

Adaptive Design Connie M. Dekker-van Doorn and Team Learning in the Operating Theatre

A Delicate Balance

Adaptive Design and Team Learning in the Operating Theatre

Connie M. Dekker-van Doorn



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A Coeken naar de Juiste Balans

Adaptive Design and Team Learning in the Operating Theatre Adaptive Design en Teamleren in de Operatiekamer

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Table of contents

Chapter 1	Introduction and outline	7
Chapter 2	Interventions to improve team effectiveness: A systematic review M. Buljac-Samardzic, C. M. Dekker-van Doorn, J.D.H. van	23
	Wijngaarden, K. P. van Wijk Published: Health Policy 94 (2010) 183–195	
Chapter 3	Discrepant perceptions among surgical team members L.S.G.L. Wauben*, C.M. Dekker-van Doorn*, J.D.H. van Wijn- gaarden, R.H.M. Goossens, R. Huijsman, J. Klein, J.F. Lange. * <u>Shared first author</u> Published: International Journal for Quality in Health Care 2011; Volume 23 Number 2: pp. 159–166 –	47
Chapter 4	Introducing TOPplus in the Operating Theatre C.M. Dekker-van Doorn, L.S.G.L. Wauben, B. Bonke, G. Kazemier, J. Klein, B. Balvert, B. Vrouenraets, R. Huijsman, J.F. Lange Published In: Eds. R. Flin, L Mitchell: Safe Surgery, Ch. 10. Ashgate Publishers, 2010	61
Chapter 5	Participatory Design: Implementation of Time Out and Debriefing in the Operating Theatre L.S.G.L. Wauben*, C.M. Dekker-van Doorn*, J. Klein, J.F. Lange, R.H.M. Goossens. * <u>Shared first author</u> Published: J. Design Research, Vol. 9, Nr. 3, 2011	81
Chapter 6	Adaptive Design: Theory-driven Design of Patient Safety Practices C.M. Dekker-van Doorn, L.S.G.L. Wauben, J.D.H. van Wijn- gaarden, R.H.M. Goossens, J.F. Lange, R. Huijsman Submitted	103
Chapter 7	Time Out Procedure in the Operating Theatre: arguments for Improved teamwork C.M. Dekker–van Doorn, L.S.G.L. Wauben, J.D.H. van Wijn- gaarden, F. van der Meulen, A.W.M.M. Koopman–van Gemert, R. Huijsman, J.F. Lange Submitted	123

Chapter 8	Multi-site Study: The Role of Process Orientation C.M. Dekker–van Doorn, L.S.G.L. Wauben, J.F. Lange, R. Huijs- man, J.D.H. van Wijngaarden Submitted: November 2014	143
Chapter 9	Conclusion and Discussion	161
	Summary	179
	Acknowledgements	191
	Biography	197
	Publications	199



1.1 Introduction

Since the publication of the Institute of Medicine (IOM) study "To Err is human", followed by "Crossing the Quality Chasm" two years later, patient safety has become an important concern for all involved: patients, professionals and health care organisations (Bleich, 2005; Kohn, 2000). Over the last 10 years, significant improvements have been made and many innovative initiatives resulted in enhanced patient safety. At both national and international level checklists and performance indicators were developed, handovers restructured and reporting systems installed (Haynes et al., 2009; Lingard et al., 2005; Pronovost, Thompson, et al., 2006; Riesenberg et al., 2009). Recently, also patients are involved in patient safety initiatives (Conrardy, Brenek, & Myers, 2010; Davis, Koutantji, & Vincent, 2008). Although we have come a long way, there is room for improvement as research shows that medical errors and, more alarming, *preventable* medical errors still occur (Bleich, 2005; Zegers et al., 2009).

A significant part of medical errors is found in acute care hospitals and most of these errors in surgery (Makary et al., 2006). In the Netherlands in 2008, approximately 1.3 million patients were admitted to the hospital. The results of a study, similar to the IOM study, showed one or more adverse events in 5,7% of patients admitted to the hospital and 2,3% of these were preventable. Almost 38.000 patients were subject to preventable harm, of which 6.000 patients ended up with permanent harm and approximately 1960 patients died (Zegers et al., 2009). Causes of errors were diverse, ranging from technical and organisational factors to human and patient factors. The wide variety of factors also shows the complexity of addressing the right factor to improve patient safety. Patient factors and the skills and performance of the individual health care professional are the primary determinants of surgical outcome, but partly beyond the scope of influence. In other industries ergonomic or human factors (physical, cognitive and organisational factors) are system related and have been identified as important factors to create a safe work environment and achieve high quality performance (Vincent, Moorthy, Sarker, Chang, & Darzi, 2004). In most health care studies on patient safety, human factors, e.g. the work environment, task & technology related factors or team performance, are identified as the main contributors to the causation of adverse events. Although human errors are inevitable, human factors can be influenced and therefore a promising field to explore for contributory influencing factors to improve patient safety (Cuschieri, 2006; Mills, Neily, & Dunn, 2008; Reader, Flin, Lauche, & Cuthbertson, 2006; Smits et al., 2010). (see Table 1.1.)

Human factors focus on the interaction among humans and the system and vary from the inability to apply existing technical knowledge and skills, to poor communication and teamwork (Leonard, Graham, & Bonacum, 2004; Mills et al., 2008).

Over the last years significant advances were made and a lot of patient safety practices initiated, e.g. reinforcing guidelines and protocols for infection prevention, fall prevention or patient handovers (Nagpal, Arora, et al., 2010; Rask et al., 2007). As a large percentage of medical errors were found to be related to surgical outcomes, causing serious harm or sometimes even death, one of the first protocols to improve patient handover was

Factor Types	Contributory Influencing Factors
Patient Factors	Condition (complexity and seriousness) Language and communication Personality and social factors
Task & Technology Factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (staff) Factors	Knowledge and Skills Competence Physical and mental health
Team Factors	Verbal communication Written communication Supervision and seeking help Team leadership
Work Environment Factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support Physical environment
Organisational and Management Factors	Financial resources and constraints Organisational structure Policy, standards and goals Safety culture and priorities
Institutional Context Factors	Economic and regulatory context National health service executive Links with external organisations

 Table 1.1 | Factor types and contributory influencing factors (Vincent, 2010)

the Universal Protocol, developed by the Joint Commission, to prevent wrong site, wrong procedure and wrong person surgery (JCAHO, 2004; Norton, 2007). Although a lot of effort was put in implementation of the universal protocol, a study celebrating the 5th anniversary showed that even a simple guideline like that is difficult to implement and preventable harm or near misses, such as wrong site surgery still occur (Stahel, Mehler, Clarke, & Varnell, 2009). Similar results were found in a systematic review on following guidelines for hand hygiene with a mean compliance rate of only 40% (Erasmus et al., 2010). In daily practice implementation of initiatives to improve patient safety appears to be difficult (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; Grol & Wensing, 2004; Hawe, Shiell, Riley, & Gold, 2004; Leape et al., 2009). First of all, it is difficult to choose the right intervention for a specific problem, within a specific context and preferably evidence-based. The second problem is finding the right method for implementation: how to engage professionals and patients whenever possible, defining relevant process and outcome measures and how to monitor the results (Greenhalgh, Robert, Macfarlane, et al., 2010).

