fichman RG, Kohli R, Krishnan R (2011) The Role of Information Systems in Healthcare:

Current Research and Future Trends. *Inform Syst Res* 22:419-428

12. Fisher JA, Monahan T (2012) Evaluation of real-time location systems in their hospital contexts. *Int J Med Inform* 81:705-712
13. Kamel Boulos MN, Berry G (2012) Real-time locating systems (RTLS) in healthcare: a condensed primer. *International Journal of Health Geographics*
14. Wamba SF (2012) RFID-Enabled Healthcare Applications, Issues and Benefits: An Archival Analysis (1997-2011). *J Med Syst* 36:3393-3398
15. Yao W, Chu CH, Li Z (2012) The Adoption and Implementation of RFID Technologies in Healthcare: A Literature Review. *J Med Syst* 36:3507-3525
16. Ergen E, Akinci B, East B, Kirby J (2007) Tracking components and maintenance history within a facility utilizing radio frequency identification technology. *J Comput Civil Eng* 21:11-20
17. World Health Organization (2005) WHO draft guidelines for adverse event reporting and learning systems.
18. Anderson JE, Kodate N, Walters R, Dodds A (2013) Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. *International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua* 25:141-150
19. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A, Vincent C (2009) Feedback from incident reporting: information and action to improve patient safety. *Quality & safety in health care* 18:11-21
20. Morello RT, Lowthian JA, Barker AL, McGinnes R, Dunt D, Brand C (2013) Strategies for improving patient safety culture in hospitals: a systematic review. *BMJ quality & safety* 22:11-18
21. Shojania KG, Thomas EJ (2013) Trends in adverse events over time: why are we not improving? *BMJ quality & safety* 22:273-277
22. Vincent C, Aylin P, Franklin BD, Holmes A, Iskander S, Jacklin A, Moorthy K (2008) Is health care getting safer? *Bmj* 337:a2426
23. Verdaasdonk EG, Stassen LP, Hoffmann WF, van der Elst M, Dankelman J (2008) Can a structured checklist prevent problems with laparoscopic equipment? *Surgical endoscopy* 22:2238-2243
24. Fisher JA, Monahan T (2008) Tracking the social dimensions of RFID systems in hospitals. *Int J Med Inform* 77:176-183

CHAPTER 4: A RFID SPECIFIC PARTICIPATORY DESIGN APPROACH TO SUPPORT DESIGN AND IMPLEMENTATION OF REAL- TIME LOCATION SYSTEMS IN THE OPERATING ROOM

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INTRODUCTION

The healthcare sector is currently facing multiple challenges including patient safety issues and high costs [1]. Studies on medical errors and adverse events have brought a focus on patient safety in healthcare, especially in the operating room (OR), which has been recognized as a common site for adverse events [2-6]. Also the use of sophisticated high-tech equipment has made the OR environment more complex and susceptible to errors [3, 7]. Despite numerous initiatives to improve patient safety, the progress has been slower than expected [4, 8-10]. Moreover, the healthcare costs are constantly increasing. The United States devote far more of its economy, 17.6% of the gross domestic product (GDP) in 2010, to healthcare than any other country. The Netherlands is the next highest, with 15% of the GDP in 2011 [11, 12]. Twenty-five percent of these costs are spent on hospital care, which has been rising with an average of 5.2% per year [12]. In order to reduce these costs, hospitals need to focus on operational efficiency, particularly in the OR where the costs are the highest [13-15].

Information technology may substantially contribute to activities to overcome the safety and cost challenges in healthcare [16]. Real-time location (RTL) systems offer automatic identification that can be used to track and trace equipment, supplies and people in real-time [17, 18]. Previous studies have shown that these systems increased efficiency, improved safety and reduced operational costs [17, 18]. One of the commonly used technologies for RTL systems is Radio Frequency IDentification (RFID). For instance, RFID technology has been used to ensure the right matching of medication and patient to prevent the risk of medication error, to quickly locate portable equipment, to detect instrument use and to track patient flow to reduce waiting times and improve allocation of staff and equipment [18-20]. Despite the advantages of RFID technology to improve the patient safety and the efficiency of processes, its implementation is slow and more difficult than expected [21]. The rate of adoption and effective use of RFID technology in healthcare is still low [22-25]. This can be explained by most health information technology projects, such as RFID technology projects, focusing on the technological aspects and the problems concerning fitting the new technology to the existing hospital infrastructure, instead of including the social, the organizational and the technological context [17, 18, 23, 26-28]. The 'Critical Success Factors Framework' by Yao et al. provides a framework to overcome technological as well as economic, social and legal barriers and to reach successful implementation of RFID technology in healthcare [21]. However, this framework does not provide practical steps on *how* to implement RFID technology.

Participatory Design (PD) provides a structure to guide the design and implementation process. PD aims to design products and systems (innovations) from a user's perspective, so these can be used in a comfortable, efficient and safe way [29-33]. PD started in the field of computer science and empowers its users by means of active participation and engagement in the design process and decision-making processes; in other words PD helps to facilitate communication and collaboration between different users and designers [30, 32-36]. Additionally, PD is useful

when requirements of the final innovation are not fixed at the start of the project [36]. PD also provides a structure to gain insight in the users' workflow, the interactions between users and between users and technology. These insights and the active participation and engagement of the users are needed to define the objectives, vision and requirements of the innovation. PD also enables development of realistic expectations, reduces resistance to change, helps to achieve a possible solution across disciplines and helps to continuously improve it [35, 37, 38]. Research has shown that applying PD leads to user-orientated designs, improved actual usage, compliance and sustainability [30, 34].

Currently, no specific approach exists for the design and implementation of RFID based RTL systems. Combining PD principles with the 'Critical Success Factors Framework' by Yao et al. [21] provides a practical approach presenting *what* critical success factors to take into account and *how* to bring it in practice in order to design and implement RFID systems successfully in healthcare. The aim of the current work is to study if a RFID specific PD approach supports design and implementation of RFID systems in the OR. In this study we focused on RFID technology to track the location of OR devices and patients within the OR complex.

METHODS

Figure 4.1 presents the RFID specific PD approach that was used for the design and implementation of two modules in two hospitals that are part of the so-called Digital Operating Room Assistant (DORA) project. These modules aimed to increase insight in the progress of the operative trajectory among patients and their family members, healthcare providers, clinical physicists, technical staff, managerial staff and management.

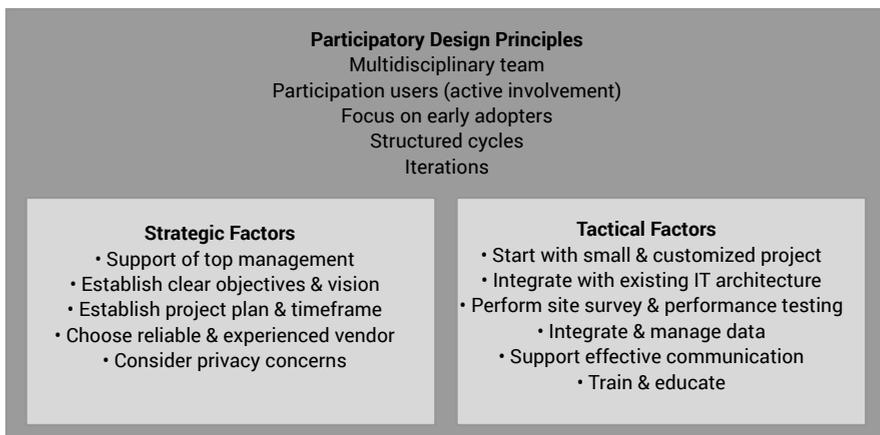


Figure 4.1. RFID specific Participatory Design approach

THE DEVICE MODULE

The Device Module of the DORA system was designed and implemented in a Dutch teaching hospital consisting of 12 ORs spread over three buildings. The Device Module monitors the presence and the safety status of OR devices and alerts the OR staff about irregularities. Also, malfunctions of OR devices can be reported through this system.

In total, 100 OR devices in four ORs (in one building) were equipped with a active RFID tag (frequency 869.3 MHz, power 10mW). Active RFID was used as the signal ranges up to 100 m (compared to less than a meter for passive RFID [18]). The system consisted of 100 active custom-made, battery powered RFID tags, 10 readers and four tablet computers (iPad3) for interfacing with the OR staff through a web application (see Figure 4.2). All data gathered by the system were saved on a server that was linked to the hospital's technical facility management system. The Device Module worked on the secured internal network of the hospital and no patient data was used. The tablet computer portrays the safety status of all detected devices within the OR to the OR staff. The background colour of the screen can either be green, indicating that the maintenance of all devices is up to date and the devices are tested to work properly, or red, indicating that maintenance is overdue or a malfunction has been reported.

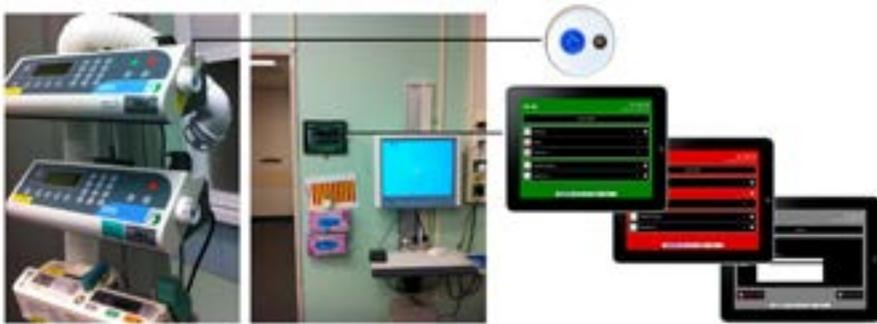


Figure 4.2. Left: RFID tags placed on OR devices. Middle: the graphical user interface on the tablet computer in the OR. Right: the tag, the green and red screen and the screen for notifying malfunctions

Each tag was equipped with a push button and a LED. The OR staff could use this button to report a malfunctioning device. This automatically opened a window on the tablet computer showing the name of the malfunctioning device and asking for explanations about the malfunction which the OR staff had to enter via the tablet computer. Subsequently, the LED on the tag would light up. The malfunction information was automatically sent to the technicians at the Department of Clinical Physics and registered in the hospital's technical facility management system. Furthermore, detailed information about the safety status or malfunction (e.g., the nature of the malfunction, the staff member who reported the malfunction, the actions taken by the Department of Clinical Physics) could also be shown on the tablet computer.

THE PATIENT MODULE

The Patient Module of the DORA system was designed and implemented in a tertiary referral and teaching hospital that houses six ORs divided over two departments. The Patient Module tracks the location of patients during their entire hospital stay, which is indicative for the steps in the operative trajectory.

Adult patients admitted for surgical day-care were tracked during their stay in the hospital using active RFID tags (frequency 433.92 MHz, power 1mW). Active RFID was used as the patient flow had to stay the same (passive RFID tags would have required the patients to move close to the readers). The battery powered RFID tags that were attached to the patient's wristband (see Figure 4.3) were used multiple times and were cleaned with alcohol between patients. The tags were tracked by readers, which were placed at eight locations in the OR complex: registration desk, waiting room, intake room, two rooms at the ward, holding, OR corridor and recovery. The patient received the tag at the registration desk (where the patient's name and personal title were linked to the tag) and the nurse from the ward collected the tag at the end of the outtake meeting. All location data gathered by the system were saved on a stand-alone server (with no direct connection to the hospital's systems and a secured connection to the R&D company). The patient's location (and consequently the phase a particular patient is in) was displayed on a screen through a web application (see Figure 4.3).



Figure 4.3. Left: RFID wristband. Right: graphical user interface including patient cards with patients names, personal title and a collared dot representing the ward nurse responsible for that particular patient

PARTICIPATORY DESIGN PRINCIPLES

Multidisciplinary team, participation users (active involvement) and focus on early adopters

A multidisciplinary team participated in the design and implementation (and redesign) process to improve full implementation of the modules [17, 39-41]. The PD principles 'multidisciplinary team' and 'participation users (active involvement)' were safeguarded by having each DORA-module designed and implemented by a multidisciplinary team of users (stakeholders) from the RFID Research and Development (R&D) company, the university of technology and the hospital. Two researchers (AG, LW) from the university also acted as project manager; one researcher per hospital. From both hospitals the users included staff members from the Department of Surgery, Department of Anaesthesiology, the OR and the Department of IT & Maintenance. For the Device Module, also staff members from Department of Clinical Physics were included. For the Patient Module, also staff members from (top) management, the nursing department and the Department of Quality & Safety were included. The multidisciplinary team consisted predominantly of 'early adopters'. They co-designed and embraced the proposed application of RFID technology before most other people do. Also, the participating university of technology and the hospitals possessed the relevant expertise in medical technology and clinical knowledge and the participating R&D companies built on proven practical applications. Including the R&D company in the multidisciplinary team allows the R&D company to advise the hospital on on-going system changes and redesign of the technology (for the future sustainability of the system) and creates a shared risk acquisition [18].

Structured cycles and iterations

For both modules the design and implementation process consisted of two 'structured cycles' ('iterations'), each entailing five steps: analyse, design, test, evaluate and decide [29]. Although each iteration is structured it is not fixed; PD is an approach to guide the design and implementation process and is not a strict protocol, which means that the exact PD structure and the planning process differs per case [29, 36, 41]. The first iteration mainly focused on the design process and the second on the implementation process. In line with the PD principles, the modules were not fully implemented directly from the start of the project (e.g. not all devices were tagged for the Device Module, and no integration with the patient records was made for the Patient Module), but the modules were designed via multiple structured iterations allowing the users to experiment and learn how to use the modules and enabling them to adapt the modules to their work environment [18].

In the *analysis* step of the first iteration, the multidisciplinary team was established and (top) management was engaged to establish a wide support. Based on meetings with users, observations and shadowing of staff and patients the current workflow was studied and the hospital's specific objectives, vision and project plan were formulated. In the *design* step, ideas were formulated and the modules were designed in cooperation with the R&D companies. Next, the modules were *tested* and *evaluated* with the users by means of usage tests, observations,

Table 4.1. Actions taken and Participatory Design principles used to implement two RFID based modules having an important impact on the design and implementation process

Factors	Device Module	Patient Module	Actions	Multidisciplinary team	Participation users	Focus on early adopters	Structured cycles	Iterations
Strategic factors								
Support of top management	x		- Support of head of OR complex, head of Department of Clinical Physics					
		x	- Support of CEO, Quality & Safety Consultant					
Establish clear objectives & vision	x		- Establish by staff and research project group *					
		x	- Establish by top management and research project group *					
Establish project plan & timeframe	x	x	- Define structured project plan					
	x	x	- Establish expected timeframe *					
Choose reliable & experienced vendor	x	x	- Co-develop with experienced RFID R&D company (not particular healthcare)					
Consider privacy concerns	x		- Do not use patient data					
		x	- Use anonymous patient data					
	x		- Use secured internal network					
	x		- Use secured access points for integration with other systems					
Tactical factors								
Start with small & customized project	x		- Focus on specific rooms and specific devices					
		x	- Focus on specific rooms and specific patient groups					
Integrate with existing IT architecture	x		- Communicate with internal technical facility management system					
		x	- Use stand-alone system (no integration, communication with other systems)					
Perform site survey & performance testing	x	x	- Perform workflow survey *					
	x	x	- Perform site survey for installation of hardware in OR complex *					
	x		- Perform interference testing *					
Integrate & manage data	x	x	- Process data by RFID R&D company					
	x		- Limit information saved in internal technical facility management system					
		x	- Use stand-alone system (no integration, communication with other systems)					
Support effective communication	x	x	- Support communication between departments					
	x	x	- Design graphical user interface *					
Train & educate	x	x	- (Repeatedly) Perform instruction sessions and distribute instruction documents for different stakeholders					
	x	x	- Be present during first days of implementation					
	x	x	- Distribute newsletters and progress reports					
		x	- Inform patients					

* actions having an important impact on the design and implementation process

STRATEGIC FACTORS

The strategic actions, which influenced both modules, were related to establishing clear objectives and vision, the project plan and the time frame. For establishing clear objectives and vision, mainly the PD principles 'multidisciplinary team' and 'participation users' were applied. The objectives and vision were not only defined by the users of that specific hospital, but also by the project group of the DORA-project consisting of researchers and stakeholders / users from the university of technology, both hospitals and both R&D companies. The objectives and vision were also checked through observations in the OR complex and meetings with the different users of the Device and Patient Module (i.e. OR nurses, nurse anaesthetists, nurses, head of the nursing department, OR team leaders, medical specialists, administrative workers and technicians of the Department of Clinical Physics). Via these observations and meetings a larger group of users was able to participate.

For establishing the expected timeframe, primarily the PD principles 'multidisciplinary team', 'structured cycles' and 'iterations' were applied. The original timeframe for the project, which was outlined by the multidisciplinary team, was six months, from first analysing the problem and stating the objectives and vision in the first iteration, until testing the Device and Patient Module in the OR in the second iteration. However, sub-iterations were needed for the tactical factor 'perform site survey and performance testing' (Device Module) that took more time than expected. Also, waiting for delivery and installation of the hardware (Device and Patient Module) caused some additional delay, changing the timeframe of the project. Finally, the timeframe was prolonged from six to ten months.

TACTICAL FACTORS

The four tactical actions with important impact on costs and time were related to the workflow survey, the installation of the hardware in the OR complex, interference testing and the custom designed GUI. Here, the PD principles 'multidisciplinary team' and 'participation users' were applied. For the design of the GUIs, also the PD principles 'structured cycles' and 'iterations' were used.

The workflow surveys in both cases were performed via observations in the OR and meetings with the users. The hospital staff experienced it supportive and effective to have the researcher/project manager present repetitively in the hospital and in the OR complex to get familiar with the staff, their workflow and the patient flow. The workflow survey related to the Device Module showed the need to simplify the workflow of the users in the OR and the Department of Clinical Physics. Checking the safety status of OR devices needed to be facilitated and the notification of malfunction needed to be simplified. The Department of Clinical Physics required information about the location of the devices and information about the malfunctions in order to improve their efficiency. The workflow survey related to the Patient Module showed the need to inform the nurses at the nursing department and the patients and family members in the waiting

room about the phases in the patients' operative trajectory. For the nursing staff, automatic information about the current phase and the time a patient entered a specific phase (see Figure 4.3) was desired. For the patients and their family, only the phases of the operative trajectory and the number of stages still to pass through were of interest.

The site surveys related to the installation of the hardware in both OR complexes were performed with the active involvement of the technical stakeholders and revealed several technical challenges. The walls between rooms did not always prevent RFID signals passing through, making it difficult to recognize the exact location of a device or patient. Both devices and patients were seen in adjacent rooms. However, this was partly solved in the software. Installation in the OR complex also required the ORs to be closed and extra cleaning due to e.g. dust. Furthermore, extra electric points and network connections had to be installed in both OR complexes. Installation of screens in the OR can also be problematic and expensive if medical screens are required. For the pilot of the Device Module, tablet computers outside the patient area temporarily solved this issue.

For the Device Module, interference tests were performed with the collaboration of the technical stakeholders. Several studies have shown the need for interference testing guidelines for RFID systems [28, 42-44]. However, no comparable interference tests were available for the active RFID used in the Device Module (low power digital radio, 869.3Mhz, 10mW). To ensure safe implementation of the Device Module in the OR, interference tests were performed for each OR device tagged. The tag was placed on a device in use for two minutes and possible interferences were observed. No interferences were observed during the tests. For the Patient Module, no interference tests were performed, as the system was already commercially available and was used in similar healthcare settings.