Research on patient safety in surgical care shows four areas, which complicate implementation of patient safety initiatives. First, the complex and dynamic character of surgical care in operating theatre (OT) makes clinical processes difficult to manage

and vulnerable to human errors (J. T. Reason, Carthey, & de Leval, 2001). Second, the professional silos with specific workflow patterns and independent medical departments, interfere with multi-disciplinary clinical care processes and make team cohesion and information-sharing at system level, across disciplines and departments, difficult (Bogner, 2003; Lingard et al., 2005). A third factor is the organisational culture. As encouraged in the afore-mentioned IOM report, health care needs to change from a punitive "blame and shame culture" to a "safe culture", without hierarchical barriers, where team members can speak up to voice concerns and errors are perceived as opportunities to learn from. With the right culture, improvements in task & technology or management & organisational factors, will result in the desired outcomes (Hudson, 2001; Lange, Dekker-van Doorn, Haerkens, & Klein, 2011a). A fourth factor that needs to be addressed in relation to patient safety is the ability to learn as a team. The professional autonomy and the individual, mono-disciplinary character of professional learning and continuing education impede the necessary exchange of knowledge and expertise between disciplines and team members and thus team learning (Burke, 2004; Edmondson, 2004).

1.2 The complexity of surgical care and human factors

The complexity of surgical care is closely related to the patient's condition, the surgical intervention and the increasing number of different medical disciplines involved. Changes in demographic trends and new surgical and technological innovations require close collaboration with other disciplines for a number of reasons. The aging patient population, with an increasing number of patients with co-morbidity and fatal diseases that are turning into chronic conditions require multidisciplinary care. Surgical and technological innovations open up new possibilities to treat patients, but require different knowledge and skills from professionals sometimes leading to new medical or technological specialties (Fendrich, van den Berg, Siewert, & Hoffmann, 2010; Heinemeyer, 2012). In addition to complexity, surgical care is dynamic. Surgical teams are ad hoc, working 7 days a week and 24 hours a day in different shifts and in changing team composition, not only in the number of team members but also in medical disciplines. Poor working conditions such as working different shifts in a row and working long hours were found to be a risk factor for patient safety, e.g. an increased risk for hospital acquired infections or for medical error (Ehara, 2008; Lockley et al., 2007; Stone, Clarke, Cimiotti, & Correa-de-Araujo, 2004).

Another dynamic factor that complicates surgical interventions is unforeseen changes in the surgical process, which requires anticipation and flexibility of team members. To perform safe surgery in such a complex and dynamic setting, surgical team members rely on each others capabilities to combine technical expertise with non-technical skills such as communication, teamwork, situation awareness, leadership and shared decisionmaking (Yule, Flin, Paterson-Brown, & Maran, 2006). One of the concepts to reduce the risk of adverse events caused by human factors is Crew Resource Management (CRM) (Powell & Hill, 2006). CRM is defined as *"using all available sources — information,* equipment and people — to achieve safe and efficient flight operations." (Lauber, 1984, p. 20).. CRM is the process used by crewmembers, to identify existing and potential threats and to develop, communicate and implement plans and actions to avoid or mitigate perceived threats (www.apa.org American Psychological Association) CRM was first developed for high reliability industries such as aviation but there is emerging evidence that CRM is also valuable for acute medical specialties in health care (Flin & Maran, 2004). Aviation is similar to healthcare as teams in aviation are often 'temporary' in team composition, like surgical teams in acute care.

A surgical team is defined as: "a unit providing the continuum of care beginning with preoperative care and extending through perioperative (during the surgery) procedures and postoperative recovery. Each specialist on the team, whether surgeon, anaesthesiologist or nurse, has advanced training for his or her role before, during and after surgery." (http://www.surgeryencyclopedia.com).

A basic surgical team includes at least five team members: the surgeon, the anaesthetist, the scrub nurse, the circulating nurse and the nurse anaesthetist, each with different functional areas, with specific tasks and responsibilities. (Table 1.2) With complex surgery, additional team members with the necessary expertise will join the team. At university and teaching hospitals attached to medical schools, interns, residents and students from various disciplines will also be added to the team. Participation of more medical disciplines depends on the kind and the complexity of the surgical intervention and the location and the kind of anaesthesia. Trauma surgery e.g. might involve the orthopaedic or plastic surgeon to repair the damaged bone or skin and underlying tissue, or a nurse specialised in cast and splints. With other interventions, a radiologist or perfusionist might join the team. In daily practice, this results in working with different team members from different units and departments in approximately every shift and with every intervention. To provide safe surgery transparency is required, so that each team member's individual contribution to the surgical process is clear and understood by all team members (Mickan & Rodger, 2000).

Surgeon	Responsible for the surgical intervention, specialized in one or more medical disciplines
Scrub Nurse	Responsible for materials and instruments and assisting the surgeon during the per- operative process
Circulating nurse	Responsible for handing over material and instruments to the scrub nurse and for all other activities that do not require a sterile position (outside the sterile area)
Anaesthesiologist	Responsible for monitoring the patient during the per-operative process and administering anaesthetics, fluids, blood products and if necessary other drugs
Nurse Anaesthetist	Responsible for preparing the patient for surgery pre-operatively; positioning, IV catheter, etc. Replaces the anaesthetist if absent.

Table 1.2 | Surgical Team Members

1.3 A systems approach and professional silos

Working with different disciplines from different units or departments, in different shifts complicates coordination and communication and increases the risk of human error. As errors can occur at each step in the surgical pathway with many different causes, safety should be looked at from a systems perspective (Cuschieri, 2006).

Errors can be divided into two main categories: 1) latent failures, which can be attributed to absent or failing barriers in organisational processes and procedures and 2) active failures, due a lack of knowledge and skills, or poor communication and teamwork (J. Reason, 2005). To provide safe and high quality care, causes of errors need to be identified along the surgical pathway, throughout the healthcare system. When causes are identified, effective action can be taken to redesign systems and care processes accordingly and centred around the patient in the clinical micro-system, the unit where the actual care is delivered (Bogner, 2003). Identifying and eliminating latent failures at system level, will positively impact the clinical micro-system. However, most healthcare delivery systems are organised around health care providers and adapted to the needs of a professional discipline or the individual healthcare professional.

The complexity of surgical care, the number of different disciplines involved and the inevitability of human error, require collaboration between professionals, across disciplines and medical domains. Therefore, rather than loosely coupled independent medical disciplines providing care, health care delivery should be process- and patient-oriented and organised within independent integrated clinical micro-units. In these clinical micro-systems different disciplines work together and can develop alternative strategies to improve patient safety (Mohr, Batalden, & Barach, 2004). Nelson et al (2006) describe a clinical micro-system as follows:

"Within the clinical micro-system, care is provided by a core team of health care professionals, for a defined population to care for, with an information environment to support the functioning of the clinical micro-system, across disciplines and throughout the whole surgical pathway. With an administrative staff, equipment and the right work environment the clinical micro-system is an independent unit within the larger macro system with its own objectives and strategies and ability to monitor the patient and the process and take effective action whenever necessary" (Nelson et al., 2003).



Figure 1.1 | Clinical micro-system of patient undergoing surgical intervention

The surgical clinical micro-system is organised around the surgical pathway and divided in three large sections: admission and preparation of the patient, the perioperative process comprising three parts: pre-operative, per-operative and post-operative care and finally the post-operative care in the clinical ward and discharge.

To be effective in a complex environment like the operating theatre, team members need technical knowledge and expertise but also teamwork skills. Good communication and teamwork are critical for patient safety. Team members should be familiar with each others' tasks and responsibilities in the surgical process, be able to anticipate to each others needs and have a shared understanding of the steps in the surgical procedure (Baker, Day, & Salas, 2006; Crofts, 2006). Therefore, team members should feel free to speak up, ask questions or voice concerns and not being hindered by hierarchical authority or an unsafe culture (Ummenhofer et al., 2001; Waring, Harrison, & McDonald, 2007).

1.4 From Individual failure to a safe culture¹

Procedures or systems to improve safety, such as protocols, checklists, or safety management systems, are often copied from high-risk industries. However, without a fundamental understanding of the differences in culture and structure between health care and industry, most procedures and instruments will be implemented top down and translate into a culture of bureaucracy and control, sometimes leading to repression (Edmondson, 2004; Hudson, 2001). The health care sector differs in certain respects from the industry. Different factors emerge that contribute to the failure of patient safety in daily practice: the professional autonomy, the traditional hierarchical structures and the so-called "Silent Power", which represents the relation between the board of directors and the medical staff and finally the professional silos that form a barrier for multi-professional collaboration (Lingard, Espin, Evans, & Hawryluck, 2004).

One of the core elements of safety systems in high-risk industries is to create a safe and open environment, where errors are identified, reported and discussed and analysed to learn from (Pronovost, Berenholtz, et al., 2006). This is in stark contrast with the current culture in many hospitals, where one finds the cause of errors in the individual professional and much less in the organisation of care and identified as a system failure. To achieve a safe working environment for professionals and patients it is important to "Create an environment where individuals can speak up and express concerns and share common 'critical language' to alert team members to unsafe situations" (Leonard et al., 2004). This requires breaking through professional and departmental barriers and reshaping the traditional hierarchy. Traditional medical schools, where professionals are educated in silos, lay the foundation for this culture. Errors are related to individual performance and teamwork is not perceived as a chance to prevent errors. Whereas in

¹ Based on: Lange, Dekker et al.2010. "Safety Culture in the Hospital: Without real culture change just cosmetic surgery."

high risk industries teamwork is one of the main contributors to better cooperation and communication, thereby reducing the risk of disaster.

To improve patient safety we need a blame-free, organisational culture, where patient safety and transparency are obvious and care delivery is patient centred (Lange, Dekkervan Doorn, Haerkens, & Klein, 2011b). But: "This will only happen when the positive attributes of the medical hierarchy govern—such as leadership, promotion of shared team responsibilities and respect for all members of the healthcare team" (Walton, 2006).

In order to be successful and improve patient safety at a more structural and sustainable level, professionals must accept that human error is inevitable, should be discussed and analysed as a team and seen an opportunity to learn from.

1.5 Professional learning, team learning and patient safety

To discuss errors and learn from as a team, safety also depends on transparency, discipline and reporting and monitoring systems, such as a safety management system (SMS) (Hofinger, 2009; Wallace, Spurgeon, Benn, Koutantji, & Vincent, 2009). The essential feature of an SMS is the assurance of quality and safety in processes and systems of the organisation on the basis of a learning cycle (Waring et al., 2007). Successful implementation of improvement initiatives such as the introduction of a time out procedure and debriefing, requires learning as a team by a thorough analysis of errors and related causes, choosing the right intervention and the right strategies for implementation. The Plan Do Study Act-cycle (PDSA) is an important tool for successful implementation of improvement initiatives, through small and frequent improvement cycles (Hughes, 2008; Ovretveit, 1999).

In order to learn from mistakes, errors must be reported in multidisciplinary reporting systems and discussed as a team to find out what went wrong and why and prevent errors from recurring. (Croskerry, 2000; Edmondson, 2004; Neale, Woloshynowych, & Vincent, 2001). However, health care professionals are educated in silos around professional content and subject matter with little attention for development of the necessary team skills (Cox et al., 2009). As a result, improving the quality of care often translates into mono-disciplinary professional guidelines and protocols with specific workflow patterns, which makes it difficult to bring teams from different disciplines together (Lingard et al., 2005; Shojania, Duncan, McDonald, Wachter, & Markowitz, 2001). Team members need a common language to exchange critical information, alert each other in case of unsafe situations and discuss errors to learn from (Leonard et al., 2004)

As adverse events are not always isolated errors but often reflect problems elsewhere in the healthcare system, learning needs to occur at individual, team and organisational level to improve quality and safety system-wide (Mikkelsen & Holm, 2007; Wang, Lave, Sirio, & Yealy, 2006). Errors caused by problems that include other disciplines and departments require a multidisciplinary approach, team learning and different types of learning. Single-Loop Learning (SLL) to solve simple problems; a one dimensional question asking a one-dimensional answer and Double-Loop Learning (DLL), to solve complicated problems that require more additional steps (Argyris, 1994). Where singleloop learning requires reflection *in* action to increase effectiveness of actions, such as ordering extra blood units when patients are loosing more blood than expected, double-loop learning requires reflection *on* actions to increase team effectiveness and improve patient care across disciplines and departments, system-wide (Clarke & Wilcockson, 2001; Edmondson, 2004).

Double-loop learning, means taking time out to reflect on the care process with the whole team, learn from it and take additional steps to solve problems. It is important to choose the right intervention and integrate it in processes or procedures in the local health care delivery system around the patient. To make it successful, the relevant professional disciplines should be engaged in that learning process. All too often patient safety initiatives are adopted by individual professionals but never fully adopted by all involved and in the end cease to exist or are abandoned (Greenhalgh, Robert, & Bate, 2004).

1.6 Time Out Procedure and Debriefing at Erasmus MC

To improve safety and engage all professionals involved, Erasmus MC, University Hospital Rotterdam, introduced a team procedure consisting of a combined time out procedure (TOP) and debriefing (plus). Although a time out procedure is meant to reflect in action and detect and correct errors before harm is done, the principle aim of TOPplus was to improve communication and teamwork among surgical team members and improving patient safety at a more sustainable level. Rather than a checklist TOPplus was based on CRM principles and developed as a multidisciplinary team procedure to actively engage all OT team members, directly involved in the surgical procedure. The time out procedure provides a moment and a structure to exchange critical information about the patient and the surgical intervention just before incision. Questions and answers are assigned to designated team members in such a way that all team members are actively engaged in the discussion. The debriefing, prior to skin closure, structures the team discussion about problems encountered during surgery and, if well registered, provides a solid base to analyse and discuss errors to learn from. Both procedures are performed with the whole team present. TOPplus provides a time and moment to reflect as a team and creates the opportunity for each team member to ask for additional information, without being hindered by hierarchical structures. This way TOPplus contributes to a basic condition to improve patient safety; creating a safe environment for all involved.

1.7 Objectives and research questions

The main objective of the study is to find out if team learning to improve patient safety in OT can be enhanced by applying theoretical concepts from other industries: Crew

Resource Management from aviation and Participatory Design from Industrial Design Engineering.

The overall research question: How to design and implement a time out procedure and debriefing to improve communication & teamwork in the operating theatre?