To support effective communication, GUIs were designed for both modules. For this tactical action, almost all PD principles were applied: 'multidisciplinary team', 'participation users', 'structured cycles' and 'iterations'. The GUIs were tailored to the needs of the specific users, presenting the information in an intuitive and easy to use way. For the Device Module, the OR staff was unaccustomed to the internal technical facility management system of the Department of Clinical Physics and would probably not use it to check the data collected by the Device Module. Furthermore, most data were not relevant for the OR staff, such as the inventory numbers of the devices or the administrative numbers for the job of the Department of Clinical Physics. A GUI was developed for the OR itself and showed only the information relevant for the OR staff (name of the device, safety status and details about the malfunction). In case of a problem, with a red screen, the OR staff could gather more information by navigating through the web application. Since, the Device Module is connected to the internal facility management

system, the Department of Clinical Physics also used this information to monitor the OR devices. This means that the GUI for the OR staff was different from the GUI for the Department of Clinical Physics. For the Patient Module, one GUI was designed for both patients and families and nurses.

ACCEPTANCE OF THE DEVICE AND PATIENT MODULE

Based on the interviews, all OR staff members mentioned to look at the tablet computer of the Device Module at least once a day. When the screen was red, 12 out of 13 staff members looked further on the tablet computer for more information or consulted a colleague. Eight out of 13 OR staff members and three out of four members of the Department of Clinical Physics found the way of notifying malfunctions with the Device Module easy to use. Five OR staff members did not use it during the pilot period, so could not give any feedback. All four members of the Department of Clinical Physics would like to continue using the Device Module in the future, as well as 10 out of 13 OR staff members. The other three OR staff members did not have an opinion on the possible future use.

For the Patient Module, all nurses agreed that they would use the Patient Module; it was intuitive and would fit their current work routine. The nurses stated that "it provides an overview of the patient flow and overall progress" and "it provides transparency within the nursing ward and it provides insights in the workload among nurses". However, they also raised questions about e.g., the names used for the different locations (they were unclear) and the location of the screen for the GUI. Twenty patients and family members were interviewed and all agreed that having more insight in the operative trajectory would make their stay more comfortable. They found that the GUI was easy to understand, but required some instructions (e.g., explanation of the terms used and the aim of the module).

Both modules are now implemented and part of the user's daily work routines. Furthermore, both hospitals were willing to pay for the permanent implementation of the modules and the modules are currently being validated with active participation of the users to adapt the modules (to redesign the modules) and to keep them enthusiastic in using it.

DISCUSSION

This study showed that a RFID specific PD approach was effective in guiding and supporting the design and implementation process of RFID technology in the OR complex. It provided practical information about how to use the critical success factors in this process and showed which actions had a key impact on the implementation process in terms of time and costs.

The most applied PD principles were the 'multidisciplinary team' and 'participation users (active involvement)'. As PD is an approach to design innovations from a user's perspective, these principles directly related to the users are almost omnipresent. Several studies have shown the importance of actively involving a multidisciplinary team of users to adapt the innovation's functionality, ease of use and suitability for the current workflow for the success of the design and the implementation process [17, 18, 36, 39, 40]. In eight out of 27 actions the PD principles 'structured cycles' and 'iterations' were used. In contrast to these eight actions, the remaining actions are mainly performed once in the first iteration. Nevertheless, iterations need to be continued on a structural basis as re-design is never finished as the work environment, the organization and its user are constantly changing [17]. For example, the lay-out of the rooms change, new ORs are built, new software is used to maintain equipment or new connections are needed for dynamic associations [17]. This also requires continuous involvement and commitment from all stakeholders [27, 36]. The PD principle 'focus on early adopters' was the most apparent in the actions related to 'focus on the small and customized project' and to 'training and educating users'. However, the multidisciplinary team consisted predominantly of 'early adopters' so this PD principle was actually more present than presented in Table 4.1.

Seven actions had an important impact on the implementation process in terms of time and costs. Nonetheless, the remaining actions also need to be taken into account, as all actions together are required to ensure a successful implementation. For instance, the decision to integrate the Device Module with the existing IT infrastructure was not time nor cost consuming, but was an important step in the implementation process. However, some additional actions played an important role in the success of the implementation. Firstly, the researchers acting as project managers / facilitators ensured explicit communication between the team members, guided the process, were optimistic about the process and outcome and were critical on the actions taken. The importance of this role has been argued in several studies [29, 39, 41]. Also, the researchers shared their experiences constantly, so they could learn from each other and improve and better anticipate the implementation process in their specific hospital. Secondly, previous collaboration between the university of technology and the hospitals created trust between them that facilitated cooperation and implementation. Hasvold and Scholl also stated that long-term cooperation, preferably with the same people accompanied by hospital staff with a permanent contract and long-term involvement will support the implementation and adoption of new designs [36]. Thirdly, the DORA-project was partly funded externally. This meant that both hospitals and R&D companies got the opportunity to develop, to implement and to test the

technology with reduced costs. This way the R&D companies could customize and optimize their innovation and the innovation could show its relative advantage before the hospital had to allocate budgets [18, 40]. For the R&D companies this also facilitated expansion of proven practical application in the healthcare sector.

Besides facilitating the design and implementation process, the involvement of the researchers and the external funding could also provide uncertainties for future development and can be seen as limitations of the current study. The facilitating role of the researchers could have influenced the process positively. However, in the following iterations, the facilitators' activities will diminish and will be taken over by the stakeholders from the hospital. The external funding was used in the first two iterations. Nevertheless, in the next iterations, maintenance and redesign of both modules will not be funded externally. The effect of the reduced involvement of the facilitators and the importance of funding on the success of future activities were not shown in this study, which makes it difficult to predict the long-term implementation success (the sustainability) of the modules. The long-term effects of the adoption of innovations are still underreported in literature. Greenhalgh et al. showed that more research on the continuation of adoption of innovations is needed to understand why people and organizations reject or accept an innovation after adoption [40]. This study focused mainly on the design and implementation of a Device and Patient Modules, which were designed to fit the current organizational structures. Now that the modules are in place and used on a daily basis, the next step is to study the rate of adoption. We will continue to follow the hospitals to study the rate of adoption, but also to study the effect of the facilitating role of the researcher and the effect of external funding by using field observation and questionnaire based surveys (e.g. the Technology Acceptance Model [45]).

Successful implementation relies on the innovation itself, but also on its suitability for the complex workflows and the multiple users group [40]. Greenhalgh et al. showed that successfully implemented innovations meet six key attributes: Relative advantage (the advantages are immediately apparent), Compatibility (matching the values of the users), Low complexity, Trialability (users can experiment), Observability (benefits are visible/measurable) and the Potential for reinvention (users can adapt, refine, modify to fit their needs) [40]. They also showed that the implementation process should rely on several implementation factors: Frontline users making decisions, Hands-on approach by top management, Human resource issues (especially training), Dedicated resources, Internal communication, External collaboration, Reinvention/development and Feedback on progress. We conclude that the RFID specific PD approach provides these key attributes and implementation factors and can therefore be seen as an effective approach to implement RFID technology in the healthcare sector.

REFERENCES

1. AHRQ (2013) Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Rockville, MD
2. Leape LL (1994) Error in medicine. *JAMA : the journal of the American Medical Association* 272:1851-1857
3. Cuschieri A (2006) Nature of human error - Implications for surgical practice. *Ann Surg* 244:642-648
4. Baines RJ, Langelaan M, de Bruijne MC, Asscheman H, Spreeuwenberg P, van de Steeg L, Siemerink KM, van Rosse F, Broekens M, Wagner C (2013) Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ quality & safety*
5. Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH (2010) Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Quality & safety in health care* 19
6. Greenberg CC (2009) Learning from adverse events and near misses. *Journal of gastrointestinal surgery : official journal of the Society for Surgery of the Alimentary Tract* 13:3-5
7. Verdaasdonk EGG, Stassen LPS, van der Elst M, Karsten TM, Dankelman J (2007) Problems with technical equipment during laparoscopic surgery - An observational study. *Surgical Endoscopy and Other Interventional Techniques* 21:275-279
8. Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ (2010) Temporal trends in rates of patient harm resulting from medical care. *The New England journal of medicine* 363:2124-2134
9. Vincent C, Aylin P, Franklin BD, Holmes A, Iskander S, Jacklin A, Moorthy K (2008) Is health care getting safer? *Bmj* 337:a2426
10. Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, Whittington JC, Frankel A, Seger A, James BC (2011) 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health affairs* 30:581-589
11. OECD (2012) OECD health data 2012.
12. NVZ (2012) Gezonde Zorg: Brancherapport Algemene Ziekenhuizen 2012.
13. Archer T, Macario A (2006) The drive for operating room efficiency will increase quality of patient care. *Current opinion in anaesthesiology* 19:171-176
14. Sieber TJ, Leibundgut DL (2002) Operating room management and strategies in Switzerland: results of a survey. *Eur J Anaesth* 19:415-423
15. Denton BT, Miller AJ, Balasubramanian HJ, Huschka TR (2010) Optimal Allocation of Surgery Blocks to Operating Rooms Under Uncertainty. *Oper Res* 58:802-816
16. Fichman RG, Kohli R, Krishnan R (2011) The Role of Information Systems in Healthcare: Current Research and Future Trends. *Inform Syst Res* 22:419-428

34. Weng C, McDonald DW, Sparks D, McCoy J, Gennari JH (2007) Participatory design of a collaborative clinical trial protocol writing system. *Int J Med Inform* 76 Suppl 1:S245-251
35. Namioka AH, Rao C (1996) Introduction to participatory design. *Field methods casebook for software design*, John Wiley & Sons, Inc., New York, pp 283 - 299
36. Hasvold PE, Scholl J (2011) Flexibility in interaction: sociotechnical design of an operating room scheduler. *Int J Med Inform* 80:631-645
37. Clemensen J, Larsen SB, Kyng M, Kirkevold M (2007) Participatory design in health sciences: Using cooperative experimental methods in developing health services and computer technology. *Qualitative Health Research* 17:122-130
38. Vimarlund V, Eriksson H, Timpka T (2001) Economic motives to use a participatory design approach in the development of public-health information systems. *Stud Health Technol Inform* 84:768-772
39. Scariot J, Heemann A, Padovani S (2012) Understanding the collaborative-participatory design. *Work: A Journal of Prevention, Assessment and Rehabilitation* 41:2701-2705
40. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O (2004) Diffusion of innovations in service organizations: systematic review and recommendations. *The Milbank quarterly* 82:581-629
41. Rittel H (1972) On the Planning Crisis: Systems Analysis of the 'First and Second Generations'. *Bedriftsokonomien*
42. van der Togt R, van Lieshout EJ, Hensbroek R, Beinat E, Binnekade JM, Bakker PJ (2008) Electromagnetic interference from radio frequency identification inducing potentially hazardous incidents in critical care medical equipment. *JAMA : the journal of the American Medical Association* 299:2884-2890
43. Davis R, Geiger B, Gutierrez A, Heaser J, Veeramani D (2009) Tracking blood products in blood centres using radio frequency identification: a comprehensive assessment. *Vox Sang* 97:50-60
44. Saito Y, Hasegawa T, Sakamaki T (2007) Efficiency and Safety of New Radiofrequency Identification System in Japanese Hospital. *St Heal T* 129:1478-1478
45. Sedlmayr B, Patapovas A, Kirchner M, Sonst A, Muller F, Pfistermeister B, Plank-Kiegele B, Vogler R, Criegee-Rieck M, Prokosch HU, Dormann H, Maas R, Burkle T (2013) Comparative evaluation of different medication safety measures for the emergency department: physicians' usage and acceptance of training, poster, checklist and computerized decision support. *BMC medical informatics and decision making* 13:79

CH 4

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DELIVERY PROCESS FOR SURGICAL INSTRUMENTS

PART III

CHAPTER 5: WHERE ARE MY INSTRUMENTS? HAZARDS IN DELIVERY OF SURGICAL INSTRUMENTS

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ABSTRACT

Unavailability of instruments is recognized to cause delays and stress in the operating room, which can lead to additional risks for the patients. The aim is to provide an overview of the hazards in the entire delivery process of surgical instruments and to provide insight in how Information Technology (IT) could support this process in terms of information availability and exchange.

The process of delivery was described according to the Healthcare Failure Mode and Effects Analysis (HFMEA) methodology for two hospitals. The different means of information exchange and availability were listed. Then, hazards were identified and further analysed for each step of the process.

For the first hospital, 172 hazards were identified and 23 hazards were classified as high risk. Only one hazard was considered as 'controlled' (when actions were taken to remove the hazard later in the process). 22 hazards were 'tolerated' (when no actions were taken and it was therefore accepted that adverse events may occur). For the second hospital, 158 hazards were identified and 49 of hazards were classified as high-risk. Eight hazards were 'controlled' and 41 were 'tolerated'. The means for information exchange and information systems were numerous for both cases, while there was not one system that provided an overview of all relevant information.

The majority of the high-risk hazards are expected to be controlled by the use of IT support. Centralised information and information availability for different parties reduce risks related to unavailability of instruments in the operating room.

INTRODUCTION

The Operating Room (OR) is known to be the most cost-intensive place of the hospital where adverse events are most likely to occur [1-9]. Weaknesses in the hospital organisation, lack of experience of the OR team, limitations in checklists, protocols and in equipment design allow adverse events to occur in a complex environment such as the OR [10]. Because of the increasing use of technology during surgery and the added complexity it induces, an increase in equipment related incidents has been reported [6, 11-13]. Equipment related incidents were observed in 15.9% of surgical procedures [6]. Around 40% of these incidents were due to the unavailability of equipment [6, 11], mostly instruments, and each incident resulted in an average of 12 minutes of extra work and 5 minutes of delay [6]. Verdaasdonk et al. have observed a larger number of incidents specifically related to instruments in 16% of the procedures [12]. Equipment related issues have also shown to increase the level of stress of the surgeon [14]. Stress is known to diminish human performances and therefore increase the potential for errors in the OR [14, 15]. Hence, managing stress-inducing factors is imperative for safer care. Moreover, a higher percentage of incidents was observed during orthopaedic procedures [6], which is considered particularly disruptive, because these surgeries highly depend on the availability and function of procedure-specific instruments [13]. These studies show that equipment-related problems represent a large part of the adverse events in the OR and that optimisation of the supply chain is likely to have a large impact on patient safety. However, although unavailability of instruments is recognized to cause delays and stress in the OR, the processes related to the delivery of instruments have received little attention in the scientific literature.

Supply chain management is also a topic of increased interest due to the increased emphasis on cost efficiency in healthcare. Hospitals are fused and may share centralised services, while others outsource services to focus on their primary processes: patient cure and care. Outsourcing the sterilisation of surgical instruments presents opportunities to reduce costs if the processes are well designed and optimised. However, poor supply chain management can lead to unavailability of instruments and therefore present risks for patients [16]. Information exchange and trust have been identified as important factors that influence the quality of supply chain management [17]. Centralising information is in this case imperative as it increases the availability and ease of access for different parties, thereby enhancing the collaboration between them [18]. Both information exchange and trust can be supported with currently available applications in Information Technology (IT). In particular, recent developments such as 'track and trace' methods have the potential to extensively improve inventory management and streamline processes in healthcare [19]. Moreover, stricter requirements are being set for the ability to trace the use of medical equipment in case of a recall due to malfunctions or contamination [20]. Still, the potential added-value of IT support for improvement and optimisation of supply chain management is unclear.

The organisational structure (e.g. outsourced or shared centralised services), information exchange and trust between the different parties all influence the delivery process of instruments [16, 17]. Each of these can induce hazards (i.e. sources of potential adverse event) at different stages of the delivery process, although this may only become apparent during the procedure. As far as known by the authors, an overview of hazards in the entire process of delivery of instruments is lacking in scientific literature. One way to obtain such an overview is through the application of a Healthcare Failure Mode and Effects Analysis (HFMEA). The first FMEAs were performed in the mid 1960's in the aviation industry and are nowadays used by many high-risk industries. HFMEAs allow identification of (previously unnoticed) errors and supports meeting high safety standards. Several adaptations of this method have been developed and successfully applied in the healthcare sector [21-23]. This study aims to provide an overview of the hazards in the entire process of delivery of surgical instruments using the HFMEA method and to provide insight in how IT could support this process in terms of information availability and exchange. As an exemplary case we focus on planned orthopaedic surgeries, because of the large amount of instrument trays needed during orthopaedic procedures and the frequent use of loaned instrument trays (i.e. specific sets of instruments provided by vendors when needed). We analysed the delivery process of loaned instrument trays in particular, as it is a more extensive process compared to instrument trays owned by the hospital.

METHODS

HOSPITAL SETTINGS AND PARTICIPANTS

The Healthcare Failure Mode and Effects Analysis (HFMEA) was performed in two Dutch hospitals with different organisational structures. The first case is an academic hospital with an internal Central Sterilisation Service Department (CSSD) located in the hospital one floor below the OR complex. The second is a teaching hospital with an outsourced CSSD located a few kilometres from the hospital.

The HFMEA performed in this study follows the guidance of a safety program for Dutch hospitals [24]. It was completed in six sessions of approximately two hours. In between sessions, email communication was used to share relevant documentation and some individual meetings were planned for discussions on specific steps of the process. Before the first session, the focus of the HFMEA was defined in both hospitals, which was the entire process of delivery of loaned trays for orthopaedic surgeries, from the moment the surgeon decides that loaned instruments are needed for a patient until the return shipment to the vendors.

A multidisciplinary team of eight team members and two HFMEA facilitators was formed for both hospitals. The team members were chosen such that all parties relevant for the process of delivery of loaned trays from the hospitals' point of view were represented. In the first case,

the team consisted of one orthopaedic surgeon, two OR nurses, one OR administrator, one OR quality advisor, one CSSD employees, one OR equipment specialist and one manager of the purchase department. For the second case, the team consisted of one orthopaedic surgeon, two OR nurses, one OR team leader, one CSSD employee, one CSSD manager and one scheduler for orthopaedic surgeries.

PROCESS

In the first two sessions, the process of delivery of loaned trays was described by the HFMEA team and translated in a flow diagram (including main steps and sub-steps). The teams also provided an estimation of the time needed for each sub-step of the process. After the sessions, the different means of information exchange and availability during the processes were listed for the two cases.

HAZARD ANALYSIS

In the third and fourth sessions, potential 'failure modes' and their causes were identified for each (sub)step of the process. Each combination of a failure mode and cause was considered to be a hazard. In the last two sessions, a score was attributed to each hazard for their occurrence (O) and severity (S) according to the hazard scoring matrix in Table 5.1. The rating and meaning of the scores were based on the Dutch guide for risk analysis [24], but were slightly adapted by the HFMEA teams to describe the occurrence and severity related to the delivery of instrument trays. Both scores were multiplied and provided the risk score ($R=O*S$). A list of high-risk hazards was provided by selecting the hazards with a risk score equal or higher than 10 or a severity equal or higher than 4. Finally, the team determined whether the hazards were 'tolerated' or 'controlled' and provided recommendations for future improvements. A hazard was considered as 'tolerated' when the HFMEA team agreed that no actions were taken later in the process to remove the hazard and it was just accepted that the adverse event may occur. On the contrary, a hazard was considered as 'controlled' when it becomes visible and can be eliminated at a later stage in the process. For instance, a hazard can be controlled by providing the needed information when needed or by actions such as an automatic control or a double check.