- 1. What is the evidence of team interventions to improve team effectiveness? (Chapter 2)
- 2. What is the perception of communication & teamwork of OT team members? (Chapter 3)
- 3. How to design a time out procedure and debriefing and improve adaptation to the local context and adoption by all professionals? (Chapter 4 and 5)
- 4. How can participatory design be reinforced to improve adaptation and adoption? (Chapter 6)
- 5. Does implementation of TOP*plus* improve perception of nontechnical skills of OT team members? (Chapter 7)
- 6. Does implementation and usage of TOP*plus* impact at process and structure level across disciplinary boundaries within the healthcare system (Chapter 8)



1.8 Thesis Outline

Figure 1.2 | Thesis Outline

In *chapter 2* of this thesis, the results are presented of a systematic review to identify team interventions or tools to improve team effectiveness. The aim of the study was to identify the effectiveness of team interventions, the groups the intervention was targeting, which outcomes were found, if these outcomes represented scientific evidence and at what level. The evidence supported our decision to use a time out procedure

and debriefing, based on the principles of Crew Resource Management (CRM), in the operating theatre as a study object.

Chapter 3 describes the differences in perception of communication and teamwork between surgical team members from the first 5 hospitals that joined the project. Good communication and teamwork improve the exchange of critical information and discussion between team members and are vital in relation to patient safety. If professionals accept that human error is inevitable and are willing to discuss errors to learn from, a substantial proportion of serious complications can be avoided.

The *chapters 4* and 5 focus on the design and further development of the Time Out Procedure plus Debriefing, TOP*plus*. Chapter 4 provides a description of the design and development of a prototype: the basic design of TOP*plus* to discuss relevant operative items systematically, actively engaging all team members and reduce avoidable damage during and after a surgical procedure. A prototype of TOP*plus* was designed and implemented in five Dutch hospitals and tested in two ways: 1) designing TOP*plus* by means of participatory design and 2) testing the design's content and usability. In chapter 5, implementation and adaptation of TOP*plus* to the local context in 15 Dutch hospitals, is discussed in detail.

Chapter 6 has a more theoretical content, based on Participatory Action Research and describes a model for implementation. The model is based on the experience of the researchers (CD/LW) during the iterative cycles of design, redesign and implementation of TOP*plus* in fifteen hospitals. During this process, it became clear that more time was needed for extra cycles to experiment and learn from as a team. This chapter elaborates on the necessity to put more emphasis on the learning process, which resulted in a new model combining participatory design and experiential learning.

Chapter 7 presents the results of a pre-post study. Based on the assumption that the way TOP*plus* was designed and implemented would positively impact communication and teamwork between professionals, we measured perception of these skills in all participating hospitals, before and following implementation. Statistical analysis included testing for reliability (Cronbach's Alpha) and for comparison and significant differences between T_0 and T_1 (Mann Whitney-U).

Chapter 8 concludes the study with the results of a multi-site study in six of the participating hospitals. The aim was to find out if implementation and usage of TOP*plus* impact at process and structure level across system boundaries and reinforce actions to improve patient safety and thus improve sustainability.

In the final chapter, *chapter 9*, a summary and overall conclusion, a critical reflection and implications and recommendations for practice and future research are presented.

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Chapter 2

Interventions to Improve Team Effectiveness: A Systematic Review

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Abstract

Objectives: To review the literature on interventions to improve team effectiveness and identify their 'evidence based'-level.

Methods: Major databases (PubMed, Web of Science, PsycInfo and Cochrane Library) were systematically searched for all relevant papers. Inclusion criteria were: peerreviewed papers, published in English between January 1990 and April 2008, which present empirically based studies focusing on interventions to improve team effectiveness in health care. A data abstraction form was developed to summarize each paper. The Grading of Recommendations, Assessment, Development and Evaluation Scale was used to assess the level of empirical evidence.

Results: Forty-eight papers were included in this review. Three categories of interventions were identified: training, tools and organisational interventions. Target groups were mostly multi-disciplinary teams in acute care. The majority of the studies found a positive association between the intervention and non-technical team skills. Most articles presented research with a low level of evidence. Positive results in combination with a moderate or high level of evidence were found for some specific interventions: Simulation training, Crew Resource Management training, Team-based training and projects on Continuous quality improvement.

Conclusions: There are only some studies available with high quality evidence on interventions to improve team effectiveness. These studies show that team training can improve the effectiveness of multi-disciplinary teams in acute (hospital) care.

Keywords: intervention studies; patient care teams; systematic review

2.1 Introduction

The well-known publication of 'To Err is Human: Building a Safer Health System' prompted a considerable rethinking of safety in health care (Kohn, 2000). The authors argued that 3 to 4 percent of patients hospitalised in the United States were harmed by care received and 44.000 to 98.000 patients died as a result of medical errors. Their conclusion was that effective teamwork and better communication between caregivers could have prevented half of them. 'To promote effective team functioning' became one of the five principles in the 1999 IOM report to create safe hospital systems (Kohn et al., 1999). The assumption is that effective teamwork leads to higher-quality decision -making and medical intervention and, in turn, better patient outcomes (Bunderson, 2003). Since the publication of the report, research on team effectiveness in health care has significantly increased.

Research in health care has focused particularly on identifying characteristics of effective teams and developing instruments for measuring their effectiveness (Lemieux-Charles & McGuire, 2006; Heinemann & Zeiss, 2002; Mickan & Rodger, 2000). Cohen and Bailey define a team as:

"A collection of individuals who are interdependent in their tasks, who share responsibility for outcomes, who see themselves and who are seen by others as an intact social entity embedded in one or more larger social systems (for example, business unit or corporation) and who manage their relationships across organisational boundaries" (Cohen & Bailey, 1997, p. 241).

Several models have been developed to conceptualise the aspects of teamwork that influence team effectiveness (Campion et al., 1993; Lemieux-Charles & McGuire, 2006; Mickan & Rodger, 2000). These models can be useful in understanding how interventions effect teams. For example, Lemieux-Charles and McGuire have presented 'The Integrated (Health Care) Team Effectiveness Model' (ITEM) (Lemieux-Charles & McGuire, 2006)(Lemieux-Charles & McGuire, 2006). This model shows that the organisational context in which a team operates (e.g. goals, structure, rewards, training environment) indirectly influences its effectiveness. This particularly has an effect on team processes (e.g. communication, leadership, decision-making), psychosocial traits (e.g. cohesion, norms) and task design (e.g. team composition, autonomy, interdependence). These aspects do have a direct influence on team effectiveness. Finally, team effectiveness can be measured by looking at objective outcomes (e.g. patient satisfaction, quality of care) and subjective outcomes (e.g. effectiveness as perceived by team members).

With respect to measuring team effectiveness, Heinemann and Zeiss (2002) have presented an overview of nine state-of-the-art instruments specific to health care teams that measure aspects such as team climate, collaboration, meeting effectiveness, attitude towards teams, team integration and development of teams. However, there are no (general) overviews of studies on different interventions to improve team effectiveness. Therefore, information on the effectiveness of these interventions is scattered. We do not know which interventions are most effective for which target group and for which outcomes. Nevertheless, health care organisations are spending an increasing amount of money and energy on programs and projects to improve team effectiveness.

To assist health care organisations in their endeavour to improve team effectiveness, synthesise scientific knowledge on relevant interventions and identify gaps in this research, we performed a systematic review with a focus on two research questions: (1) Which types of interventions to improve team effectiveness in health care have been researched empirically, for which target groups and for which outcomes? (2) To what extent are these findings evidence based?

This article presents the findings of this systematic review.

2.2 Methods

Data sources

A systematic literature search was conducted using the PubMed, Web of Science, PsycInfo and Cochrane databases. We restricted the initial search to English articles with abstracts published in peer-reviewed journals between 1990 and April 2008. According to Lemieux-Charles and McGuire (2006), research interest in team effectiveness in health care started around 1990. Although research on interventions to improve team effectiveness seemed to appear somewhat later, we chose 1990 as a point of departure for the sake of thoroughness. Our search terms were team tool(s), team intervention(s), team building, team development, team training, team innovation, team program, team education, teamwork, team improve(ment) and team management. Rather than combining search terms, every term was used separately in each data base. When the search term consisted of two elements 'AND' was used; e.g. 'team AND tool(s)'. A summary of the search results is presented in Table 2.1. The search produced 6508 references, including some duplicate articles due to parallel searches.

Database	Hits
Pubmed	3082
Web of Science	1819
PsychInfo	1477
Cochrane	130
Total	6508

Table 2.1. Summary of results

Inclusion/exclusion criteria

Articles included matched the following criteria: (1) peer-reviewed English-language publication: (2) a focus on health care, (3) a focus on how to improve (and not only measure) team effectiveness and (4) empirically researched results. No selection was made based on the design of the study, as long as empirical data was presented. Review articles that focused on interventions to improve team effectiveness were studied only to

identify other relevant empirical studies. Because we wanted to include both qualitative and quantitative articles, we did not require clear outcome measurements. Nor did we select studies based on a definition of a team because they were often lacking. Editorial letters, books and book summaries were excluded.

Selection process

A three-staged process was followed: (1) screening the title and abstract (authors MB, CD and JW), (2) examining the abstracts (MB, CD, JW and KW) and (3) summarizing accepted articles (MB, CD, JW and KW). If the title or abstract did not provide enough information to meet our criteria, the article was referred to the next stage of the process. The first stage resulted in 550 references. In the second stage two researchers, using the same inclusion criteria examined each abstract. When both researchers concluded that an abstract did not match the criteria, it was excluded. When only one of the researchers reached this conclusion a third researcher was asked to make the final decision. Stage two resulted in 90 articles, which were summarized using a standard format: (1) research question/subject, (2) target group (n), (3) methodology, (4) intervention, (5) results, (6) conclusion and (7) general remarks. The search included only one review that focused on interventions to improve team effectiveness, namely interprofessional education. This review was analysed to identify additional studies; but none was found (Reeves et al., 2008). After reading the full length articles, 42 articles did not match the inclusion criteria after all. In the end, 48 studies remained.

Organisation of results

Based on our findings a categorical description of interventions to improve team effectiveness was constructed. Articles were clustered accordingly. Three categories were identified: (1) training, (2) tools and (3) organisational interventions. Training involves a systematic process through which a team is trained (often by facilitators) to master and improve different aspects of team functioning (Harrison, 1990). We identified four types: (1) simulations, (2) training based on Crew Resource Management (CRM), (3) interprofessional training and (4) team training. Simulations attempt to recreate characteristics of the real world. A simulated scenario can have a specific focus on (a segment of) a complex task or be designed to fully simulate a medical or nursing intervention. CRM is a management concept used in the aviation industry to improve teamwork. It has been adapted to high risk, complex medical departments such as emergency departments and operating theatres. CRM encompasses a wide range of knowledge, skills and attitudes including communication, situational awareness, problem solving, decision-making and teamwork (Helmreich, 2000). Interprofessional training incorporates different learning methods that aim to improve cooperation between different disciplines (Furber et al., 2004). Team training includes different forms of training that focus on specific aspects of team functioning such as goal-setting and team building. Tools are specific instruments that teams can use independently to improve team effectiveness (e.g. checklists, goal sheets) through better communication. *Organisational interventions* are actions or changes that focus on the organisational context but are expected to have an effect on team functioning, like integrated care or quality interventions, for example. Each intervention will be described using the same structure: target group, outcomes and level of empirical evidence (Table 2.2).

Interventions	n
Training	32
Simulation training	7
Training based on CRM	8
Interprofessional training	6
Team training	11
Tools	8
Organisational interventions	8
Total	48

 Table 2.2 | Overall information of results

- *Target group* consists of two categories: sector (acute care versus long-term care) and team composition (mono-, multi-, or inter-disciplinary²).
- Outcomes represent the effect of the intervention. These can be objective outcomes focused on patients (e.g. functional status), teams (e.g. clinical quality of care) and organisations (e.g. cost-effectiveness) or subjective outcomes, namely perceived effectiveness by team members (Lemieux-Charles & McGuire, 2006).
- *The level of empirical evidence* is based on the Grading of Recommendations Assessment, Development and Evaluation scale (GRADE).

The GRADE system is used because it gives a general rating of not only the level of evidence, but also the quality of the article. The GRADE rating scale has four levels of quality of evidence: (A) high, (B) moderate, (C) low and (D) very low (GRADE, 2007). A-Quality evidence implies that further research is highly unlikely to change the confidence in the estimated effect of the intervention. The category comprises multicentre random control trials (RCT), one large high-quality multi-centre trial and high-quality pre and post-surveys. B-Quality evidence implies that further research is likely to have an important impact on the confidence in the estimated effect and may change it. This category consists of one-centre RCT, RCT with severe limitations and pre- and post-surveys. C-Quality evidence implies that further research is very likely to have an important impact on the confidence of the estimated effect and is likely to change it. This category consists of high-quality qualitative studies, quasi-experimental designs and pre- and post-surveys with limitations. D-Quality evidence implies that any estimated effect is

² Multi-disciplinary teams are less well developed as inter-disciplinary teams. Members of multidisciplinary teams focus on their own discipline and work in a parallel to each other. Inter-disciplinary teams have a high integration of disciplines (Heinemann & Zeiss, 2002).

very uncertain. This category consists of low-quality qualitative studies and pre- and post-surveys with severe limitations. Levels of evidence of our studies were judged by two researchers. When the two differed in opinion, a third researcher was asked to make the final judgment. Due to the lack of homogeneity across studies, statistical data could not be pooled; the interventions and outcome indicators differed too much.

2.3 Results

The results of the 48 articles are summarised in Table 2.3. Most were published after 2000, only six between 1990 and 2000. The majority (32) evaluated a type of training to improve team effectiveness, mostly in multi-disciplinary teams in acute (hospital) care. The outcome indicators were highly diverse and often related to the so-called non-technical skills of teams such as communication, cooperation, coordination and leadership (Flin & Maran, 2004). The majority of the studies had a low quality of evidence (C). Most studies comprised a pre- and post-survey, experimental design, or used qualitative methods. Little statistical evidence directly related to the effectiveness of the interventions was found.

Training

Of the 32 articles that presented a type of training (simulation-based training, CRM training, interprofessional training, or team training), multi-disciplinary teams in acute (hospital) care were the most common target group, although inter-disciplinary teams in acute care and long-term (elderly) care were also significantly present. Outcomes were diverse, except for studies on CRM training, which mostly focused on safety by improving attitude and team climate (i.e. shared perceptions of the team's work procedures and practices). Nine articles had a high or moderate quality of evidence, three of which presented training based on CRM.

Simulation training

We identified seven studies on simulations using audio-video, computers, manikins, human bodies, or actors. The scenarios were often combined with educational interventions and/or observation (schemes), which are used for debriefing. Teams in acute (hospital) care were the target group for all studies. Most simulations were aimed at team functioning in crisis situations. Both subjective and objective outcomes were used focusing on information sharing, perception, or team performance in terms of task completion (e.g. number, efficiency, effectiveness). Most studies found a positive association between simulation training and non-technical team skills.