After the six sessions, the authors selected the high-risk hazards that could be controlled by the use of IT support to centralise, store and exchange information. In this study, IT support includes the following features:

- o A digital OR schedule taking the availability of instrument trays into account
- o Information on the necessity of (loaned) instrument trays for each surgery
- o Information on the status of (loaned) instrument trays (order, delivery, sterilisation, transport, use in OR, etc.). This information could partly be provided by a 'track and trace' system for instrument trays. Tracking and tracing of single instruments is not taken into account in this study, as the technology is not yet fully implemented in hospitals.

Table 5.1. Hazard scoring matrix

Rating	Occurrence (O)	Severity (S)
1	Never	No influence
2	Rare (less than once every 3 months)	Alternative routine, no consequences for patient
3	Occasional (more than once every 3 months)	Alternative routine, minor consequences for patient
4	Frequent (more than once a month)	Surgery is delayed/cancelled, temporary consequences for patient
5	Often (more than once a week)	Surgery is delayed/cancelled, serious consequences for patient

RESULTS

PROCESS

Case I: Hospital with internal CSSD

The entire process for the hospital with internal CSSD consisted of seven main steps and 57 sub-steps and had a duration of 690 minutes (see Table 5.4). The main steps and an example of sub-steps are shown in Figure 5.1.

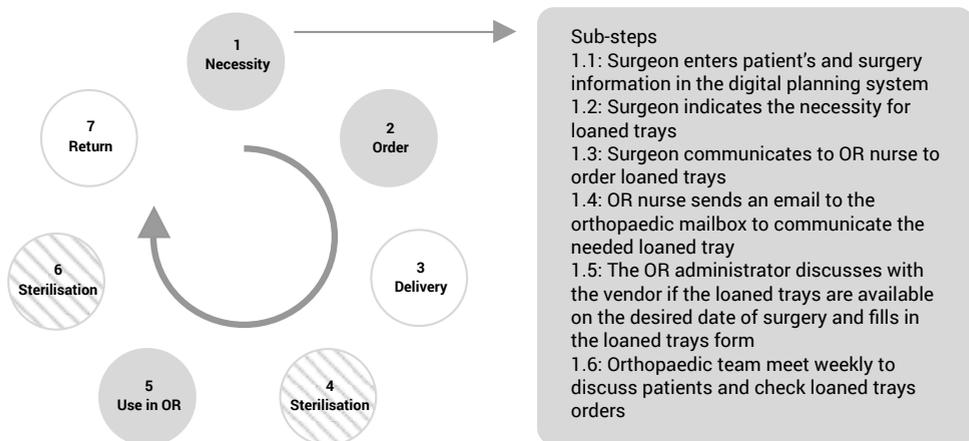


Figure 5.1. Entire process of delivery of loaned trays in the case of internal CSSD (left) and sub-steps of the first step 'Necessity' (right). Steps 1, 2 and 5 (in grey) are performed mainly by the OR staff, steps 3 and 7 (in white) are performed by the vendor and step 4 and 6 (striped) by the CSSD.

Step 1: The orthopaedic surgeon determines the necessity for loaned instrument trays and communicates this to an OR nurse who writes down the information in an email. The OR administrator contacts the supplier to reserve the loaned trays for the specific date and fills out an ordering form. The procedures for which loaned instrument trays are needed are discussed each week with a surgeon and an OR nurse.

Step 2: First, the order is placed in the ordering system of the hospital and then at the vendor. An overview of the orders is sent to the CSSD and is printed.

Step 3: The vendor delivers the instrument trays at the CSSD and the content is then checked by the CSSD employee.

Step 4: The instrument trays are cleaned and sterilised at the CSSD.

Step 5: The instrument trays are transported to the OR complex, set out according to the OR schedule and finally used during the surgical procedure. After surgery, the instruments are counted and placed back in the trays to be sent back to the CSSD.

Step 6: The instrument trays are transported back to the CSSD, are cleaned and sterilised.

Step 7: The supplier collects the instrument trays at the CSSD. The OR administrator updates the used materials in the ordering system of the hospital and the supplier sends an invoice to the hospital.

The different means of information exchange during the entire process are shown in Table 5.2 and the different systems where information was available are shown in Table 5.3

Case II: Hospital with external CSSD

The entire process for the hospital with external CSSD consisted of ten main steps and 71 sub-steps and had a duration of 715 minutes (see Table 5.4). The main steps and an example of sub-steps are shown in Figure 5.2.

Step 1: The orthopaedic surgeon determines the necessity for loaned trays. The surgical procedures requiring loaned trays are discussed each week with a surgeon, an OR nurse, the OR team leader and the orthopaedic scheduler. An OR nurse notes in an agenda when the loaned trays are requested and contacts the supplier to reserve the loaned trays for the specific date.

Step 2: An OR nurse fills in an ordering form and transmits the information to the OR purchaser who places the order in the ordering system of the hospital. The CSSD is informed about the order and updates the information in their own paper files.

Step 3: The vendor delivers the instrument trays at the CSSD and the content is then checked by the CSSD employee.

Step 4: The instrument trays are cleaned and sterilised at the CSSD.

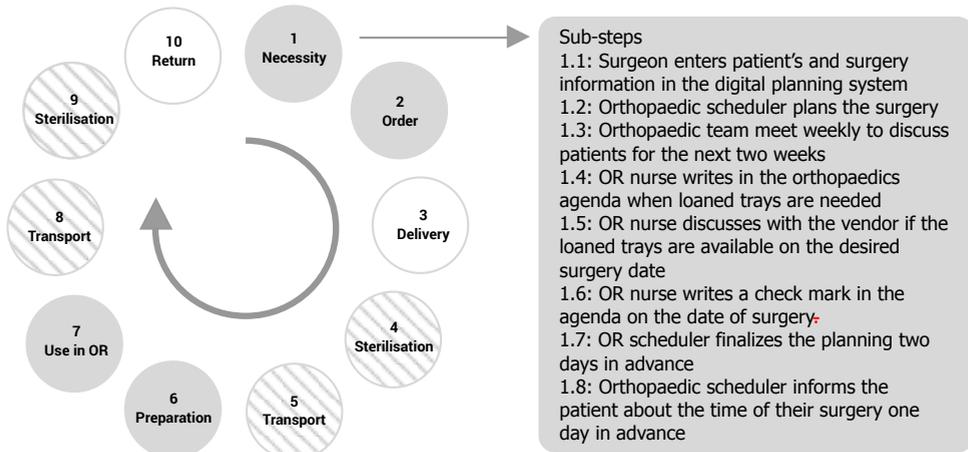


Figure 5.2. Entire process of delivery of loaned trays in the case of external CSSD (left) and sub-steps of the 1st step 'Necessity' (right). Steps 1, 2, 6 and 7 (in grey) are performed mainly by the OR staff, steps 3 and 10 (in white) are performed by the vendor and step 4, 5, 8 and 9 (striped) by the CSSD.

Step 5: The instrument trays are delivered to the hospital.

Step 6: The delivery is checked and the instrument trays are set out according to the OR schedule.

Step 7: The instrument trays are used during the surgical procedure. After surgery the instruments are counted and placed back in the trays to be sent back to the CSSD.

Step 8: The instrument trays are transported back to the CSSD.

Step 9: The instrument trays are cleaned and sterilised at the CSSD.

Step 10: The supplier collects the instrument trays at the CSSD, checks the content and sends an invoice to the hospital, which is later checked by the OR purchaser.

Again, the different means of information exchange during the entire process are shown in Table 5.2 and the different systems where information was available are shown in Table 5.3.

Table 5.2. The different means of information exchange during the entire process:

	Case I	Case II
Oral communication between two persons	6	4
Action to transfer information into digital systems (digital forms, emails, barcodes)	18	13
Action to transfer information into written systems (written forms, written agenda, planning overview on whiteboard, prints, faxes, labels)	10	12

Table 5.3. The different systems where information was available during the process

	Case I	Case II
The digital patient planning system of the hospital	✓	✓
Mailboxes	✓ (3)	✓ (2)
A written form to order loaned trays	✓	
A digital form to order loaned trays		✓
A planning overview on a whiteboard in OR complex for the orthopaedic team	✓	
A paper agenda for the orthopaedic team		✓
The digital ordering system of the hospital	✓	✓
A map with printed orders of the OR	✓	✓
A paper agenda and whiteboard of the CSSD	✓	✓
A map with printed orders of the CSSD		✓
Barcodes and labels on instrument trays	✓	✓
The digital system of CSSD	✓	✓
A delivery overview on a whiteboard in the OR complex		✓
A fax from the CSSD to the OR		✓
A form for used implants during surgery	✓	✓
A certification of decontamination	✓	✓

HAZARD ANALYSIS

The hazards found for both hospitals were very diverse. Examples of high-risk hazards when the surgeon is entering patient's and surgery information in the digital planning system (step 1.1 in both cases) are: "Information about the surgery (type of implant and needed equipment) is not complete in the digital patient planning system" and "Information is not correctly filled out in the digital patient planning system, because of lack of knowledge of the surgeon in training". Examples of high-risk hazards during the weekly meeting of the orthopaedic team (step 1.6 for case I and step 1.3 for case II) are: "No overview of the defect instrument trays" and "Patient is scheduled and operated in between two meetings".

The hazards that could be controlled by the use of IT support are diverse as well. An example of such a high-risk hazard is: "A tray is double booked for a surgery, because within one discipline (e.g. orthopaedic surgery) there is no knowledge about the planning of another discipline (e.g. trauma surgery). A digital OR schedule, taking the availability of instrument trays into account, could control this hazard. Another example is: "A tray is not available just before the start of the

surgery, because it was used for an emergency surgery". This hazard could be controlled by tracking and tracing information that would identify directly when an instrument tray is taken to another OR and would automatically inform the responsible person.

Case I: Hospital with internal CSSD

172 hazards were identified and 23 of them were defined as high-risk (Table 5.4). Only one hazard was considered as 'controlled' later in the process, the other 22 hazards were considered as 'tolerated'. 16 high-risk hazards could be controlled by the use of IT support.

Case II: Hospital with external CSSD

158 hazards were identified and 49 of them were defined as high-risk (Table 5.4). Eight hazards were considered as 'controlled' later in the process, the other 41 hazards were considered as 'tolerated'. 31 high-risk hazards could be controlled by the use of IT support.

Table 5.4. Results of hazard analysis for both cases

Main step	Sub-steps		Time [min]		Hazards		High-risk hazards		High-risk hazards currently controlled		High-risk hazards that could be controlled by IT support	
	I	II	I	II	I	II	I	II	I	II	I	II
Necessity	6	8	125	130	29	37	11	16	0	2	9	14
Order	7	8	50	45	20	14	1	4	0	0	1	3
Delivery	8	8	110	70	27	28	4	4	0	3	2	1
Sterilisation	6	6	100	95	5	8	1	2	0	1	1	2
Transport	-	4	-	60	-	4	-	1	-	0	-	0
Preparation	-	8	-	95	-	20	-	7	-	1	-	6
Use in OR	11	9	100	55	49	26	4	13	1	0	2	4
Transport	-	4	-	55	-	1	-	0	-	0	-	0
Sterilisation	10	8	135	95	22	9	1	2	0	1	0	1
Return	9	8	70	15	20	11	1	0	0	0	1	0
Total	57	71	690	715	172	158	23	49	1	8	16 (70%)	31 (63%)
Total risk score					813	1096	258	510				

DISCUSSION

Using the HFMEA methodology, an overview of the hazards involved in the entire process of delivery of loaned instruments for orthopaedic surgery was provided for two hospitals with different organisational structures (internal and external CSSD). The results showed a higher number of main process steps for the hospital with external CSSD caused by the transportation to and from the OR. Furthermore, the process step "Preparation" was added for case II just before the "Use in the OR". The HFMEA team made this decision, because the number of sub-steps would have been too high to describe in one process step. However, the time needed for the entire process was comparable. The hazards analysis showed that the first case presented the most hazards, but less high-risk hazards. When focussing on the high-risk hazards, the largest differences in numbers between the two cases were found for the process steps "Necessity", "Preparation" and "Use in OR". The same holds for the differences in numbers of hazards that could be controlled by IT support. The larger number of high-risk hazards observed for case II for these process steps brings more opportunities to control these hazards. Van de Klundert et al. pointed out that outsourcing of the CSSD may induce a higher risk of instruments unavailability and increased costs depending on the extend of logistics optimisation [16]. This is in line with the highest total risk scores found for case II, which could probably be improved by optimising the supply chain.

Although the observed differences between the two cases are remarkable, the results do not allow us to draw conclusions on what approach is safer. HFMEA is considered to be a strong tool for qualitative analysis [25]. It provides insight in the different types of hazards and how the risks could be minimized. However, despite the structured approach of the HFMEA and the scoring of the hazards by each individual team member prior to the sessions, the determination and scoring of hazards still depends on the opinion of the team members, and are as such susceptible to subjectivity [26]. Nevertheless, this method enhances awareness among the team members as well as communication and cooperation between the different hospital areas [25, 26]. As such, this study provides insight in the type of hazards observed in both hospitals and how IT could support the delivery of surgical instruments.

Regarding the means of information exchange, the number of actions needed to transfer information into digital systems or written systems is high for both cases. The same holds for the number of information systems used during the processes. Many of these actions and information systems were introduced to create an overview or to exchange information between parties. Besides the fact that it is time consuming, these actions induce hazards at different stages of the process. The use of IT to centralise information and to provide information availability for different parties reduces the number of actions and information systems, and hereby, it is expected to reduce the induced hazards. This is also underlined by the fact that more of the high-risk hazards could be controlled by the use of IT support for case I than for case II. The effect of IT support on the number of hazards and on the risk score is not precisely

known because no complete HFMEA has been performed on a redesigned supply chain, but we expect that the number, occurrence and severity of the hazards will decrease. The effect of IT support on hazards related to the delivery of surgical instruments should be assessed in future studies.

In this paper, the processes and hazards were described for only two hospitals and only for orthopaedic surgery. Another limitation is the focus on the supply chain only. Some hazards, mostly in the process step "Use in the OR", are difficult to be controlled by the use of IT, because they are related to cleaning and sterilisation procedures. Examples of such hazards are: "An instrument is not cleaned correctly" and "Sterile packaging is damaged", which are noticed once the instrument tray is opened for use in the OR. A more detailed analysis of the procedures of the CSSD is necessary to be able to identify possible means for IT to control these hazards.

Christian et al. recognized the OR as vulnerable to problems with information exchange leading to delays or extra work for the staff, and recommended to focus on these problems for future patient safety initiatives [9]. The results of the current study are in line with these recommendations, as a large part of the high-risk hazards is expected to be resolved by centralising information and ensuring information availability for different parties. Therefore, it can be inferred that IT support can reduce risks related to unavailability of instruments in the OR. Leape et al. identified process design as a source of medical error [27], mentioning that many processes in hospitals have not been well thought out as hospitals were never 'designed' but just grew. The same is true for the high number of information systems and means of information exchange that was found in this study. Although these systems were introduced to support the exchange of information for the staff, the lack of a structured approach in designing the tools results in increased risks. The supply chain in both hospitals was not designed at once, but is a product of many years of adaptations of the process. When redesigning the supply chain and implementing IT, the necessities of the staff to retrieve information should be taken into account and supported by the IT system. For instance, information about the OR schedule should be centralised and conveniently accessible for all parties, as well as information about the availability of instrument trays, provided by track and trace technology. Moreover, agreements on the tasks and responsibilities of the different parties should be integrated in the redesign of the supply chain.

To conclude, this study revealed a large number of (high-risk) hazards in the delivery process of surgical instruments. The majority of the high-risk hazards are expected to be controlled by the use of IT support. Therefore, centralised information and information availability for different parties are expected to reduce risks related to unavailability of instruments in the operating room. The insights gained in this study are a valuable foundation for redesigning the supply chain of surgical instruments.

REFERENCES

1. Archer T, Macario A (2006) The drive for operating room efficiency will increase quality of patient care. *Current opinion in anaesthesiology* 19:171-176
2. Sieber TJ, Leibundgut DL (2002) Operating room management and strategies in Switzerland: results of a survey. *Eur J Anaesth* 19:415-423
3. Denton BT, Miller AJ, Balasubramanian HJ, Huschka TR (2010) Optimal Allocation of Surgery Blocks to Operating Rooms Under Uncertainty. *Oper Res* 58:802-816
4. Leape LL (1994) Error in medicine. *JAMA : the journal of the American Medical Association* 272:1851-1857
5. Cuschieri A (2006) Nature of human error - Implications for surgical practice. *Ann Surg* 244:642-648
6. Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH (2010) Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Quality & safety in health care* 19
7. Baines RJ, Langelan M, de Bruijne MC, Asscheman H, Spreuwenberg P, van de Steeg L, Siemerink KM, van Rosse F, Broekens M, Wagner C (2013) Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ quality & safety*
8. Greenberg CC (2009) Learning from adverse events and near misses. *Journal of gastrointestinal surgery : official journal of the Society for Surgery of the Alimentary Tract* 13:3-5
9. Christian CK, Gustafson ML, Roth EM, Sheridan TB, Gandhi TK, Dwyer K, Zinner MJ, Dierks MM (2006) A prospective study of patient safety in the operating room. *Surgery* 139:159-173
10. Reason J (2000) Human error: models and management. *Bmj* 320:768-770
11. Weerakkody RA, Cheshire NJ, Riga C, Lear R, Hamady MS, Moorthy K, Darzi AW, Vincent C, Bicknell CD (2013) Surgical technology and operating-room safety failures: a systematic review of quantitative studies. *BMJ quality & safety* 22:710-718
12. Verdaasdonk EGG, Stassen LPS, van der Elst M, Karsten TM, Dankelman J (2007) Problems with technical equipment during laparoscopic surgery - An observational study. *Surgical Endoscopy and Other Interventional Techniques* 21:275-279
13. Catchpole KR, Giddings AE, Wilkinson M, Hirst G, Dale T, de Leval MR (2007) Improving patient safety by identifying latent failures in successful operations. *Surgery* 142:102-110
14. Arora S, Hull L, Sevdalis N, Tierney T, Nestel D, Woloshynowych M, Darzi A, Kneebone R (2010) Factors compromising safety in surgery: stressful events in the operating room. *Am J Surg* 199:60-65
15. Tucker AL (2004) The impact of operational failures on hospital nurses and their patients. *J Oper Manag* 22:151-169

16. van de Klundert J, Muls P, Schadd M (2008) Optimizing sterilization logistics in hospitals. *Health Care Manage Sci*:23-33
17. Claassen MJT, van Weele AF, van Raaij EM (2008) Performance outcomes and success factors of vendor managed inventory (VMI). *Supply Chain Manag* 13:406-414
18. Simchi-Levi D, Kaminsky P, Simchi-Levi E (2003) *Designing and Managing the Supply Chain*, McGraw-Hill, New York, NY
19. Fisher JA, Monahan T (2012) Evaluation of real-time location systems in their hospital contexts. *Int J Med Inform* 81:705-712
20. FDA (2014) *Medical Device Tracking*. _____
21. Esmail R, Cummings C, Dersch D, Duchscherer G, Glowa J, Liggett G, Hulme T, Patient S, Adverse Events T (2005) Using Healthcare Failure Mode and Effect Analysis tool to review the process of ordering and administrating potassium chloride and potassium phosphate. *Healthcare quarterly* 8 Spec No:73-80 _____
22. DeRosier J, Stalhandske E, Bagian JP, Nudell T (2002) Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system. *The Joint Commission journal on quality improvement* 28:248-267, 209 _____
23. Habraken MM, Van der Schaaf TW, Leistikow IP, Reijnders-Thijssen PM (2009) Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care. *Ergonomics* 52:809-819 _____
24. Veiligheidsmanagementsysteem (2012) *Guide for risk analysis (Praktijkgids Prospectieve Risico Inventarisatie)*. _____
25. Linkin DR, Sausman C, Santos L, Lyons C, Fox C, Aumiller L, Esterhai J, Pittman B, Lautenbach E (2005) Applicability of Healthcare Failure Mode and Effects Analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* 41:1014-1019 _____
26. van der Eijk AC, Rook D, Dankelman J, Smit BJ (2013) Defining hazards of supplemental oxygen therapy in neonatology using the FMEA tool. *MCN The American journal of maternal child nursing* 38:221-228 _____
27. Leape LL (1997) A systems analysis approach to medical error. *Journal of evaluation in clinical practice* 3:213-222

CHAPTER 6: JUST-IN-TIME DELIVERY OF STERILISED SURGICAL INSTRUMENTS

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ABSTRACT

The unavailability of the required surgical instruments at the start of a procedure is undesirable. It causes delays and stress in the Operating Room (OR), which can lead to additional risks for the patients. Issues with availability of surgical instruments may become visible just before the start of the procedure but are induced earlier in the delivery process. Therefore, efficient and safe supply chain management is essential. Just in time (JIT) is a concept widely applied in industrial sectors to improve efficiency and quality. The aim of this study is to design a JIT process for the delivery of surgical instruments and to assess the potential risks.