Six of the seven studies had a low or very low quality of evidence. One found no association (based on the quantitative data) between the intervention (i.e. lecture-based teaching (LBT), simulation-based teaching (SBT), or a combination of lecture and simulation training (LAS) and team effectiveness. The qualitative data showed a slight indication of a positive effect between the intervention and team effectiveness (Birch et

al., 2007). One study with a moderate quality of evidence found a positive association between participation in emergency training and patient-actor perception using manikins or patient-actors. Training that make use of patient-actors seemed to yield the best results (Crofts et al., 2008).

Training based on CRM

Eight studies on training were based on one or more principles of CRM. For all studies the *target group* was teams in the acute (hospital) care and often (multi-disciplinary) emergency/trauma teams. In half of the studies improving attitudes towards teamwork and safety was an (subjective) *outcome* (Grogan et al., 2004; Leonard et al., 2004; Morey et al., 2002; Wallin et al., 2007). All but one found a positive association between CRM training and attitudes. Other (subjective) outcomes consisted of improving communication, collaboration, team behavior, workload, culture and climate. But also objective outcomes were used; reducing adverse outcomes and medical errors. One article also presented an interesting tool: a briefing checklist for the operating theatre (Makary et al., 2007).

The quality of *evidence* in this subgroup varied from high (A) to very low (D). Five of the eight studies presented a low or very low quality of evidence. Most found improvements in several aspects of team effectiveness such as culture, attitude, communication (with exception of nurses), team skills, perceived risk for wrong-site surgery and perceived collaboration. Only one study found no difference in team performance (Shapiro et al., 2004). This study had a low quality of evidence. One study had a high quality of evidence (Nielsen et al., 2007) and two had a moderate quality of evidence (Grogan et al., 2004; Morey et al., 2002). These found that training based on CRM principles will likely result in improved team behavior, improved attitudes towards teamwork, improved assessments of institutional support and reduced medical errors (Morey et al., 2002; Nielsen et al., 2007). No evidence, however, confirmed that CRM-based training reduces adverse outcomes (except for time from decision to performance) or subjective workload (Morey et al., 2002; Nielsen et al., 2007).

Interprofessional training

For five of the six studies on interprofessional training, the *target group* was interdisciplinary teams in long-term (elderly) care. One study (Watts et al., 2007) had multidisciplinary teams in acute (hospital care) as the target group. The interventions mostly involved many training sessions. Only subjective *outcomes* were measured focusing on learning and retaining information, attitudes, awareness and team climate.

All studies had a low or very low quality of *evidence*. Two studies found no positive associations and one did not present clear outcomes concerning team effectiveness (Clark, 2002; Clark et al., 2002; Cooley, 1994). The other three studies found that interprofessional training resulted in improvements in team skills, team climate, awareness of professional roles, attitude, learning and retaining information and in morale

Table 2.3 Summary of results	of results			
Author(s) (year)	Intervention	Target Group (n)	Outcomes	Quality of Evidence
TRAINING				
		Simulation training		
Birch et al. (2007)	Lecture based teaching (LBT), simulation based teaching (SBT), or a combination (LAS)	Multidisciplinary teams in the cure sector (hospitals: obstetric and midwifery) (n= 36 participants/ 6 teams & 18 interviews)	Quantitative results are not significant. Qualitative show improvement in knowledge and confidence for all team members, improvement in transferable skills and less anxiety for SBT group, improvement in communication and teamwork for SBT and LAS group.	C Mixed methods; Pre and post survey & semi structured interviews
Blum et al. (2005)	Simulation based team training to improve communication skills	Mono-disciplinary (anaesthesia) teams in the cure sector (n=22 pilot teams & 10 experimental teams)	No differences in group information sharing (all p values >0.2)	C Experimental study; surveys
Crofts et al. (2008)	Emergency training using mannequins or patient- actors	Multiclisciplinary teams in the cure sector (n=139 participants/ 23 team pre and 132 participants/ 24 teams post)	Improving patient-actor perception of care (all scores $p=0.017$ to >0.001) PPH (safety $p=$ 0.048, communication $p=0.035$, respect=0.077) Eclampsia (safety $p=0.214$, communication $p=0.071$, respect $p=0.140$) Shoulder dystocia (safety $p=0.532$, communication $p=0.502$, respect $p=0.719$)	B RCT
DeVita et al. (2004)	Crisis TEAM Training (computerized human simulator)	Multidisciplinary emergency teams in the cure sector (n> 200 participants)	Improving efficiency and effectiveness of tasks in crisis situations (treatment <i>p</i> =0.002, task completion <i>p</i> <0.001)	C Observational study
DeVita et al. (2005)	Computerized human patient simulator	Multidisciplinary emergency teams in the cure sector (n=138 participants)	Improving simulated survival and team task completion (overall survival p =0.002, overall TCR p <0.001) TCR= percentage of required tasks completed	C Observational study
Hunt et al. (2007)	Educational intervention during simulated trauma resuscitations (mannequin)	Muttidisciplinary trauma teams in the cure sector (n=18 departments)	Improving performance of teams (mean number of tasks, primary survey tasks, secondary survey tasks and procedural tasks all $p<0.001$)	C Pre and post survey
Mackenzie et al. (2007)	Audio- video data review	Multidisciplinary emergency and trauma teams in the cure sector (n= 4 cases in comparison to 49 video records)	Identifies more performance details (p<0.05)	D Observational study

Introduction and Outline | Chapter 2

Author(s) (year)	Intervention	Target Group (n)	Outcomes	Quality of Evidence
		Training based on CRM	W	
Awad et al. (2005)	Medical team training (MTT) Training session based on CRM	Multidisciplinary OT teams in the cure sector (n= one surgical service)	Improving communication of anaesthesiologist (p<0.0008) and surgeons (p<0.0004). But not for nurses (p=0.7)	C Pre and post survey
Grogan et al. (2004)	Aviation- based tearmwork training	Multidisciplinary teams in the cure sector (n= 489 participants training/ 463 participants ECC/ 338 pre and post surveys)	Improving attitudes (20 of the 23 items p <0.01)	B Pre and post survey
Leonard et al. (2004)	Human factors training	Multidisciplinary teams in the cure sector	Better culture, improving attitude towards teamwork and safety climate	D Case study
Makary et al. (2007)	OR briefing program	Multidisciplinary OT teams in cure sector (n=306 participants pre & 116 participants post)	Reducing perceived risk for wrong-site surgery and improving perceived collaboration among OT personnel (p<0.001)	C Pre and post survey
Morey et al. (2002)	Formal teamwork training (based on CRM)	Multidisciplinary emergency teams in the cure sector (n= 684 participants/ 6 departments as experimental group & 374 participants/ 3 departments as control group)	Improving team behavior (ρ =0.012), reducing medical errors (ρ =0.039), no differences in subjective workload (ρ =0.668), improving staff attitudes towards teamwork (ρ =0.047) and staff assessment of institutional support (ρ =0.040)	B Quasi- experimental design: pre and post survey (control group)
Nielsen et al. (2007)	Teamwork training curriculum (based on CRM)	Multidisciplinary teams in the cure sector (n= 1.307 participants/ 7 intervention hospitals & 8 control hospitals)	No differences on adverse outcomes $(p>0.05, only one process measure 'time from decision to performance' p=0.03)$	A RCT
Shapiro et al. (2004)	Simulation based teamwork training	Multidisciplinary emergency teams in the cure sector (n= 20 participants/ 2 experimental & 2 control teams)	No differences in team performance (quality of team behavior, experimental group p=0.07, comparison group $p=0.55$)	C High quality observational study
Wallin et al. (2007)	Target-focused medical emergency team training using human patient simulators	Multidisciplinary emergency teams in the cure sector (n= 15 participants)	Improving team skills but no differences in attitude towards safe teamwork ('junior team member should not have control over patient management' p =0.025, all other items non significant p >0.05)	C Observational study