The JIT delivery process of surgical instruments was designed for a Dutch hospital working with an external Central Sterile Supply Department (CSSD). Hazards (i.e. sources of potential adverse events) were identified according to the Healthcare Failure Mode and Effects Analysis (HFMEA) methodology. The risks of applying JIT principles to the delivery of surgical instruments were compared to the risks involved with the current situation of the hospital at the time of this study (supply driven delivery).

The results showed that the total (high-)risk score of the JIT situation was similar to the current situation, although the number of (high-risk) hazards was slightly higher. However, almost half of the hazards were 'controlled' (when actions to remove the hazard were taken later in the process), in contrast to the current situation in which only about 10% of the (high-risk) hazards were 'controlled'.

The JIT delivery of surgical instruments is expected to present less risks compared to the current situation. The multiple requirements for information technology support and a higher level of trust between the CSSD and OR department should be taken into account in order to improve the supply chain management of surgical instruments.

INTRODUCTION

Today, the healthcare industry is focusing more and more on process and cost efficiency [1-3]. Supply Chain Management (SCM), which is the management of flow of goods and services from the supplier to customer, is therefore gaining importance in healthcare [1, 2]. SCM techniques have been applied mainly to optimise inventory levels and ordering processes of pharmaceuticals [1] and materials like linen and equipment [4]. Recent studies also focus on capacity planning and scheduling of patients as means to improve efficiency [2, 3]. Particular attention went to the Operating Room (OR) as it is the most cost-intensive place of the hospital [5, 6]. Studies were performed to improve OR scheduling [7-10] and resources capacity planning, such as nurses [11, 12] or medical equipment [13]. Remarkably, the logistics of surgical instruments did not receive much attention in scientific literature, despite hospitals' large investments and high sterilisation costs needed for safe use during surgery [14].

Each type of surgery requires a certain set of sterile surgical instruments, organised in multiple instrument trays. Specific instruments can also be packed individually. After use in the OR, the instrument trays are sent back to the Central Sterilisation Service Department (CSSD). Then, the instrument trays are going through the sterilisation process (which consists of cleaning, disinfection and sterilisation) and delivered back to the OR in a sterile packaging, ready for a next procedure. Instrument trays are usually delivered to the OR directly after sterilisation and stored in a dedicated room at the OR complex. Sets of instrument trays specifically needed for each surgery are collected and prepared prior to surgery, mostly by OR personnel. Besides the fact that this entire process of sterilisation, delivery and use of surgical instruments is time-consuming, it also represents an important aspect of performing safe surgery. A previous study has shown that there is a large amount of hazards throughout the entire delivery process of surgical instruments [15]. The unavailability of surgical instruments represented around 40% of equipment-related incidents in the OR [16, 17]. Each incident induces an average of 12 minutes of extra work for the OR team and 5 minutes of delay [16], and moreover, it increases the potential for errors in the OR [18, 19]. The importance of having sterilised surgical instruments timely available for each procedure shows the need for a high quality SCM.

Just in time (JIT) is a SCM concept widely applied in industry to improve efficiency and quality [20]. It is a demand driven and flow oriented approach with the aim to eliminate waste and safety stocks, and achieve continuous improvement [20]. JIT can be divided in five main principles: 1) total quality management (continuous improvement, individual responsibility of workers), 2) production management (demand driven system, standardization), 3) supplier management (long term relationship, effective communication), 4) inventory management (reduce inventory) and 5) human resources management (motivation of all workers). JIT principles present opportunities to improve the supply chain of surgical instruments and consequently increase the timely availability of surgical instruments for each procedure. However, methods originally developed for industrial settings are often problematic in the healthcare sector [1]. Firstly, the

supply chain of surgical instruments represents a 'closed loop system' between the supplier (CSSD) and customer (OR) as the instruments are reusable and will be sent back to the supplier after each use, in contrary to other industrial products that are not meant to be sent back after use. Secondly, safety stocks are needed for the surgical instruments required for unplanned but frequent emergency surgeries. Thirdly, the healthcare sector focuses primarily on quality of care and safety of patients, which differs from industrial settings. Therefore, risks involved with innovations in SCM must be carefully studied before implementation as costs and process efficiency should not conflict with patient safety. As far as known by the authors, the risks related to this field of innovations have not yet been described for the healthcare setting. The aim of this study is to design a JIT process for the delivery of surgical instruments and to assess the potential risks.

METHODS

DESIGN OF A JIT PROCESS FOR THE DELIVERY OF SURGICAL INSTRUMENTS

This study was performed in a Dutch teaching hospital which comprises eight ORs and performs around 11,500 procedure a year. The hospital uses 1300 instrument trays consisting of 600 different types. The sterilisation process is outsourced by a CSSD located four kilometres away from the hospital. Two JIT principles were used in the design of a JIT process for the delivery of surgical instruments: 1) Production management; a demand driven approach was introduced, where only the required instrument trays for the procedures were prepared at the CSSD and delivered to the OR complex. The storage for instrument trays was divided in two locations: a main storage area was located at the CSSD, and a small emergency storage was kept in the OR complex in case of emergency surgeries and unexpected problems with instrument trays. 2) Supplier management where effective communication between customer and supplier was facilitated. Here, information was centralised and exchanged through a digital patient planning system and was made accessible for the personnel involved.

We designed a JIT process, taking the JIT principles production management and supplier management into account. We gathered the needed information and adapted the design of the JIT process through individual meetings with the different team members presented in next section. The JIT process was described in main-steps and sub-steps.

RISKS ASSESSMENT

The risks involved with the application of JIT principles to the delivery of surgical instruments were assessed by means of a Healthcare Failure Mode and Effects Analysis (HFMEA), a method widely used to identify errors and meet high safety standards [21, 22].

Focus. The HFMEA focussed on the entire process of delivery of instrument trays for orthopaedic surgeries; from the decision to schedule a surgical procedure until the return of the instrument trays to the storage area at the CSSD.

Team. To perform the HFMEA a multidisciplinary team was formed consisting of one orthopaedic surgeon, two OR nurses, one OR team leader, one CSSD employee, one CSSD manager, one scheduler for orthopaedic surgeries and two HFMEA facilitators.

Risk analysis. Potential 'failure modes' and their causes were identified for each sub-step of the process. Each combination of a failure mode and a cause was defined as a hazard and scored on a five point scale on occurrence (O) and severity (S). The rating and meaning of the scores (Table 6.1) were slightly adapted from national guidelines by the HFMEA team to describe the occurrence and severity related to the delivery of instrument trays. The risk score (R) was obtained by multiplying both scores ($R=O*S$). The hazards with a risk score equal or higher than 10 or a severity equal or higher than 4 were selected as high-risk hazards. Finally, the HFMEA team defined each high-risk hazard as 'tolerated' or 'controlled'. A hazard was defined as 'tolerated' when no actions were taken to remove the hazard at a later stage of the process and, therefore, the possibility for an adverse event to occur was just accepted. A hazard was defined as 'controlled' when there was a possibility to eliminate the hazard later in the process. For instance, controlling hazards can be done by actions such as an automatic or double check or by providing information to the right person at the right moment. This HFMEA was performed prospectively, as the JIT principles were applied at a conceptual level and were not yet implemented in practice.

Table 6.1: Hazard scoring matrix based on national guidelines for HFMEA [15, 22].

Rating	Occurrence (O)	Severity (S)
1	Never	No influence
2	Rare (less than once every 3 months)	Alternative routine, no consequences for patient
3	Occasional (more than once every 3 months)	Alternative routine, minor consequences for patient
4	Frequent (more than once a month)	Surgery is delayed/cancelled, temporary consequences for patient
5	Often (more than once a week)	Surgery is delayed/cancelled, serious consequences for patient

COMPARISON WITH CURRENT RISKS

The risks of applying JIT principles to the delivery of surgical instruments were compared to the risks involved with the current situation of the hospital at the time of this study, where the delivery of instrument trays was supply driven. This means that the instrument trays were sterilised and sent back as soon as possible to the dedicated storage room at the OR complex. The hospital worked with six deliveries a day. The required sets of trays were prepared by the OR personnel at the end of the day prior to procedures.

For the current supply driven situation, a HFMEA was performed in the same manner as presented above for the JIT situation. The HFMEA was performed earlier for the current situation than for the JIT situation, because it allowed to take the results of the risk analysis into account while designing the JIT process. The process of delivery of instrument trays for the current situation was described by the HFMEA team in main-steps and sub-steps. Note however that the HFMEA team had practical experience with the risks of the current situation, in contrast with the prospective JIT situation.

Based on both HFMEA's, the numbers of (high-risk) hazards were compared as well as the number of 'controlled' (high-risk) hazards. Additionally, the number of hazards related to non-effective communication was determined.

RESULTS

DESIGN OF A JIT PROCESS FOR THE DELIVERY OF SURGICAL INSTRUMENTS

The entire process of JIT delivery of surgical instruments consisted of seven main steps and 36 sub-steps. The process is visualised in Figure 6.1 and an overview of the main and sub-steps is shown in Table 6.2.

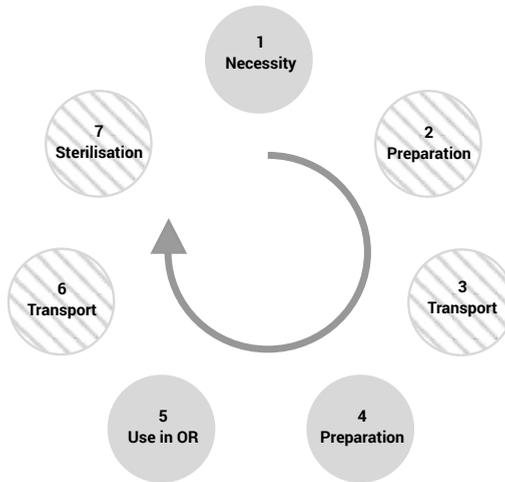


Figure 6.1: Entire process of JIT delivery of surgical instruments. Steps 1, 4 and 5 (in grey) are performed mainly by the OR staff and step 2, 3, 6 and 7 (striped) by the CSSD.

Table 6.2: Main and sub-steps of the process of JIT delivery of surgical instruments.

Main steps	Sub-steps
1. Necessity	<p>1.1: Patient's and surgery information are entered in the digital patient planning system by the surgeon.</p> <p>1.2: The procedure is planned by the orthopaedic scheduler.</p> <p>1.3: Weekly, the orthopaedic team discusses patients for the next two weeks and completes missing information in the planning system.</p> <p>1.4: The needed instrument trays for the non-standard procedures are digitally selected by an OR nurse.</p> <p>1.5: The planning is finalised two days in advance and is checked for missing information by the OR scheduler.</p> <p>1.6: The patient is informed about the time of the surgery one day in advance.</p> <p>1.7: An automatic final check is performed by the planning system to ensure that the availability of instrument trays is in accordance with the OR schedule for the next day.</p>
2. Preparation	<p>2.1: A list with required instrument trays for the OR schedule of the next day is printed at 4 PM.</p> <p>2.2: The instrument trays are collected in carts by a CSSD employee.</p> <p>2.3: The instrument trays sorted for each procedure are scanned and prepared for transport in carts before 5 AM.</p>

- 3. Transport
 - 3.1: The carts are transported to the central storage of the hospital at 5.30 AM.
 - 3.2: The carts are transported to the OR department.
 - 3.3: The carts are scanned and handed over to OR personnel.
- 4. Preparation
 - 4.1: The carts are brought to the preparation area or to the emergency storage.
 - 4.2: The carts are completed with additional instrument trays from the emergency storage if needed.
 - 4.3: The carts are completed with additional materials such as disposable and sterile sheets.
 - 4.4: The completeness of the carts is checked by an OR nurse.
 - 4.5: The instrument trays are taken from the cart and arranged on an instrument table ready for the start of the procedure.
 - 4.6: The sterile packagings are checked for eventual damage.
 - 4.7: The instrument trays are scanned and linked to the digital patient planning system.
 - 4.8: Sub-steps 4.5 to 4.7 are repeated for each procedure of the day.
- 5. Use in OR
 - 5.1: The instrument tables are brought to the OR.
 - 5.2: The procedure is performed.
 - 5.3: The instruments are placed back in trays, checked for completeness, packed and placed back in a cart.
 - 5.4: The soiled carts are brought to the soiled area in the OR department.
 - 5.5: The carts are scanned and made ready to be transported
- 6. Transport
 - 6.1: The carts are transported to the central storage of the hospital.
 - 6.2: Empty carts are brought to the OR department to be filled with soiled instrument trays.
 - 6.3: The carts are loaded in the trucks.
 - 6.4: The carts are transported to the CSSD.
- 7. Sterilisation
 - 7.1: The instrument trays are scanned at arrival at the CSSD and specific cleaning and sterilisation requirements are identified.
 - 7.2: The instrument trays are cleaned and disinfected.
 - 7.3: The instruments are reorganised in the trays, checked for completeness and packed.
 - 7.4: The instrument trays are sterilised.
 - 7.5: The instrument trays are scanned and linked to the sterilisation process.
 - 7.6: The instrument trays are brought to the storage area of the CSSD.

RISK ASSESSMENT

The results of the risk analysis are shown in Table 6.3. 74 hazards were identified. 47% (n=35) of the hazards were considered as 'controlled' later in the process, the others were considered as 'tolerated'. 34 hazards were defined as high-risk, and 41% (n=14) of these were considered as 'controlled' later in the process. The highest number of (high-risk) hazards were found in the main steps 'Necessity' (n=23), 'Preparation in OR' (n=20) and 'Use in OR' (n=12).

The high-risk hazards in the main step 'Necessity' were related to incomplete or incorrect information filled in in the patient planning system. An example of a 'tolerated' hazard is "A wrong procedure code is chosen". Such a hazard is neither visible nor controlled in the process until it is discovered in the OR and can cause a surgery to be delayed or cancelled. An example of a 'controlled' hazard is "The OR scheduler forgets to check the procedures that miss information". This hazard is controlled by an added feature in the patient planning system that provides an overview of these procedures.

The high-risk hazards in the main step 'Preparation in the OR' were mainly related to missing instrument trays in the emergency storage and incorrect deliveries. An example of a 'tolerated' hazard is "The sterile packaging of an instrument tray is damaged". An example of a 'controlled' hazard is "The delivery is incomplete because the list of instrument trays coupled with a particular procedure code is incomplete". This is controlled by appointing an OR nurse to each domain of surgery, who is responsible for keeping the digital lists up-to-date.

The high risk hazards in the main step 'Use in OR' were related to non-sterility of instruments and unexpected course of the procedure that requests additional instruments. All the hazards were considered as 'tolerated'. An example is "An instrument has accidentally come into contact with a non-sterile area".

COMPARISON WITH CURRENT RISKS

For the current supply driven situation, the process consisted of six main steps and 34 sub-steps. The difference between the processes of delivery in the JIT situation and the current situation are shown in Figure 6.2. The results of the hazard analysis for each main step are shown in Table 6.3. Comparing the results for the JIT situation with the ones for the current situation, the highest number of (high-risk) hazards was observed in the same main-steps ('Necessity', 'Preparation in OR' and 'Use in OR') and the total (high)risk scores were similar. Both total risk scores equalled 556 and the total high risk scores equalled 348 and 369 respectively for the JIT and current situation. However, the JIT situation presented a larger amount of 'controlled' hazards (n=35) and high-risks hazards (n=14) compared to the current situation (n=5, n=4).

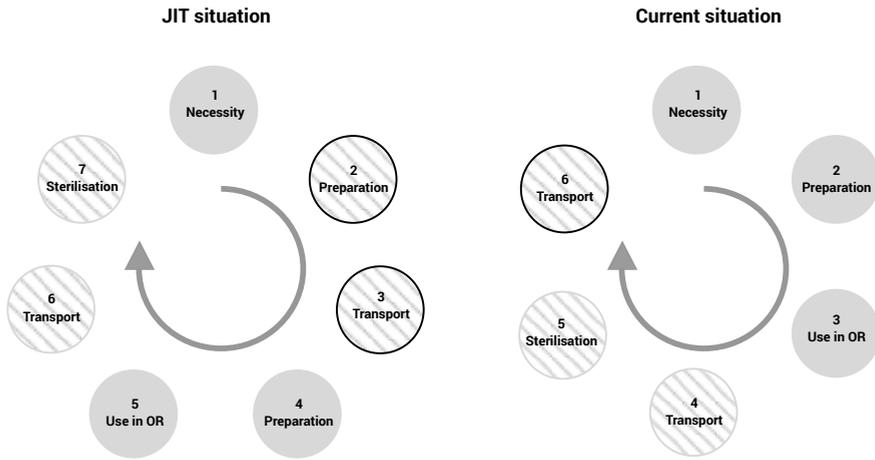


Figure 6.2: Process of delivery of instrument trays for the JIT situation (left) and for the current situation (right). Steps in grey are performed mainly by the OR staff and striped steps in the CSSD. The differences between both processes are highlighted by black borders.

Table 6.3: Results of hazard analysis for the JIT and current situation.

Main step	Sub-steps		Hazards		Controlled hazards		High-risk hazards		Controlled high-risk hazards	
	JIT	Current	JIT	Current	JIT	Current	JIT	Current	JIT	Current
Necessity	7	5	23	25	12	2	6	10	4	2
Preparation at CSSD	3	-	9	-	7	-	4	-	2	-
Transport to OR	3	-	3	-	2	-	0	-	0	-
Preparation in OR	8	7	20	14	9	1	14	7	6	1
Use in OR	5	7	12	20	2	1	6	13	0	0
Transport to CSSD	4	4	1	1	0	0	0	0	0	0
Sterilisation	6	6	6	4	3	1	4	2	2	1
Transport to OR	-	5	-	1	-	0	-	0	-	0
Total	36	34	74	65	35 (47%)	5 (8%)	34	32	14 (41%)	4 (13%)
Total risk score			556	556			348	369		

The high-risk hazards in the main step "Necessity" in the JIT situation differed from the ones in the current situation. For the latter, the hazards were related to a lack of overview of the ability of instrument trays and a lack of centralisation of information. However, some high-risk hazards related to filling in incorrect information about the procedure were similar.

Some high-risk hazards in the main step "Preparation in OR" related to incorrect delivery (such as a damaged sterile packaging or an incomplete instrument tray) were similar for both situations. Others were different as they related to the lack of overview about the delivery of instrument trays and to unavailability of up-to-date information about the required instruments for a particular procedure. More high-risk hazards were observed for the JIT situation because opening the sterile packaging of the instrument trays and preparing the instrument table for a procedure was chosen by the HFMEA team to be part of this main step, in contrary to the current situation where it was taken into account in the main step "Use in OR". For the JIT situation, the preparation is done in a sterile area common for multiple ORs, and is consequently more separated from the use in the OR.

The high-risk hazards in the main step "Use in OR" were similarly related to the non-sterility of instruments and unexpected course of the procedure. The JIT situation presented less high-risk hazard in this main step because of the same reason as mentioned above.

For the current situation, 17 hazards were related to non-effective communication or information sharing. These were caused by a lack of information in the patient planning system (n=4), a lack of overview of trays used for other procedures (n=7), trays being sterilised or defect (n=2), and by lists of required instrument trays for a specific procedure being not up-to-date (n=4). Only two of these hazards were considered as 'controlled' later in the process. For the JIT situation, 10 hazards were related to non-effective communication of information sharing. These were caused by errors in filling in information in the patient planning system (n=7) or by digital lists of required instrument trays for a specific procedure being not up-to-date (n=2). Only one hazard was caused by a lack of overview of trays used for other procedures. Seven of these hazards were considered as 'controlled' later in the process.

DISCUSSION

An overview of the risks of applying JIT principles to the delivery of surgical instruments was provided by performing a HFMEA. The risks involved in the JIT situation were compared to the ones involved in the current situation for delivery of surgical instruments at the time of this study. The results showed that the total risk score of the JIT situation was similar to the current situation and showed a slightly lower total high-risk score, although the number of (high-

risk) hazards was slightly higher. However, in the JIT situation, almost half of the hazards were 'controlled' later in the process, in contrast to the current situation in which only about 10% of the (high-risk) hazards were 'controlled'. Therefore, the JIT delivery of surgical instruments is expected to present less risks compared to the current situation.

A limitation is the prospective character of the risk analysis of the JIT situation. The HFMEA team did not yet experience the hazards involved in this JIT situation. Nonetheless, at the time of this study, the hospital was already performing small-scale JIT pilots and the personnel already acquired some practical knowledge. Additionally, this study only focused on the risks involved with changing the SCM of surgical instruments. The effect on costs and process efficiency were not taken into account.

This study focuses on the application of the two JIT principles production management and supplier management. In our opinion, the changes induced by the production management principle are accountable for an increase in safety. Such a change is, for instance, the fact that the OR personnel must be more attentive in communicating the required instruments for a procedure. Moreover, bottlenecks in the process are rapidly detected in a JIT situation and immediate solutions are enforced [20]. For example, the lists of required instruments for a specific procedure are not up-to-date. This will induce an incomplete delivery and will motivate the personnel to keep the lists updated. The JIT principle supplier management was achieved with the support of Information Technology (IT), by centralising information in a digital planning system, which facilitated information exchange and accessibility. The importance of IT as a tool to apply JIT principles was recognised in previous studies [1, 23, 24]. Although effective communication is not necessarily related to IT, it is almost inevitable to rely on IT systems in the case of complex processes involving a large number of personnel. This is also confirmed by the study van de Klundert et al. [14], who underline the value of IT in optimizing the logistics of sterilised instruments. Moreover, supplier management also relies on a high level of trust between supplier and customer. This was underlined by the HFMEA team as an area that needs to be improved in order to implement JIT principles in practice.

The risk analysis was performed assuming that the process was supported by an IT system that fulfilled certain requirements. The results of the HFMEA are inseparable from these requirements as many of the hazards and risk scores depend on the features of the IT system. An example is the check performed by the OR scheduler the day prior to the scheduled surgical procedures. This check is supported by IT as the patient planning system displays the procedures that miss information and automatically checks if the planning is achievable according to the availability of instrument trays. The most important requirements were the followings: information about the stage of processing and availability of the instrument trays must be available (with the help of track and trace technology), the system must be able to work with two inventories (one at the CSSD and a small emergency inventory at the OR), lists of required instruments for all procedures must be available, systematically filling in information about surgical procedures

and searching information in the system must be supported by intuitive interface design. Furthermore, this study was performed assuming an adequate emergency inventory that is closely monitored (with the help of track and trace technology) in order to be replenished as soon as possible.

The above-mentioned requirements for adequate emergency inventory lead to recommendations for future studies. Inventory management, one of the main JIT principles, should be closely studied in order to reduce and optimise inventory at the CSSD and the emergency inventory at the OR. The two other JIT principles, total quality management and human resources management, should be further studied as well in order to fully optimise the SCM of sterilised surgical instruments.

To conclude, this study revealed that the JIT delivery of surgical instruments is expected to present less risks compared to the current situation. The JIT process relies on multiple requirements for IT support and a high level of trust between CSSD and OR in order to facilitate effective communication. The insights gained in this study are valuable for improving the SCM of surgical instruments.

REFERENCES

1. de Vries J, Huijsman R (2011) Supply chain management in health services: an overview. *Supply Chain Manag*:159-165
2. Dobrzykowski D, Deilami VS, Hong P, Kim SC (2014) A structured analysis of operations and supply chain management research in healthcare (1982-2011). *Int J Prod Econ* 147:514-530
3. Rais A, Viana A (2010) Operations Research in Healthcare: a survey. *International Transactions in Operational Research* 18:1-31
4. Dacosta-Claro I (2002) The performance of material management in health care organizations. *International journal of health planning and management* 17:69-85
5. Archer T, Macario A (2006) The drive for operating room efficiency will increase quality of patient care. *Current opinion in anaesthesiology* 19:171-176
6. Sieber TJ, Leibundgut DL (2002) Operating room management and strategies in Switzerland: results of a survey. *Eur J Anaesth* 19:415-423
7. Eijkemans MJ, van Houdenhoven M, Nguyen T, Boersma E, Steyerberg EW, Kazemier G (2010) Predicting the unpredictable: a new prediction model for operating room times using individual characteristics and the surgeon's estimate. *Anesthesiology* 112:41-49
8. Dexter F, Epstein RH, Traub RD, Xiao Y (2004) Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453

9. Guinet A, Chaabane S (2003) Operating theatre planning. *Int J Prod Econ* 85:69-81
10. Jebali A, Alouane ABH, Ladet P (2006) Operating rooms scheduling. *Int J Prod Econ* 99:52-62
11. Wright PD, Bretthauer KM, Cote MJ (2006) Reexamining the Nurse Scheduling Problem: Staffing Ratios and Nursing Shortages. *Decision Sciences* 37:39-70
12. Burke EK, De Causmaecker P, Vanden Berghe G, Van Landeghem H (2004) The state of the art of nurse rostering. *J Sched* 7:441-499
13. Pasin F, Jobin M-H, Cordeau J-F (2002) An application of simulation to analyse resource sharing among health-care organisations. *International Journal of Operations & Production Management* 22:381-393
14. van de Klundert J, Muls P, Schadd M (2008) Optimizing sterilization logistics in hospitals. *Health Care Manage Sci*:23-33
15. Guedon ACP, Wauben LSGL, Van der Eijk AC, Vernooij ASN, Meeuwssen FC, van der Elst M, Hoeijmans V, Dankelman J, Van den Dobbelsteen JJ (2015) Where are my instruments? Hazards in delivery of surgical instruments. *Surgical endoscopy*
16. Wubben I, van Manen JG, van den Akker BJ, Vaartjes SR, van Harten WH (2010) Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Quality & safety in health care* 19
17. Weerakkody RA, Cheshire NJ, Riga C, Lear R, Hamady MS, Moorthy K, Darzi AW, Vincent C, Bicknell CD (2013) Surgical technology and operating-room safety failures: a systematic review of quantitative studies. *BMJ quality & safety* 22:710-718
18. Arora S, Hull L, Sevdalis N, Tierney T, Nestel D, Woloshynowych M, Darzi A, Kneebone R (2010) Factors compromising safety in surgery: stressful events in the operating room. *Am J Surg* 199:60-65
19. Tucker AL (2004) The impact of operational failures on hospital nurses and their patients. *J Oper Manag* 22:151-169
20. Gupta AK (2012) JIT in Healthcare: An Integrated Approach. *International Journal of Advances in Management and Economics* 1:20-27
21. DeRosier J, Stalhandske E, Bagian JP, Nudell T (2002) Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system. *The Joint Commission journal on quality improvement* 28:248-267, 209
22. Dutch Safety Program (2012) Guide for risk analysis (VMS Veiligheidsprogramma. Praktijkgids Prospectieve Risico Inventarisatie).
23. Claassen MJT, van Weele AF, van Raaij EM (2008) Performance outcomes and success factors of vendor managed inventory (VMI). *Supply Chain Manag* 13:406-414
24. Simchi-Levi D, Kaminsky P, Simchi-Levi E (2003) *Designing and Managing the Supply Chain*, McGraw-Hill, New York, NY

PART IV: OPERATING ROOM SCHEDULING

PART IV

CHAPTER 7: REAL-TIME ESTIMATION OF SURGICAL PROCEDURE DURATION

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ABSTRACT

Efficiency in the Operating Room (OR) is a topic of growing interest. Planning of care is a crucial element to ensure optimal use of the ORs. Currently, OR scheduling is considered as a complex task based on predictions of surgery duration. The latter are often based on average times, but turn out to be inaccurate in practice because of various factors (such as complexity, patient's characteristics, unexpected events, etc). The aim of this study is to develop a prediction system that estimates in real-time the remaining duration of a surgical procedure.

The prediction system was based on monitoring the progress of a procedure by recording the activation of a single piece of equipment in the OR, the electrosurgical device. Support Vector Machines was then used as a classifier to predict the remaining surgical procedure duration and thereby the optimal timing to start preparing the next patient for surgery. The classifier was trained with data on the activation of the electrosurgical device during 55 laparoscopic cholecystectomies.

The performance tests showed a mean error rate about 0.2, which means that about 80% of the procedures were classified correctly.

The real-time prediction system is a promising tool to improve OR planning and decrease unnecessary patients' waiting times.

INTRODUCTION

The attention for process and cost efficiency in the Operating Room (OR), which is the largest cost and revenue center of hospitals, has grown in the past few years [1, 2]. Various studies have underlined the importance of adequate OR scheduling [3-6]. These studies show that factors such as the availability of personnel and equipment, elective and urgent surgeries, and preparation of patients prior to surgery influence the planning. Moreover, a reliable prediction of surgery duration for each individual case is needed to achieve an optimal OR planning [5, 6]. The many factors that have to be taken into account make OR planning complex and often inaccurate [5, 6]. Information on the progress of a surgery is crucial to constantly adjust the planning and keep it optimal throughout the day [5, 7]. In the hospital involved in this study, updates about the progress of a surgery are exchanged by means of phone calls between the OR team and the OR scheduler or by entering the OR to discuss it. Both ways are disrupting the surgical process and are therefore not desirable [8, 9].

Currently, an OR team member makes a phone call to the preoperative holding area when the next patient needs to be prepared for surgery. The timing of the phone call is watched by the nurse anesthetists and the surgeons, and is dependent on their personal views on the progress of surgery. This timing influences directly the journey of the patient in the hospital. A too optimistic view on the remaining surgery duration induces longer waiting times for the patients and overload of the preoperative holding area [10]. In contrary, if the patients are prepared too late, the OR will remain unnecessarily unused. An optimal timing for the start of the preparation of the next patient is desired in order to reduce waiting times, improve patients' experience and to streamline the patient flow to the preoperative holding area with the OR schedule. Monitoring the progress of procedures and providing automatically a reliable update of the estimation of the end time of surgery, and subsequently the timing for preparing the next patient, would therefore be valuable.

Previous studies investigated various monitoring methods for workflow mining in the OR [11-18]. They mainly monitored the usage of devices and instruments in order to recognize the surgical phase at each moment of the surgery. The two main methods for phase recognition were Dynamic Time Warping and Hidden Markov Models [15]. Dynamic Time Warping is a very reliable method for phase recognition but the main limitation is that data on whole procedures must be recorded before the method can be applied [12, 15]. Therefore, it is not suited for real-time predictions. Studies using Hidden Markov Models showed a high accuracy when data on the entire surgery was available [13, 15]. For this method, instrument and device usage was manually obtained from video data. Although it is technically feasible, the limitation is the necessity to develop sensors for monitoring automatically the numerous signals during surgery. For real time applications, this method is applicable but obtaining an accurate prediction is challenging [15]. For the sake of simplicity and practicality, we are aiming to limit the monitoring of the progress of the procedure to one single piece of equipment. A supervised classifier is

used to predict for each point in time if the next patient can be called into the OR. In contrast to unsupervised Hidden Markov Models that model the phases of a procedure, a supervised classifier is not aiming at describing the phases, but focuses on predicting the timing for preparing the next patient as accurately as possible. Support Vector Machines (SVM) has been selected as the best performing classifiers among various others for the set of data presented in this paper.

The aim of this study is twofold: 1) to determine the optimal timing for the preparation of the next patient and 2) to develop a real-time prediction system that estimates this optimal timing according to the progress of the procedure, by registering signals from a single piece of equipment in the OR.

METHODS

TIMING FOR PREPARATION OF PATIENTS

For this study, laparoscopic cholecystectomies were selected to test the prediction system. These procedures are performed frequently and are relatively standardized.

Data on surgical procedure duration, timing of the phone call to the preoperative holding area to start preparing the next patient and patient waiting times were gathered for laparoscopic cholecystectomies at a Dutch teaching hospital between 01/2013 and 10/2014. 157 procedures were selected, after removing the procedures that were missing data on procedure duration or timing of the phone call. Then, the optimal timing of the phone call was determined, taking additional information provided by the OR personnel and the protocols of the hospital into account.

PREDICTION SYSTEM

Monitoring the activation of electrosurgical device

During laparoscopic cholecystectomy procedures, an electrosurgical device (Valleylab, Force FX or Valleylab, Force Triad) is used to remove the gallbladder from the liver. This device was selected as the piece of equipment to monitor as its activation matches certain stages of the procedure. A current sensor (Figure 7.1) was developed to record the amount of current delivered to the electrosurgical device. The current sensor was placed between the power plug of the device and socket in the OR and logged the current used by the device approximately 10 times per second. This provided an accurate recording of the activation of the electrosurgical device during the procedure.

The data corresponding to laparoscopic cholecystectomies were filtered out by using the time of the first incision and the last suture registered in the hospital's digital planning system (Chipsoft EZIS). An example of raw data of a procedure is shown in Figure 7.2.



Figure 7.1. Electrosurgical device and current sensor (encircled)

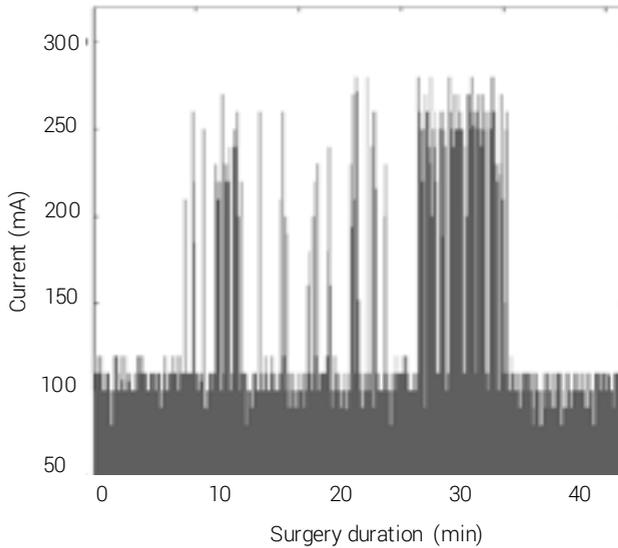


Figure 7.2. Example of raw data obtained from the current sensor

Pattern recognition

The activation pattern of the electrosurgical device was used as input to recognize the progress of the surgery. Activations were defined when the measured value was larger than a selected threshold. From the activation patterns the following features were extracted each five minutes:

- o First time the device was activated
- o Last time the device was activated
- o Number of activations
- o Total duration of activation
- o Number of activations with minimum intervals of 30 sec
- o Binary indicating if the procedure was already finished

With these features, a prediction is made if, at a certain time point, the next patient should be called in for preparation or not. This means that there are two classes. One class tells that the surgery takes less than a certain time and hereby that it is time to start preparing the next patient. The other class tells the surgery takes a longer time and the preoperative holding can wait to prepare the next patient.

In this study, Support Vector Machines (SVM) was used as pattern recognition method. SVM is a binary classifier that attempts to linearly separate the time points in their distinct classes. After a SVM classifier is trained on the available example data (training data for which the end time of surgery is known), it can be applied to new and unseen data. The SVM classifier was trained to make a prediction based on the features extracted from the current sensor during 55 laparoscopic cholecystectomies using PRTTools (statistical toolbox for MATLAB).

The features were normalized to make each feature weight the same in classification. Using forward feature selection, the above-mentioned features were determined to positively affect the performance of the classifier. Additionally, various features on patient and surgeon (patient age and BMI, surgeon ID, and surgeon in training ID) were tested, but did not increase the performance and were therefore abandoned.

Real-time prediction system

In order to use the prediction in real-time, the classifier must work with data of an on-going surgery. During the first 15 minutes after the first incision, the features are extracted from the data of the current sensor, they are scaled and placed in the classifier to obtain a prediction result. After the first 15 minutes, the classifier makes its first prediction on whether or not the next patient can be prepared. The system will keep making prediction every five minutes until the prediction that it is time to prepare the next patient or until 45 minutes have past. Therefore 6 classifiers had to be trained (15, 20, 25, 30, 35 and 45 minutes). The minimum of 15 minutes

and the maximum of 45 minutes were set based on the availability of data to train the system. A prediction every five minutes was chosen to keep the amount of classifiers to train (and therefore the computation time) to a minimum and yet to provide enough accuracy about the timing.