Chapter 2 | Introduction and Outline

Table 2.3 Summary of results	of results (continued)			
Author(s) (year)	Intervention	Target Group (n)	Outcomes	Quality of Evidence
		Interprofessional training	ing	
Clark (2002)	Interdisciplinary team training	Interdisciplinary teams in elderly care (n=30 participants)	Program met educational needs of participants and taught lessons for future similar programs (p value not presented)	C Post survey
Clark et al. (2002)	Interdisciplinary clinical team training	Interdisciplinary teams in elderly care (n=66 participants/ 8 teams pre & 15 participants/ 3 teams post)	No significant improvements	C Pre and post survey
Cooley (1994)	Training on interdisciplinary teams on communication and decision- making skills	Interdisciplinary teams in cure sector (n=25 participants)	Effects of training are minimal	C Mixed methods; high quality observations & post survey
Coogle et al. (2005)	Geriatric interdisciplinary team training (ITT) program	Interdisciplinary team in elderly care (n=61 participants)	Positive changes in team skills (p<0.05) and attitudes (p<0.05) (but, critical amount of training necessary)	C Pre and post survey
Lichtenberg et al. (1990)	Interdisciplinary team training in geriatrics (ITTG)	Interdisciplinary teams in elderly care (n=22 participants as experiment group, n=10 participants as control group)	Learning and retaining information (<i>p</i> <0.0005) Improving the morale of participants	C Mixed methods; post survey (control group) & interviews
Watts et al. (2007)	Interprofessional learning program	Multidisciplinary teams in the cure sector (n=71 participants/ 9 teams at t1, 64 participants at t2 and 42 participants at t3)	Multidisciplinary teams in the cure sector Improving team climate (p<0.001) and awareness of (n=71 participants 4 t1, 64 professional roles participants at t2 and 42 participants at t3)	C Pre and post survey

Author(s) (year)	Intervention	Target Group (n)	Outcomes	Quality of Evidence
		Team training		
Berman et al. (2000)	Assessment training	Multidisciplinary teams in the care sector (n= 19 participants)	Increasing team members' participation (p =0.003), improving staff members' perception of the efficacy of treatment planning and implementation (p <0.001) No differences in team development (p =0.254)	C Pre and post survey
Crofts (2006)	Leadership program	Multidisciplinary teams in the cure sector Impact program variable (n= 6 hospitals)	Impact program variable	C Post survey & feedback
DiMeglio et al. (2005)	Team building intervention	Mono-disciplinary nurse teams in the cure sector (n=165 participants pre & 118 participants post)	Improving group cohesion (p<0.001), nurse interaction (p<0.001), job enjoyment (p<0.05) and turnover	C Quasi experimental design; pre and post survey
Frankel et al. (2006)	Fair en just culture principles, tearwork training and communication and leadership walkrounds	Multi- and mono-disciplinary teams in the cure sector	No reliable results available	D Case study
Gibson (2001)	Goal setting training program	Mono-disciplinary nursing teams in the cure sector (n=120 participants/ 51 teams as intervention group & 67 participants/ 20 teams as control group)	Increasing self efficacy (p<0.05), individual effectiveness (p<0.001), group efficacy (p<0.05) but not team effectiveness	B Quasi experimental design; pre and post survey (control group)
Le Blanc et al. (2007)	Team-based burnout intervention program	Interdisciplinary teams in the cure sector (n=260 participants/ 9 wards as experimental group t1, 231 participants t2, 208 participants t3 and 404 participants/ 20 wards as control group at t1, 145 participants t2, 96 participants t3)	Decreasing emotional exhaustion and depersonalization (p value unknown)	B Quasi experimental study; pre and post survey (control group)
Manzo & Rodriquez (1998)	Team building activity	Teams in health care (n=20 participants)	Helps to reinforce the concepts of an effective team at work.	D Observational study
Stoller et al. (2004)	Teambuilding and leadership training	Multidisciplinary teams in the cure sector (n=30 participants)	Improving development tearmwork and leadership skills (p<0.001)	D Pre and post survey

Chapter 2 | Introduction and Outline
Author(s) (year)	Intervention	Target Group (n)	Outcomes	Quality of Evidence
Strasser et al. (2008)	Staff training program	Interdisciplinary teams in the cure sector (n=227 participants/ 15 teams as intervention group & 237 participants/ 16 teams as control group & 487 patients)	Patient outcomes: improving functional outcome $(\rho=0.032)$ and no differences in length of stay (LOS) or community discharge.	A RCT
Thompson et al. (2008)	Training based on the principles of CAT (cognitive analytic therapy)	Multidisciplinary mental health staff (n=12 participants)	Improving team cohesion and clinical confidence of individual workers	C Interviews
Wilshaw & Bohannon (2003)	Training with time out or debriefing approach	Multidisciplinary mental health care teams (n=35 participants)	Improving competences (p<0.001)	D Pre and post survey
TOOLS				
Benett & Danczak (1994)	Significant Event Analysis (SEA)	Multidisciplinary teams in primary care	Changes in practice were made	D Case study
Crofts (2006)	Critical case review	Teams in the cure sector (n= 45 cases)	Improvement in resolving difficutties and managing and communicating patient case issues	D Case reviews
Evans et al. (1999)	Goal Attainment Scaling (GAS)	Interdisciplinary teams in elderly care (n=102 participants)	Improving team processes and increasing accountability for patient care (p value unknown)	D Descriptive study
Lingard et al. (2005)	Preoperative team checklist	Multidisciplinary OT teams in cure sector (n=33 participants & 11 interviews)	Improving information exchange and team cohesion	C Observational study & interviews
Lingard et al. (2008)	Preoperative checklist and team briefing	Multidisciplinary OT teams in cure sector (n=77 participants & 86 pre and 86 post observations)	Reducing number of communication failures (p<0.001) and promoting proactive and collaborative team communication	C Mixed methods; pre and post survey & observations
Phipps & Thomas (2007)	Daily goal sheets	Multidisciplinary critical care teams in the cure sector (n=26 participants pre & 22 participants post)	Improving perception of communication from a nursing perspective (p=0.05) and improving care (for surgical service) (p=0.04)	C Pre and post survey
Simpson et al. (2007)	ICU quality improvement checklist	Multidisciplinary ICU teams in cure sector	Improvement in attention of core issues, team's collegiality and team bonding	D Descriptive study