The accuracy of the prediction system and the effect of the number of samples were tested by randomly splitting the data 25 times. 70 percent of the data was used to train the classifier and the remaining 30 percent of the data was used for testing the performance. The mean error and standard deviation were obtained for each of the classifiers. Finally, a simulation was performed where 17 procedures (30 percent of the data) are progressively processed by the classifier, until the prediction model determined it was time to start preparing the next patient, as it would do when tested in a real environment. The results of the simulation were compared to the ideal prediction, 25 minutes before the end of the procedures.

RESULTS

TIMING FOR PREPARATION OF PATIENTS

During the course of a procedure, the next patient is already prepared for surgery. That means that first, a phone call has to be made from the OR to the preoperative holding area to start the process. Then, the patient is transferred from the nursing department to the preoperative holding area. This should take a maximum of 15 minutes according to the hospital's protocols. Afterwards, the necessary preparations are performed before the patient can enter the OR. This should take a maximum of 10 minutes. 25 minutes are thus needed for the preparation of a patient. After discussions with the OR personnel, it was decided that 10 minutes extra buffer time was advisable. The time needed between the phone call and the patient entering the OR was set at 35 minutes. Consequently, these 35 minutes equals the preparation and waiting time for the patient.

For the 157 observed procedures, the mean preparation and waiting time for the patient was 47 minutes (SD: 17 min, median: 43 min). Plotting the preparation and waiting time on the y-axis and the procedure length of the previous surgery and the x axis (Figure.7.3) showed that the timing of the phone call was not optimal and that the majority of the patients had to wait for an unnecessarily long time.

PREDICTION SYSTEM

After the last suture of a surgery, the patient needs to wake up, to be transferred to the recovery area and the OR needs to be cleaned, which take a minimum of 10 minutes. The optimal timing for the phone call to start preparing the next patient was therefore set at 25 minutes before the

last suture of the surgery. The time that separates the two classes of the SVM classifier was consequently set at 25 minutes.

The accuracy of the prediction system for all classifiers is shown in Table 7.1 in terms of mean error rate and standard deviation. A prediction was considered as inaccurate when the classifier predicted the surgery to be in the wrong class (e.g. the classifier predicted a surgery to take less than a certain time, but it turned out to take a longer time).

The effect of the sample size on the mean error rate is shown in Figure 7.4. The 45 minutes classifier is not displayed due to the low amount of samples available for one of its classes.

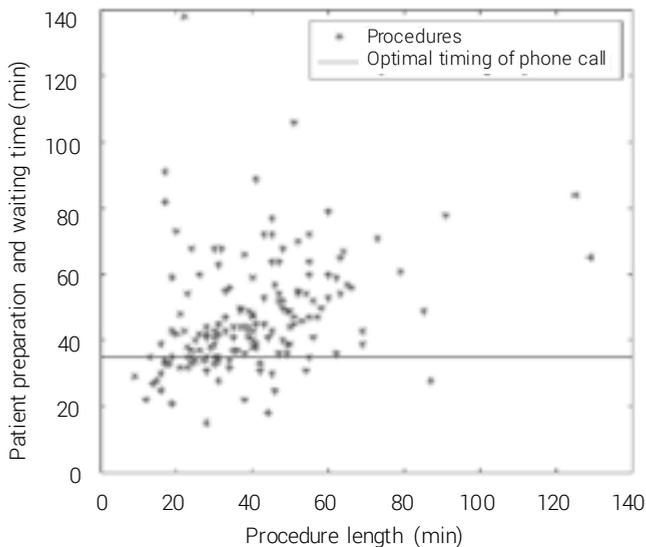


Figure 7.3. Timing of the phone call to prepare the next patient

Table 7.1. Mean error rate and standard deviation of all classifiers

	Mean Error	SD
15 min classifier	0.25	0.10
20 min classifier	0.31	0.11
25 min classifier	0.22	0.08
30 min classifier	0.21	0.08
35 min classifier	0.16	0.07
40 min classifier	0.21	0.09

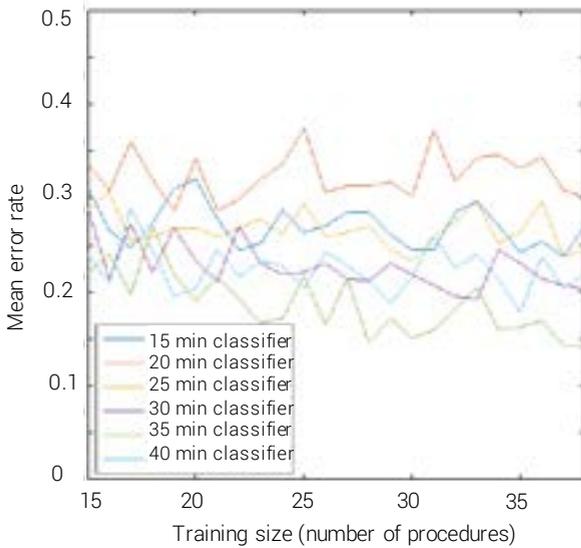


Figure 7.4. Mean error rate with increasing training sample size

The mean error rate gives an indication of the performance of the prediction system in terms of right or wrong choice of class (i.e. shorter or longer than a certain duration). Additional information on the performance, in terms of proximity to the ideal time of prediction, is provided in Fig. 7.5, which shows the results of the simulation using 17 procedures. The x-axis represent the procedure duration and the y-axis the time at which the prediction model determined the next patient should be prepared. The red line represents the ideal time of the prediction, 25 minutes before the end of the procedure. Predictions beneath the red line were considered too early, while procedures above the line were considered too late. The closer a sample procedure is to the red line, the better the prediction. Predictions within a scope of ten minutes of the ideal line, shown in the figure between the two yellow lines, were considered as sufficiently close to the ideal prediction to be used in practice.

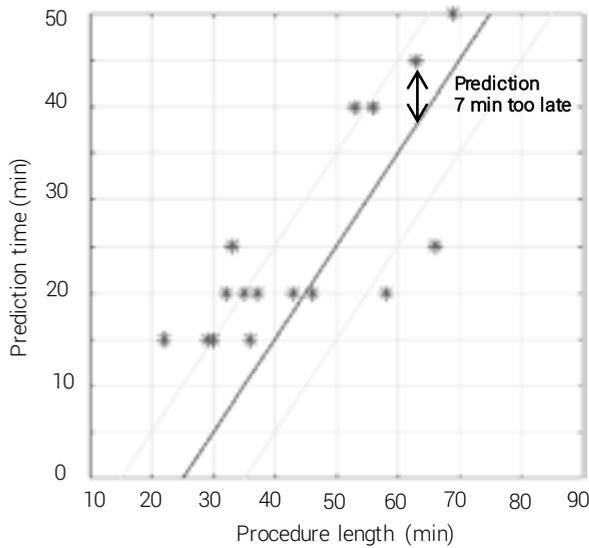


Figure 7.5. Simulation using 17 procedures. The bold line represents the ideal prediction time. The two thin lines represent the range that is acceptable in practice.

DISCUSSION

This paper presents a real-time system to predict the remaining duration of a surgical procedure, and hereby the optimal timing to start preparing the next patient. The system is based on monitoring the activation of a single piece of equipment in the OR, the electrosurgical device.

First, the optimal timing for preparation of the next patient was determined as 25 minutes before the last suture, according to historical data and discussions with OR personnel. Then, the prediction system was presented and the accuracy of the prediction was tested. Using the data of 55 laparoscopic cholecystectomies, an estimated error rate of 0.2 was found by splitting the available data in a set of 70% training data and 30% testing data. A slightly downward trend in error rate was observed when more samples were used for training the classifiers. The error rate is expected to decrease further if more data of procedures would be available.

Differences in the activation pattern of the electrosurgical device were observed between surgeons. Some of them activated the electrosurgical device before clipping the cystic duct, while others clipped first. This may have negatively affected the performance of the classifiers as the prediction system did not take into account which surgical method was applied. In the future, the classifiers could be trained for each surgeon to improve performance of the prediction system, keeping in mind that enough samples have to be available to train the classifiers. This leads us to a limitation of the proposed method; a certain minimum amount of training data have to be available first in order to properly train the classifiers.

This paper focused on laparoscopic cholecystectomies. However, the same prediction system could be used for other procedures. The classifiers would only have to be trained using data of the other types of procedures. Moreover, the prediction model used data on the activation of a single device in the OR. The same method could also be applied for activations of other devices by adding features from these devices to the existing list of features (assuming data about the use of these devices is available). The performance could hereby be improved further. Especially surgeries where equipment is used at a specific phase within the procedure would benefit from the extra features. This would allow the real-time prediction system to be widely usable to update the OR planning.

At this moment, parts of the prediction system are not automated yet, but it would be desirable in order to benefit at best from the application when used in an OR. The system should be started automatically at the first incision and the prediction for optimal timing for the phone call should be provided automatically to the appropriate OR personnel.

To conclude, the real-time prediction system presented in this paper is a promising tool to improve OR planning, decrease patients' waiting times and streamline the patient flow from the nursing department to the preoperative holding area and the OR.

REFERENCES

1. Cardoen B, Demeulemeester E, Beliën J (2010) Operating room planning and scheduling: A literature review. *European Journal of Operational Research* 201:921-932
2. Denton BT, Miller AJ, Balasubramanian HJ, Huschka TR (2010) Optimal Allocation of Surgery Blocks to Operating Rooms Under Uncertainty. *Oper Res* 58:802-816
3. Archer T, Macario A (2006) The drive for operating room efficiency will increase quality of patient care. *Current opinion in anaesthesiology* 19:171-176
4. Dexter F, Epstein RH, Traub RD, Xiao Y (2004) Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453
5. Dexter F, Epstein RH, Lee JD, Ledolter J (2009) Automatic updating of times remaining in surgical cases using bayesian analysis of historical case duration data and "instant messaging" updates from anesthesia providers. *Anesthesia and analgesia* 108:929-940
6. Eijkemans MJ, van Houdenhoven M, Nguyen T, Boersma E, Steyerberg EW, Kazemier G (2010) Predicting the unpredictable: a new prediction model for operating room times using individual characteristics and the surgeon's estimate. *Anesthesiology* 112:41-49
7. Vermeulen IB, Bohte SM, Elkhuisen SG, Lameris H, Bakker PJ, La Poutré H (2009) Adaptive resource allocation for efficient patient scheduling. *Artificial intelligence in medicine* 46:67-80

8. Healey AN, Sevdalis N, Vincent CA (2006) Measuring intra-operative interference from distraction and interruption observed in the operating theatre. *Ergonomics* 49:589-604
9. Healey AN, Primus CP, Koutantji M (2007) Quantifying distraction and interruption in urological surgery. *Quality & safety in health care* 16:135-139
10. Wauben LSGL, Guedon ACP, De Korne DF, van den Dobbelsteen JJ (2015) Tracking surgical day care patients using RFID technology. *BMJ Innovations*:1-8
11. Blum T, Padoy N, Feußner H, Navab N (2008) Workflow mining for visualization and analysis of surgeries. *International journal of computer assisted radiology and surgery* 3:379-386
12. Blum T, Padoy N, Feußner H, Navab N (2008) Modeling and online recognition of surgical phases using hidden markov models. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2008*, Springer, pp 627-635
13. Padoy N, Blum T, Feussner H, Berger M-O, Navab N (2008) On-line Recognition of Surgical Activity for Monitoring in the Operating Room. *AAAI*, pp 1718-1724
14. Ahmadi S-A, Sielhorst T, Stauder R, Horn M, Feussner H, Navab N (2006) Recovery of surgical workflow without explicit models. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2006*, Springer, pp 420-428
15. Padoy N, Blum T, Ahmadi S-A, Feussner H, Berger M-O, Navab N (2012) Statistical modeling and recognition of surgical workflow. *Medical Image Analysis* 16:632-641
16. Padoy N, Blum T, Essa I, Feussner H, Berger M-O, Navab N (2007) A boosted segmentation method for surgical workflow analysis. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2007*, Springer, pp 102-109
17. Bouarfa L, Jonker PP, Dankelman J (2011) Discovery of high-level tasks in the operating room. *J Biomed Inform* 44:455-462
18. Blum T, Feußner H, Navab N (2010) Modeling and segmentation of surgical workflow from laparoscopic video. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2010*, Springer, pp 400-407

CHAPTER 8: 'IT IS TIME TO PREPARE THE NEXT PATIENT'. REAL-TIME PREDICTION OF PROCEDURE DURATION IN LAPAROSCOPIC CHOLECYSTECTOMIES

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ABSTRACT

Operating Room (OR) scheduling is crucial to allow efficient use of ORs. Currently, the predicted durations of surgical procedures are unreliable and the OR schedulers have to follow the progress of the procedures in order to update the daily planning accordingly. The OR schedulers often acquire the needed information through verbal communication with the OR staff, by phone or by physical attendance in the OR, which causes undesired interruptions of the surgical process. The aim of this study was to develop a system that predicts in real-time the remaining procedure duration and to test this prediction system for reliability and usability in an OR.

The prediction system was based on the activation pattern of one single piece of equipment, the electrosurgical device. The prediction system was tested during 21 laparoscopic cholecystectomies, in which the activation of the electrosurgical device was recorded and processed in real-time using pattern recognition methods. The remaining surgical procedure duration was estimated and the optimal timing to prepare the next patient for surgery was communicated to the OR staff.

The mean absolute error was smaller for the prediction system (14 minutes) than for the OR staff (19 minutes). The timing to start preparing the next patient was mostly predicted later than optimal by the prediction system and mostly earlier than optimal by the OR staff. The OR staff doubted whether the prediction system could take all relevant factors into account but were positive about its potential to shorten waiting times for patients.

The activation of the electrosurgical device was used to automatically and objectively predict the remaining duration in laparoscopic cholecystectomy procedures. The prediction system is a promising tool to achieve optimal OR scheduling and to streamline the patient flow from the nursing department to the OR.

INTRODUCTION

Optimization of efficiency in healthcare is crucial to ensure a viable healthcare system for the future [1-4]. The Operating Room (OR), which is the most cost-intensive place of the hospital, is an area of particular interest with respect to efficiency measures [4-6]. Several studies have stated that many factors have to be taken into account in order to achieve optimal use of hospitals' surgical capacities [4, 7-9]. Factors such as personnel and equipment resources, the time to prepare patients and unplanned emergency surgeries influence the daily planning of an OR complex. Moreover, the importance of reliable predictions of surgical procedure durations to achieve optimal OR scheduling has been emphasized [7-10]. Surgical procedures that take longer than expected induce successive scheduled procedures to be postponed or cancelled. Furthermore, this causes undesired longer waiting times for patients, recurrent communication between the nursing staff and patients (and accompanying family), and an overload of the preoperative holding area [11]. On the contrary, procedures that finish earlier than expected can cause ORs to remain unused and OR teams to be unnecessarily waiting for the next patients [7]. Both scenarios are undesirable.

OR schedules are often based on estimates of surgical procedure durations, and do not account for variability in patient parameters or even the composition of the surgical team. Therefore, OR schedulers cannot fully rely on these estimated procedure durations [8] and need other methods to adapt their OR schedule as the day progresses. Typically, visual inspection is used to be informed about the progress of a procedure. However, the progress is not always easily recognizable and the scheduler needs to be familiar with many types of procedures. The alternative is to use verbal communication with the OR staff, through phone calls or physical presence in the OR, for asking an estimate of the remaining procedure duration. This causes disruptions of the surgical process and compromises safety in the OR [12, 13], which obviously should be avoided. The patient flow is currently regulated by an OR team member who calls the preoperative holding area to start the preparation of the next patient for surgery. Additionally, the estimated remaining procedure duration is based on the personal experience and routines of the OR staff. This lack of objective measurements adds complexity to the task of OR schedulers as they need to interpret the various situations and opinions in order to adapt and optimize the OR schedule. It also directly influences the patient's experience in the hospital. A recent study has shown that the timing to start preparing the next patient was not optimal for laparoscopic cholecystectomies leading to a large variation in preparation and waiting times in the preoperative holding area (average of 47 minutes, with a standard deviation of 17 minutes) [14]. Besides, prompt changes in personnel or dealing with less experienced OR schedulers

may have consequences for the efficient allocation of ORs as well as for the waiting times of patients. Gaining insight in the progress of surgical procedures and providing automatic and objective updates of the remaining procedure duration is of importance to achieve optimal OR scheduling and optimal patient flow.

The usage of devices and instruments can provide essential information about the progress of a procedure [10, 15-21]. Patterns in the usage of devices and instruments can be detected for various types of procedures. These patterns can then be used to detect the actual phase of a surgical procedure. Several pattern recognition approaches explored in previous studies have presented the potential of automatic recognition of the phase of procedures. However, there are many limitations regarding the application in real-time as the data of the entire procedure must be available [16, 18]. Other methods have shown to be usable for real-time applications but these required signals of numerous devices and instruments that currently cannot be obtained automatically [10, 18]. Automatic detection of these signals is however feasible by using techniques such as image analysis of laparoscopic videos [20, 22, 23], RFID technology [24, 25] or a multi-sensor OR table [26], but it is not yet implemented in daily practice. As far as the authors know, no system based on pattern recognition for prediction of end time of surgery has yet been implemented and tested in an OR.

In this study, we aim to monitor the progress of the procedure with one single piece of equipment, for simplicity and practical purposes. The challenge is to automatically obtain predictions of the end time rather than modelling all phases of a procedure and to provide an advice to the OR staff about the optimal timing to prepare the next patient. The goal of this study is: 1) to develop a real-time prediction system for the remaining procedure duration, based on methods that we presented in [14], and 2) to test the prediction system for reliability and usability in an OR.

METHODS

MONITORING THE ACTIVATION OF ELECTROSURGICAL DEVICE

In laparoscopic cholecystectomy procedures, the electrosurgical device is activated during the removal of the gallbladder from the liver, which matches a certain stage of the procedure. Therefore, the activation of the electrosurgical device is suited to monitor for pattern recognition purposes. Activations of the electrosurgical device were detected with a current sensor. The amount of current delivered to the device was logged approximately 10 times per second. Each peak in the amount of current corresponds to an activation of the device. This method is similar to the one used in [14]. An example of the activation pattern of the electrosurgical device during an entire surgical procedure is shown in Figure 8.1.

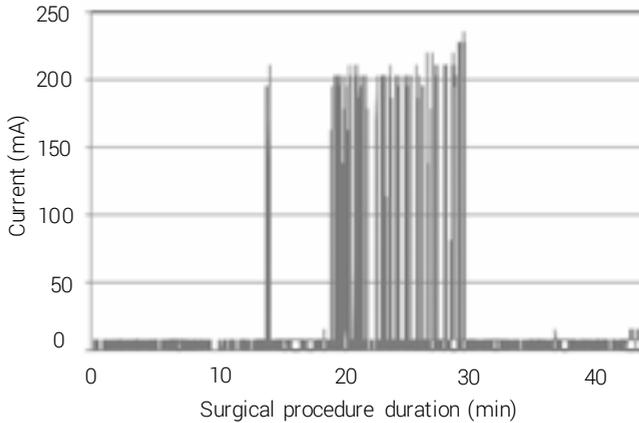


Figure 8.1. Example of the activation pattern of the electro-surgical device during an entire procedure.

PATTERN RECOGNITION

In [14], the activation pattern of the electro-surgical device was measured during 57 laparoscopic cholecystectomies performed by three different surgeons assisted by surgeons in training. The activation patterns of these procedures, with known end time, were used to train a classifier that classifies the data in two classes; procedures that are shorter and procedure that are longer than a certain amount of time. The Support Vector Machine (SVM) was selected as the best performing classifier and was chosen as algorithm for the prediction system. This classifier was trained using PRTools (statistical toolbox in MATLAB). More detailed information about the methods used can be found in our previous publication [14].

REAL-TIME PREDICTION SYSTEM FOR REMAINING PROCEDURE DURATION

The classifier uses data of on-going surgical procedures in order to make a prediction automatically. Therefore, a real-time prediction system was developed (Figure 8.2) that consisted of the following parts:

Server. The central part of the system was a server storing all the data gathered from the different parts of the system in a Structured Query Language (SQL) database. The server also hosted a webpage that served as an interface to the users in the OR to start the system at the time of the first incision of the procedure. Afterwards, the webpage was also used to provide feedback about the timing to start preparing the next patient.

Current sensor. The current sensor was connected with the server through Wi-Fi. As soon as the system was started, data were gathered and stored in a database.

Computer. A computer extracted the data from the database, classified the procedure and obtained a prediction result. When it is time to prepare the next patient, the prediction is added to the database.

Tablet. The webpage was updated when it was time to prepare the next patient. The webpage was accessed on a tablet, which was used to communicate the advice to the OR staff as well as to gather feedback about the usability of the prediction.

The optimal timing to start preparing the next patient was set 25 minutes before the last suture of the procedure. A margin of ten minutes was considered as an acceptable prediction. These timings were based on observations in the preoperative holding area and discussions with OR staff. If after the first 15 minutes of measurements the prediction is such that the remaining procedure duration will be longer than 25 minutes, then the system will continue to measure data for another 5 minutes and a new prediction will be made. This process repeats until the system predicts it is time to start preparing the next patient or until 45 minutes have past.



Figure 8.2. Schematic overview of the real-time prediction system.

ACCURACY OF THE SYSTEM

The accuracy of the prediction system was tested during 21 laparoscopic cholecystectomies performed during ten days. The procedures were performed by three different surgeons assisted by surgeons in training. The mean absolute error between the predicted and the actual total duration of a procedure was calculated. The accuracy of the prediction system was then compared with the mean absolute error of the OR staff's predictions.

USABILITY OF THE SYSTEM

The usability of the prediction system was tested by gathering feedback from the OR staff when it was time to prepare the next patient according to the prediction system. This was done through the web-based interface asking if the timing was adequate, too early or too late (see Figure 8.3). The answer was chosen according to the opinion of the surgeon and the nurse anaesthetist. After each day of testing, questions about the accuracy, benefits and potential utilisation were asked to the nurse anaesthetist, who is responsible for the phone call to start preparing the next patient.



Figure 8.3. Webpage for gathering feedback of the OR staff (right).

RESULTS

ACCURACY OF THE SYSTEM

The accuracy of the prediction system is shown in Figure 4. Ideal predictions would be placed along the red line representing the optimal timing to prepare the next patient, which was 25 minutes before the last suture. Predictions that were located above the red line were considered as being too late, while the ones located below the red line were considered as being too early. Predictions within the margin of ten minutes of the ideal predictions, indicated in Figure 4 between the two yellow lines, were considered as acceptable to be used in practice. The mean absolute error of the prediction system was 14 minutes.

The results of the prediction system and the corresponding predictions of the OR staff for each procedure are shown in Figure 8.5. Predictions of the system and the OR staff corresponding to the same procedure are linked with a black line. However, not all system's predictions presented in Figure 8.5 have a corresponding OR staff's prediction as some procedures were scheduled at the end of the day so no patient had to be prepared for a next surgery. The mean absolute error of the OR staff's prediction was 19 minutes.

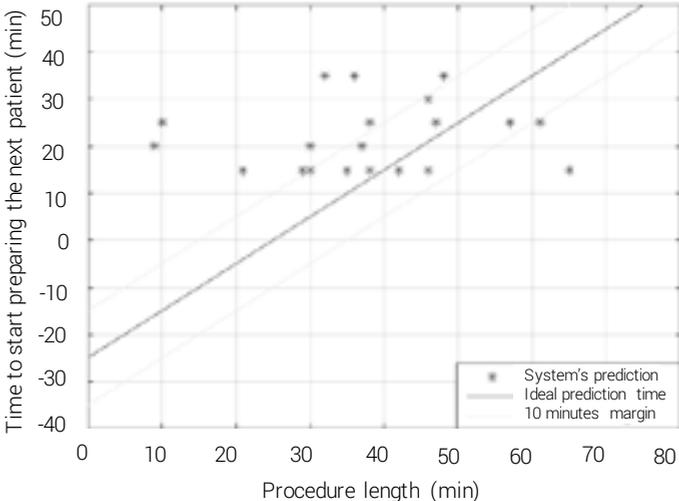


Figure 8.4. Timing to start preparing the next patient predicted by the prediction system.

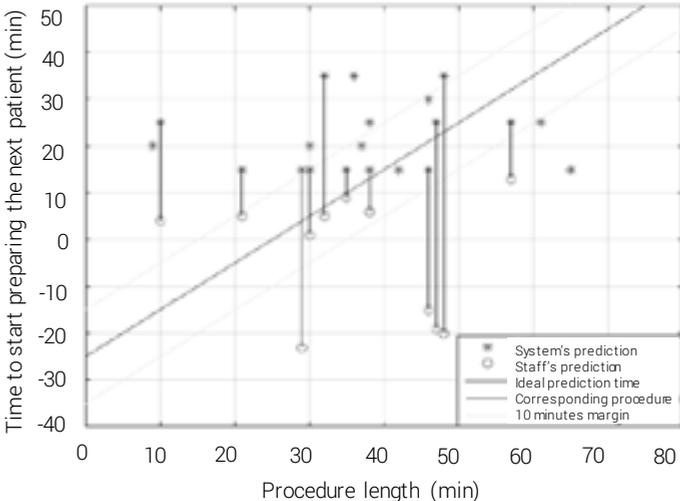


Figure 8.5. Timing to start preparing the next patient predicted by the prediction system and by the OR staff.

USABILITY OF THE SYSTEM

The feedback regarding the predicted timing to start preparing the next patient gathered through the web-based interface was as follows: one prediction was considered as too early, six were considered as being correct and fourteen as too late.

Nine out of the ten nurse anaesthetists completed the questionnaire at the end of each day of testing. The accuracy of the system was rated as 'satisfactory' by six respondents, as 'unsatisfactory' by two and one did not respond to this question. The benefits of the prediction system were rated as 'satisfactory' by three respondents and as 'unsatisfactory' by six. Furthermore, three respondents saw potential in the prediction system in the future, four did not and three respondents were undecided. The main doubts pointed out by the respondents regarded factors that could not be taken into account by technology, such as the performing surgeon, or the timing of lunchbreaks when the nursing area is understaffed and when the preparation of patients is taking longer. The main expected benefits of such a system are the shorter waiting times for patients and the support to inexperienced nurse anaesthetists.

DISCUSSION

This study presents a real-time prediction system for the remaining procedure duration that is based only on the activation of the electrosurgical device. This prediction system informs the OR staff about the optimal timing to start preparing the next patient. The reliability and usability of the system's predictions were tested during 21 laparoscopic cholecystectomies. The mean absolute error was smaller for the prediction system (14 minutes) than for the OR staff (19 minutes). The system's predictions were more reliable for procedures with average or long duration than for the ones with short duration. For the latter, there was not enough time for the prediction system to gather data and provide feedback to the OR staff as the initial predictions were made after the first 15 minutes of the procedure. For procedures longer than 40 minutes, the mean absolute error was 9 minutes and therefore within the margins of reliable predictions. For these procedures, the system's predictions outperformed the OR staff's predictions, which presented a mean absolute error of 29 minutes.

The timing to start preparing the next patient was mostly predicted later than optimal by the system and mostly earlier than optimal by the OR staff. As mentioned by Eijkemans et al., having ORs remaining unused for a while is undesirable [7] and the tendency of OR staff to start preparing the next patient earlier than needed is therefore understandable. It is preferable to have one patient waiting rather than an entire OR team. The prediction system focussed on obtaining minimal error but could be adjusted to lower the risk to have the OR team unnecessarily waiting.

The reliability reached in this study relied on the monitoring of only one piece of equipment and

on a data of 57 laparoscopic cholecystectomies. Monitoring the use of additional equipment in the OR and gathering a larger dataset to train the prediction system is expected to further improve the reliability. Additional equipment in the OR could provide valuable information in order to improve the reliability of the predictions for short surgeries. Moreover, differences in surgical methods were detected between surgeons. Some clipped the cystic duct before activating the electro-surgical device, while others activated the device earlier. Training the prediction system for each individual surgical approach is expected to improve the reliability as well.

The opinions of the OR staff regarding the usability of the system varied. Some doubts were put forward about factors that could not be taken into account by such a prediction system, such as the surgeon's speed and shortage of personnel at specific times of the day. However, the surgeon's speed was recognized in the activation pattern of the electro-surgical device. Surgeons in training, who generally work slower than experienced surgeons, activated the electro-surgical device for a shorter time with longer intervals between activations. This type of pattern was recognized by the prediction system as a slower procedure. Dealing with shortage of personnel at specific times of the day was not incorporated in the prediction system but this type of information can easily be added to the prediction system in the future. According to the OR staff, the potential benefits of the prediction system were the shorter waiting times for patients and the support to inexperienced nurse anaesthetists. Nevertheless, the main benefit lays in the enhanced access to information on the progress of the procedure from outside the OR. This information can be used by the OR schedulers without having to interrupt the surgical process. Additionally, information on the progress of the procedure is valuable for the nursing staff, who can anticipate the preparation and transport of patients from and to the nursing department [11]. It can also reduce the efforts of the nursing staff to update the persons accompanying patients about their progress.

To conclude, the activation of the electro-surgical device was used to predict automatically and objectively the remaining duration in laparoscopic cholecystectomy procedures with a reasonable accuracy. Therefore, it is a promising prediction system to achieve optimal OR scheduling and optimal patient flow from the nursing department to the OR.

REFERENCES

1. de Vries J, Huijsman R (2011) Supply chain management in health services: an overview. *Supply Chain Manag*:159-165
2. Dobrzykowski D, Deilami VS, Hong P, Kim SC (2014) A structured analysis of operations and supply chain management research in healthcare (1982-2011). *Int J Prod Econ* 147:514-530
3. Rais A, Viana A (2010) Operations Research in Healthcare: a survey. *International Transactions in Operational Research* 18:1-31

4. Archer T, Macario A (2006) The drive for operating room efficiency will increase quality of patient care. *Current opinion in anaesthesiology* 19:171-176
5. Cardoen B, Demeulemeester E, Beliën J (2010) Operating room planning and scheduling: A literature review. *European Journal of Operational Research* 201:921-932
6. Denton BT, Miller AJ, Balasubramanian HJ, Huschka TR (2010) Optimal Allocation of Surgery Blocks to Operating Rooms Under Uncertainty. *Oper Res* 58:802-816
7. Eijkemans MJ, van Houdenhoven M, Nguyen T, Boersma E, Steyerberg EW, Kazemier G (2010) Predicting the unpredictable: a new prediction model for operating room times using individual characteristics and the surgeon's estimate. *Anesthesiology* 112:41-49
8. Dexter F, Epstein RH, Traub RD, Xiao Y (2004) Making management decisions on the day of surgery based on operating room efficiency and patient waiting times. *Anesthesiology* 101:1444-1453
9. Dexter F, Epstein RH, Lee JD, Ledolter J (2009) Automatic updating of times remaining in surgical cases using bayesian analysis of historical case duration data and "instant messaging" updates from anesthesia providers. *Anesthesia and analgesia* 108:929-940
10. Padoy N, Blum T, Feussner H, Berger M-O, Navab N (2008) On-line Recognition of Surgical Activity for Monitoring in the Operating Room. *AAAI*, pp 1718-1724
11. Wauben LSG, Guedon ACP, De Korne DF, van den Dobbelen JJ (2015) Tracking surgical day care patients using RFID technology. *BMJ Innovations*:1-8
12. Wiegmann DA, ElBardissi AW, Dearani JA, Daly RC, Sundt TM (2007) Disruptions in surgical flow and their relationship to surgical errors: An exploratory investigation. *Surgery* 142:658-665
13. Arora S, Hull L, Sevdalis N, Tierney T, Nestel D, Woloshynowych M, Darzi A, Kneebone R (2010) Factors compromising safety in surgery: stressful events in the operating room. *Am J Surg* 199:60-65
14. Guédon ACP, Paalvast M, Meeuwssen FC, Tax DMJ, van Dijke AP, Wauben LSG, Van der Elst M, Dankelman J, Van den Dobbelen JJ (2015) Real-time estimation of surgical procedure duration. *IEEE Healthcom. 1st International Workshop on Intelligent Operating rooms, Boston, USA*
15. Blum T, Padoy N, Feußner H, Navab N (2008) Workflow mining for visualization and analysis of surgeries. *International journal of computer assisted radiology and surgery* 3:379-386
16. Blum T, Padoy N, Feußner H, Navab N (2008) Modeling and online recognition of surgical phases using hidden markov models. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2008, Springer*, pp 627-635
17. Ahmadi S-A, Sielhorst T, Stauder R, Horn M, Feussner H, Navab N (2006) Recovery of surgical workflow without explicit models. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2006, Springer*, pp 420-428
18. Padoy N, Blum T, Ahmadi S-A, Feussner H, Berger M-O, Navab N (2012) Statistical modeling and recognition of surgical workflow. *Medical Image Analysis* 16:632-641
19. Padoy N, Blum T, Essa I, Feussner H, Berger M-O, Navab N (2007) A boosted segmentation

- method for surgical workflow analysis. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2007*, Springer, pp 102-109
20. Bouarfa L, Jonker PP, Dankelman J (2011) Discovery of high-level tasks in the operating room. *J Biomed Inform* 44:455-462
 21. Blum T, Feußner H, Navab N (2010) Modeling and segmentation of surgical workflow from laparoscopic video. *Medical Image Computing and Computer-Assisted Intervention—MICCAI 2010*, Springer, pp 400-407
 22. Speidel S, Delles M, Gutt C, Dillmann R (2006) Tracking of instruments in minimally invasive surgery for surgical skill analysis. *Lect Notes Comput Sc* 4091:148-155
 23. Tonet O, Thoranaghatte RU, Megali G, Dario P (2007) Tracking endoscopic instruments without a localizer: A shape-analysis-based approach. *Comput Aided Surg* 12:35-42
 24. Kranzfelder M, Schneider A, Fiolka A, Schwan E, Gillen S, Wilhelm D, Schirren R, Reiser S, Jensen B, Feussner H (2013) Real-time instrument detection in minimally invasive surgery using radiofrequency identification technology. *The Journal of surgical research* 185:704-710
 25. Neumuth T, Meissner C (2012) Online recognition of surgical instruments by information fusion. *International Journal of Computer Assisted Radiology and Surgery* 7:297-304
 26. Glaser B, Danzer S, Neumuth T (2015) Intra-operative surgical instrument usage detection on a multi-sensor table. *International Journal of Computer Assisted Radiology and Surgery* 10:351-362

CHAPTER 9: DISCUSSION

This thesis has proposed a new approach to supporting healthcare professionals in improving patient safety and efficiency, by adapting support systems to different situations in the operating room (OR). With this approach in mind, systems were developed to support three different processes: the safe use of OR devices, the delivery of surgical instruments and OR scheduling.

First, a safety status system was developed to support both the monitoring of OR devices and the communication between the OR and the department of Clinical Physics regarding malfunctioning devices (Part II). The safety status system tracks and traces OR devices in the OR department, and provides and exchanges information about their safety status through an intuitive interface in the OR. It thereby supports efficient management and safe use of OR devices. Second, a new process was designed to deliver surgical instruments 'just in time' for surgical procedures (Part III). In this process, information about surgical instruments is centralised and is available for the relevant professionals, which makes the process less sensitive to errors. IT support plays a key role to improve efficiency and safety related to the availability of surgical instruments. Lastly, a prediction system was developed to automatically monitor the progress of surgical procedures and estimate the optimal time to start preparing the next patient (Part IV). The prediction system is based on the activation of a single OR device during procedures. Such a prediction system is a useful tool to optimize OR planning without having to interrupt the surgical process.

The developments continued after the publications presented in this thesis. For the safety status system, the localisation of OR devices was improved by adding Infrared technology, and modifications were introduced regarding the process for OR devices that present malfunctions but are still safely usable in the OR. The safety status system was then fully implemented in the ORs of the Reinier de Graaf hospital in September 2015. For the just-in-time process, the hospital put much effort in the development of IT systems and in training the OR and CSSD staff for the new work processes. The process was then fully implemented in the hospital in September 2015. Track & trace technology was integrated and provides real-time information on the location of the instrument trays, which presents opportunities for further analysis and optimisation of processes. For the prediction system, the development was in a too early stage to be fully implemented in practice. Further research is encouraged to train the system on more procedures and to improve the accuracy of the predictions by monitoring additional relevant features in the OR.

PROVIDING ADAPTIVE SUPPORT

Adaptive support improves patient safety and efficiency by supporting healthcare professionals in a manner that is adapted to the situation. It means that adaptive support systems monitor and recognize processes in the OR in real-time, and provide support that is dependent on the predictability of the processes. Automation and standardisation are provided where possible,

and flexibility and autonomy when needed. Adaptive support is provided in various ways by the systems developed in this thesis.

The safety status system (Part II) automates tracking of OR devices and checks for correct maintenance and defects that were (meant to be) done by the professionals. Notifying malfunctions and information exchange are also facilitated by the system. For these processes, the users are actively kept involved by providing them information through an intuitive interface, which raises their awareness for patient safety and sense of responsibility for reporting [1-3].

For the delivery of surgical instruments (Part III), the focus was on gaining the understanding needed to develop adaptive support systems. In adaptive support, technology has a key role in recording and analysing data and thereby gaining understanding. Nevertheless, there was no technology available that could provide us with the intended insights at the time of this study. No registrations of hazards were performed and almost no digital data was available about the entire process of delivery of surgical instruments. Performing a HFMEA with a multidisciplinary team that was representative for all steps of the process was a time consuming practice but provided the information we were aiming for. These insights have led to a set of requirements for information technology to support a safer and more efficient process.

The prediction system for OR scheduling (Part IV) recognizes the progress of a surgical procedure in real-time and provides information on the optimal timing to start preparing the next patient. It support the OR staff to achieve optimal OR scheduling and to streamline the patient flow from the nursing department to the OR.

IMPACT ON PATIENT SAFETY AND EFFICIENCY

Patient safety is a broad concept. Safety is defined as a state where 'as few things as possible go wrong' or 'as many things as possible go right' [4]. The quality of care received during the entire stay in the hospital is dependent on the performance of many professionals, which is influenced by the working environment [5-7]. A wide variety of factors are recognized to contribute to patient safety, such as patient factors, and individual staff and team performance [5]. Others are related to the work environment, task and technology, organisation and management, and institutional context [5]. This shows the complexity of setting up reliable patient safety metrics. As stated by Jha et al., a robust measurement program to systematically identify, track and report adverse events is lacking [8]. It is therefore very difficult to draw conclusions about the impact of the studies performed in this thesis on patient safety in terms of adverse events. Nonetheless, the impact of these studies on specific factors that are recognized to influence patient safety can be described. Especially the impact on efficiency is highlighted as it closely relates to the safe delivery of care [9, 10]. Efficient processes are streamlined and less sensitive to errors. This leaves more room for professionals to focus on their tasks.

The safety status system increases the efficiency of searching for devices that need periodic maintenance or to search for devices to complete the equipment required for a certain procedure. Efficiency is also gained by having information directly digitalised in the management system of the Clinical Physics department. Moreover, the safety status system brought into light subjects to be considered, such as what should be the processes regarding devices that were notified as malfunctioning but are still safe to use in the OR, or what should be communicated to the OR staff about devices under repair. This system enhanced the settlement of agreements on work processes and responsibilities that influence the safe use of OR devices. It increased the situation awareness of the OR staff regarding the safe use of OR devices.

For the delivery of surgical instruments, analysing the hazards had a clear link with safety. In the process design based on just-in-time principles, information was centralised and the means of communication reduced, which made the process less sensitive to errors. Efficiency is not gained in terms of time, but in terms of controlled hazards. When an unexpected event occur, finding the required information to adjust work processes is more controlled and streamlined. Therefore, the just-in-time process is expected to be safer than the current delivery system. Bottlenecks in the process are rapidly detected in a JIT situation and finding sustainable solutions is enforced [10]. The unavailability of surgical instruments just prior to procedures is expected to decrease, which consequently diminishes stress of the OR staff and the potential for errors in the OR [11, 12]. Furthermore, performing a HFMEA enhanced communication and cooperation between the different hospital areas [13, 14].

The prediction system to support OR scheduling reduces the undesired interruptions of the surgical process and thereby enhances safety in the OR [11, 15]. It also allows nurses to anticipate the preparation and transport of patients between the OR and nursing department and to reduce the time needed to exchange information with other departments and with persons accompanying patients. Note that the impact of support systems on efficiency and patient safety will be more visible when the systems are implemented for a longer time. Especially systems that record data will benefit further investigation of this impact.

MULTIPLE DISCIPLINES AND LIVING LABS

This thesis shows the value of collaboration with multiple disciplines. Considering the variety of factors that contribute to patient safety, it is necessary to involve multiple disciplines in developments aiming to improve patient safety. The departments of Clinical Physics and Information Technology, the CSSD and the OR department participated actively in the studies presented in this thesis. Professionals with different tasks were involved, especially within the OR department (i.e. OR assistants, nurse anaesthetists, surgeons, anaesthesiologists, team leaders, OR schedulers and managers). Additionally, this thesis involved various disciplines

within the university such as electronics, IT, logistics, pattern recognition and philosophy. A company was, moreover, actively involved in the development of the safety status system. After jointly performing the development and tests, the company went on with further improvements, marketing and implementation of the system.

This list of participants shows not only the broad scope that characterises patient safety studies, but also the extensive communication required to collaborate with all these parties. The efforts needed to make such a broad collaboration work should not be underestimated. Even if it is tempting to sometimes neglect parties that disagree the chosen approach, they should stay engaged for gaining broad knowledge and avoiding longer term difficulties and undesired delays. Moreover, early involvement of users in developing new systems is encouraged as it leads to better acceptance and sustainable usage in practice [16-18].

As stated by Koppel et al., meticulous attention is required to the actual use of systems in situ [19]. Systems should be assessed in the environment they are meant for. The assessment of systems is not a single event; it should be an on-going process [19]. It is therefore required to be able to test systems during actual OR practices. Implementing and assessing systems in ORs entail time consuming activities. New devices need to be approved for safe use in the OR, professionals need to be informed and trained for new work processes and clear agreements need to be established on how to gather and exchange research data, while taking the privacy of patients and professionals into account. These time consuming activities had to be done for every study. They provided many insights that were used to set up a living lab: one OR of the hospital that is equipped to facilitate permanently patient safety research in a more efficient way and in a real environment. Therefore, monitoring equipment was installed in the OR, IT infrastructure was built to safely exchange data from the hospital's health data records and legal agreements were established between the hospital and the university. The added value of such a living lab is not only to facilitate research; it strengthens collaboration between hospital and university and creating a shared vision for further developments.

To conclude, the Digital Operating Room Assistant can be seen as an approach to support surgical practice in the same adaptive manner as operating room assistants. This approach stands for the development of support systems that are adaptive to the different situations in the OR, automating and standardising processes when possible, and providing information and increasing awareness when needed. This thesis provides insights into how such technology can be developed, with the involvement of various disciplines, to make the surgical process easier and safer.

REFERENCES

1. World Health Organization (2005) WHO draft guidelines for adverse event reporting and learning systems.
2. Anderson JE, Kodate N, Walters R, Dodds A (2013) Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. *International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua* 25:141-150
3. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A, Vincent C (2009) Feedback from incident reporting: information and action to improve patient safety. *Quality & safety in health care* 18:11-21
4. Hollnagel E, Wears RL, Braithwaite J (2015) From Safety-I to Safety-II: A White Paper. The Resilient Health Care Net: Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.
5. Vincent C, Moorthy K, Sarker SK, Chang A, Darzi AW (2004) Systems Approaches to Surgical Quality and Safety. From Concept to Measurement. *Ann Surg* 239
6. Dankelman J, Grimbergen CA (2005) Systems approach to reduce errors in surgery. *Surgical endoscopy* 19:1017-1021
7. Vincent C, Aylin P, Franklin BD, Holmes A, Iskander S, Jacklin A, Moorthy K (2008) Is health care getting safer? *Bmj* 337:a2426
8. Jha AK, Classen DC (2011) Getting moving on patient safety—harnessing electronic data for safer care. *The New England journal of medicine* 365:1756-1758
9. de Vries J, Huijsman R (2011) Supply chain management in health services: an overview. *Supply Chain Manag*:159-165
10. Gupta AK (2012) JIT in Healthcare: An Integrated Approach. *International Journal of Advances in Management and Economics* 1:20-27
11. Arora S, Hull L, Sevdalis N, Tierney T, Nestel D, Woloshynowych M, Darzi A, Kneebone R (2010) Factors compromising safety in surgery: stressful events in the operating room. *Am J Surg* 199:60-65
12. Tucker AL (2004) The impact of operational failures on hospital nurses and their patients. *J Oper Manag* 22:151-169
13. Linkin DR, Sausman C, Santos L, Lyons C, Fox C, Aumiller L, Esterhai J, Pittman B, Lautenbach E (2005) Applicability of Healthcare Failure Mode and Effects Analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* 41:1014-1019
14. van der Eijk AC, Rook D, Dankelman J, Smit BJ (2013) Defining hazards of supplemental oxygen therapy in neonatology using the FMEA tool. *MCN The American journal of maternal child nursing* 38:221-228
15. Wiegmann DA, ElBardissi AW, Dearani JA, Daly RC, Sundt TM (2007) Disruptions in surgical flow and their relationship to surgical errors: An exploratory investigation. *Surgery* 142:658-665

16. Pilemalm S, Timpka T (2008) Third generation participatory design in health informatics-making user participation applicable to large-scale information system projects. *J Biomed Inform* 41:327-339
17. Weng C, McDonald DW, Sparks D, McCoy J, Gennari JH (2007) Participatory design of a collaborative clinical trial protocol writing system. *Int J Med Inform* 76 Suppl 1:S245-251
18. Guedon AC, Wauben LS, de Korne DF, Overvelde M, Dankelman J, van den Dobbelsteen JJ (2015) A RFID specific participatory design approach to support design and implementation of real-time location systems in the operating room. *J Med Syst* 39:168
19. Koppel R, Wetterneck T, Telles JL, Karsh BT (2008) Workarounds to barcode medication administration systems: their occurrences, causes, and threats to patient safety. *J Am Med Inform Assoc* 15:408-423

SUMMARY

The Operating Room (OR) is a complex environment, where a large variety of patients and diseases can be treated and many unexpected events occur (such as emergency surgeries and unexpected progress of procedures). In practice, OR assistants support OR processes as well as they can, in order to deliver safe and efficient care. Therefore, they have to be aware of this complex environment, understand the situation at hand, and act accordingly. Technological support systems in the OR should strive to support OR processes in the same way OR assistants do it. **The objective of this thesis** is to develop technology to support healthcare professionals in improving patient safety and efficiency in the OR.

Part I - Approaches to improve patient safety

The first part of this thesis presents a new approach on how to improve patient safety. This approach, called adaptive support, stands for the development of support systems that are adaptive to the different situations in the OR: automating and standardising processes when possible, and providing information and increasing awareness when needed. Technology plays a key role in adaptive support, especially in recording and analysing data to gain a deep understanding of OR processes, in real-time recognition of a situation and in designing adaptive support systems.

Each of the following three parts of this thesis presents one topic that has been selected to test our approach in practice: OR devices, surgical instruments and OR scheduling.

Part II - Monitoring safety of operating room devices

A safety status system was developed to support both the monitoring of OR devices and the communication between the OR and the department of Clinical Physics regarding malfunctioning devices. The safety status system tracks and traces OR devices in the OR department, and provides and exchanges information about their safety status through an intuitive interface in the OR. It thereby supports efficient management and safe use of OR devices.

Part III - Delivery process for surgical instruments

A new process was designed to deliver surgical instruments 'just in time' for surgical procedures. In this process, information about surgical instruments is centralised and is available for the relevant professionals, which makes the process less sensitive to errors. IT support plays a key role to improve efficiency and safety related to the availability of surgical instruments.

Part IV - Operating room scheduling

A prediction system was developed to automatically monitor the progress of surgical procedures and estimate the optimal time to start preparing the next patient. The prediction system is based on the activation of a single OR device during procedures. Such a prediction system is a useful tool to optimize OR planning without having to interrupt the surgical process.

The 'Digital Operating Room Assistant' can be seen as an approach to support surgical practice in the same adaptive manner as operating room assistants. This thesis provides insights into how such technology can be developed, with the involvement of various disciplines, to make the surgical process easier and safer.

SAMENVATTING

De operatiekamer (OK) is een complexe omgeving, waar een grote variëteit aan patiënten en ziektes behandeld wordt en onverwachte gebeurtenissen vaak voorkomen (zoals spoedoperaties en onverwachte wendingen van operaties). In de praktijk worden deze OK processen zo goed mogelijk ondersteund door de operatieassistenten, zodat veilige en efficiënte zorg verleend kan worden. Daarvoor moeten zij zich echter bewust zijn van deze complexe omgeving, de huidige situatie goed begrijpen en hun handelingen daarop aanpassen. Technologische support systemen in de OK zouden processen moeten ondersteunen op dezelfde manier als operatieassistenten dat doen. **Het doel van dit proefschrift** is om technologie te ontwikkelen die zorgprofessionals kan helpen in het verbeteren van patiëntveiligheid en het verhogen van efficiëntie in de OK.

Deel I - Benaderingen voor het verbeteren van patiëntveiligheid

Het eerste deel van dit proefschrift beschrijft een nieuwe benadering voor het verbeteren van patiëntveiligheid, genoemd adaptieve support. Het houdt in dat support systemen adaptief zijn aan de verschillende situaties in de OK: processen worden geautomatiseerd en gestandaardiseerd wanneer mogelijk, informatie wordt gedeeld en de bewustwording van de situatie wordt verhoogd wanneer dit nodig is. Technologie speelt hierin een cruciale rol, met name voor het meten en analyseren van data, inzicht krijgen in OK processen, situaties herkennen in real-time en adaptieve support systemen ontwikkelen.

In de volgende delen van dit proefschrift wordt beschreven hoe deze benadering in de praktijk is getest voor drie onderwerpen: OK apparaten, chirurgische instrumenten en OK planning.

Deel II - Monitoren van de veiligheid van operatiekamer apparaten

Een monitoringssysteem is ontwikkeld om de veiligheidsstatus van OK apparaten te checken en de communicatie tussen de OK en de klinische fysica afdeling te ondersteunen. Dit systeem volgt de apparaten in het OK complex en geeft informatie over hun veiligheidsstatus met behulp van een intuïtieve interface in de OK. Op deze manier wordt het veilig gebruik van OK apparaten bevorderd.

Deel III - Leveringsproces van chirurgische instrumenten

Een nieuw proces is ontworpen voor het 'just in time' leveren van chirurgische instrumenten. In dit proces wordt informatie over chirurgische instrumenten gecentraliseerd en beschikbaar gesteld voor de relevante professionals. Dit maakt het proces minder gevoelig voor fouten. IT support speelt een belangrijke rol in het verbeteren van efficiëntie en veiligheid wat betreft de tijdige levering en aanwezigheid van chirurgische instrumenten.

Deel IV - Operatiekamer planning

Een voorspellingssysteem is ontwikkeld om automatisch het verloop van chirurgische procedures te monitoren en om een schatting te maken van het optimale tijdstip om de volgende patiënt voor te bereiden. Het voorspellingssysteem is gebaseerd op de activatie van één OK apparaat tijdens de procedures. Dit systeem maakt het mogelijk om de OK planning te optimaliseren zonder het chirurgisch proces te hoeven onderbreken.

De 'digitale operatieassistentie' kan beschouwd worden als een benadering om chirurgie te ondersteunen in dezelfde adaptieve manier als operatieassistenten dat doen. Dit proefschrift geeft inzichten in hoe technologie ontwikkeld kan worden, met de inzet van verschillende disciplines, om het chirurgisch proces makkelijker en veiliger te maken.

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CURRICULUM VITAE

28 June 1984	Born in 's-Gravenhage, the Netherlands.
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PUBLICATIONS

Guédon ACP, Spruit S, Wauben LSGL, van der Elst M, Doorn N, Dankelman J, van den Dobbelsteen JJ, Klein J. A delicate balance: adaptive support to improve patient safety. *Submitted for publication.*

Guédon ACP, Paalvast M, Meeuwssen FC, Tax DMJ, van Dijke AP, Wauben LSGL, van der Elst M, Dankelman J, van den Dobbelsteen JJ. It is time to prepare the next patient. Real-time prediction of procedure duration in laparoscopic cholecystectomies. *Submitted for publication.*

Guédon ACP, Rakers TJ, Wauben LSGL, Meeuwssen FC, Hoeijmans V, van der Elst M, Dankelman J, van den Dobbelsteen JJ. Just-in-time delivery of sterilised surgical instruments. *BMJ Innovations*, 2016.

Guédon ACP, Wauben LSGL, van der Eijk AC, Vernooij ASN, Meeuwssen FC, van der Elst M, Hoeijmans V, Dankelman J, van den Dobbelsteen JJ. Where are my instruments? Hazards in delivery of surgical instruments. *Surgical Endoscopy*, 2015.

Guédon ACP, Paalvast M, Meeuwssen FC, Tax DMJ, van Dijke AP, Wauben LSGL, van der Elst M, Dankelman J, van den Dobbelsteen JJ. Real-time estimation of surgical procedure duration. *Proceedings of IEEE Healthcom 2015*, Boston, USA.

Meeuwssen FC, Guédon ACP, van Dijke AP, Wauben LSGL, Klein J, van der Elst M, Dankelman J, van den Dobbelsteen JJ. Real-time monitoring of electrosurgical applications for excellent training and performance evaluation. *Proceedings of IEEE Healthcom 2015*, Boston, USA.

Wauben LSGL, Guédon ACP, van den Dobbelsteen JJ. DORA: Tracking Patients and Devices. Tijdschrift voor Human Factors, 2015.

Wauben LSGL, Guédon ACP, de Korne DF, van den Dobbelsteen JJ. Tracking surgical day care patients using RFID technology. BMJ Innovations, 2015.

Guédon ACP, Wauben LSGL, de Korne DF, Overvelde M, Dankelman J, van den Dobbelsteen JJ. A RFID Specific Participatory Design Approach to Support Design and Implementation of Real-Time Location Systems in the Operating Room. Journal of Medical Systems, 2015.

Guédon ACP, Wauben LSGL, Overvelde M, Blok JH, van der Elst M, Dankelman J, van den Dobbesteem JJ. Safety status system for operating room devices. Technology and Health Care, 2014.

van Ooij P, Potters WV, Guédon ACP, Schneiders JJ, Marquering HA, Majoie CB, van Bavel E, Nederveen AJ. Wall shear stress estimated with phase contrast MRI in an in vitro and in vivo intracranial aneurysm. Journal of Magnetic Resonance Imaging, 2013.

van Ooij P, Guédon ACP, Marquering HA, Schneiders JJ, Majoie CB, van Bavel E, Nederveen AJ. k-t BLAST and SENSE accelerated time-resolved three-dimensional phase contrast MRI in an intracranial aneurysm. Magnetic Resonance Materials in Physics, Biology and Medicine, 2013.

van Ooij P, Guédon ACP, Poelma C, Schneiders JJ, Rutten MC, Marquering HA, Majoie CB, Van Bavel E, Nederveen AJ. Complex flow patterns in a real-size intracranial aneurysm phantom: phase contrast MRI compared with particle image velocimetry and computational fluid dynamics. NMR Biomed, 2012.

STELLINGEN

behorende bij het proefschrift

DIGITAL OPERATING ROOM ASSISTANT

Annetje Guédon

1. Standaardisatie doet geen recht aan de complexiteit van de zorg.
2. Track & Trace systemen betalen zichzelf terug.
3. 'Just in time' dwingt procesverbetering af.
4. Kletsen met operatieassistenten is productief.
5. Naast PEL (Production Engineering & Logistics) en TEL (Transport Engineering & Logistics) moet MEL (Medical Engineering & Logistics) opgericht worden als nieuwe master specialisatie.
6. Patiëntveiligheid is een kwestie van kennis.
7. Niet haasten in de ochtend verhoogt efficiëntie.
8. 'Wij kunnen er niet voor zorgen dat zaken goed gaan alleen door het voorkomen dat ze verkeerd gaan. Het is duidelijk dat we ook moeten weten hoe ze goed gaan.' (*E. Hollnagel in From Safety-I to Safety-II: A White Paper*)
9. Een chirurg alleen kan niet verantwoordelijk zijn voor patiëntveiligheid.
10. Het echte feest is in de keuken.

Deze stellingen worden opponeerbaar en verdedigbaar geacht en zijn als zodanig goedgekeurd door de promotor prof. dr. J. Dankelman en de copromotor dr. J.J. van den Dobbelen.

PROPOSITIONS

belonging to the thesis

DIGITAL OPERATING ROOM ASSISTANT

Annetje Guédon

1. Standardisation does not do justice to the complexity of healthcare.
2. Track & trace systems pay for themselves.
3. Just-in-time forces process improvement.
4. Chatting with operating room assistants is productive.
5. Next to PEL (Production Engineering & Logistics) and TEL (Transport Engineering & Logistics), a new specialisation MEL (Medical Engineering & Logistics) must be started.
6. Patient safety is a matter of knowledge.
7. Taking the time in the morning increases efficiency.
8. 'We cannot make sure things go right just by preventing them from going wrong. Patently, we also need to know how they go right.'
(E. Hollnagel in From Safety-I to Safety-II: A White Paper)
9. An individual surgeon cannot be responsible for patient safety
10. The real party is in the kitchen.

These propositions are regarded as opposable and defensible, and have been approved as such by the promotor prof. dr. J. Dankelman and copromotor dr. J.J. van den Dobbelsteen.