Author(s) (year) Intervention	Intervention	Target Group (n)	Outcomes	Quality of Evidence
Verhoef et al. (2008)	Rehabilitation Activities Profile	Multidisciplinary teams in cure sector (n=31 participants pre & 29 participants post)	Improving team members' satisfaction (only in day patient setting)	C Pre and post survey
ORGANISATIONAL INTERVENTI	TERVENTION			
Cendan & Good (2006)	Interdisciplinary work flow assessment and redesign	Interdisciplinary OT teams in the cure sector (n= 4 participants, 401 operations and 253 turnover time evaluated)	Decreasing OT turnover time (p<0.001)	C High quality observational study
Engels et al. (2006)	Continuous quality improvement	Practices in primary care (n=24 practices as intervention group & 21 practices as control group)	Increasing number and improving quality of improving projects undertaken and self-defined objectives met (p unknown)	A RCT
Friedman & Berger (2004)	Reconstructing patient care teams	Multidisciplinary OT teams in the cure sector	Decreasing length of stay (p<0.001), maintaining level of patient satisfaction	C Survey data from the past
Henderson et al. (2006)	EBP (Evidence Based Practice) team-based intervention	Multidisciplinary teams in the cure sector (n=39 participants pre & 38 participants post)	No differences in attitudes towards research and the potential to use research findings	D Pre and post survey
Huby & Rees (2005)	Integrated care pathways	Multidisciplinary teams in health care	It was not optimal effective in improving integration	C Case study
Ledlow et al. (1999)	Animated computer simulation for decision support	Individuals and teams in health care	Developing tearwork and increasing ownership of necessary changes and improvements	C Case study
Macfarlane et al. (2004)	Quality team development program	Multidisciplinary teams in primary care (n=34 participants)	Improving teamwork and patient services	C Interviews
Moroney & Knowles (2006)	Multidisciplinary ward rounds with standard documentation labels	Multidisciplinary teams in cure sector (n=64 participants)	Improving accuracy of predicted discharge dates, decreasing time to carry out clinical interventions Increasing patient involvement, higher development of nurses, higher job satisfaction and improvement in multidisciplinary team relationships Happier working environment, improving staff retention and reducing absence	C Mixed methods; survey; observations; reflections; data collection

Chapter 2 | Introduction and Outline

Team training

Eleven studies used different forms of training but focused on specific aspects of team functioning, namely, team building, leadership, team assessments, staff, goal setting, or burnout. The target group and the outcomes (mostly subjective) of this subgroup were diverse due to the different subjects, but in most studies, positive results were found.

Although in practice team training is often used for team building, only three articles with a (very) low quality of evidence focused on team building (DiMeglio et al., 2005; Manzo & Rodriguez, 1998; Stoller et al., 2004. These studies found improvements in group cohesion, nurse interaction, turnover, competences and teamwork skills. Two studies did not present clear outcomes (Crofts, 2006; Frankel et al., 2006). Frankel, Leonard and Denham (2006) described a combination of interventions – training and tools – within a program. They presented a communication and a leadership tool, namely, the situational briefing model SBAR (Situation, Background, Assessment and Recommendation) and Leadership WalkRounds. SBAR is supposed to help providers organise their thoughts and communication to increase mutual understanding (Frankel et al., 2006). In a Leadership WalkRound, senior leaders of a health care organisation ask front-line staff about specific events, contributing factors, near misses and potential problems, then prioritize events and discuss possible solutions (Frankel et al., 2006). The studies did not present precise information on the evaluation of these tools, which makes it difficult to judge their value.

A study with a moderate quality of evidence on a team-based burnout intervention program found that the program is likely to decrease emotional exhaustion and depersonalization (Le Blanc et al., 2007). Another B-grade study demonstrated that goalsetting training programs are likely to increase self-efficacy and individual effectiveness. However, there was no evidence that the training increased team effectiveness (Gibson, 2001). A study with a high quality of evidence demonstrated that staff training programs are likely to improve patients' functional outcome (Strasser et al., 2008).

Tools

Eight articles studied the use of specific tools to improve team effectiveness. These tools are often presented as easy and less extensive to implement compared to other team interventions. Tools can roughly be divided into checklists, goal sheets and case analysis. Teams were given a training or instruction to use these tools in their daily practice, with the intention of improving communication by making processes, goals and case discussions more explicit. Three types of checklists were identified: preoperative, rehabilitation activities profile and quality improvement. These checklists had to be completed by the teams at a given moment. Two ways of analysing cases to gather themes for improvement are significant event analysis and critical case reviews (Benett & Danczak, 1994; Crofts, 2006b). The *target group* of most studies was multi-disciplinary teams in acute (hospital) care. Various *outcomes* (mostly subjective) were presented: communication failure, team communication, information exchange, team cohesion, satisfaction, team process, accountability, core issues and patient case issues. All

studies had a low or very low quality of *evidence* and showed positive results, especially on communication and team unity.

Organisational intervention

Earlier interventions were aimed at team processes, psycho-social traits and/or task design, which directly influence team outcomes (see Introduction; ITEM model Lemieux-Charles & McGuire, 2006). Organisational interventions are mostly aimed at the organisational context which indirectly effects team outcomes. This category contained eight articles. It involves interventions that focus on decision-making, continuous quality improvement and redesign of care processes. The *target group* in the studies was often less specific, but mostly multi-disciplinary teams in acute (hospital) care. Some *outcomes* focused on specific aspects of team effectiveness as perceived by team members (such as teamwork, attitude, satisfaction, work ownership) and others presented a more general focus but with objective outcomes (such as quality and quantity of improvement projects, integration, discharge dates, turnover time).

Seven of the eight studies had a low or very low quality of *evidence*. Some of these interventions aimed to improve team effectiveness indirectly, such as with inter-disciplinary work flow assessment and redesign, or reconstructing patient care teams (Cendan & Good, 2006; Freidman & Berger, 2004). These interventions seemed to help teams to provide insight in the strong and weak aspects of patient processes and were likely to result in shorter length of stay (Freidman & Berger, 2004) and operation room turnover time (Cendan & Good, 2006). Other interventions were directly related to improving team effectiveness (Ledlow et al., 1999; Macfarlene et al., 2004; Moroney & Knowles, 2006). These interventions seemed to improve teamwork, patient services, ownership, satisfaction, patient involvement, relationships and work environment. Only one study on continuous quality improvement intervention presented a high quality of evidence (Engels et al., 2006). This intervention is likely to result in a higher number of quality improvement projects, a higher quality of these projects and improve achievement of self-defined objectives.

2.4 Conclusion and Discussion

We began with the question: Which types of interventions to improve team effectiveness in health care have been researched empirically, for which target groups and for which outcomes? We identified 48 relevant articles whose studies focused on training, tools and organisational interventions as primary intervention types. No study, however, evaluated precisely the same intervention. Most looked at training programs, which can be, either simulations, training based on CRM, interprofessional training, or (general) team training. The majority of the interventions aimed at improving the effectiveness of multi-disciplinary teams in acute (hospital) care. Because different outcomes were used, the findings are difficult to compare or to synthesize across studies. Most studies focused on non-technical team skills as outcome, for example, communication, cooperation,

coordination and/or leadership and most used subjective outcome indicators (i.e. perceived effectiveness by team members, see introduction). The majority of the studies found a positive association between the intervention and non-technical team skills.

Our second research question was: *To what extent are these findings evidence-based?* Most articles (37) presented a low or very low level of evidence (e.g. small sample pre- or post-studies, observational studies, case-studies). Only eight articles presented evidence-based on a study with a high or moderate quality of evidence (e.g. RCT, high quality pre- or post-survey). These were mostly training programs: simulation training (1), CRM-training (3) and team-based intervention training (3). Articles with high or moderate quality of evidence found positive associations with team behaviour, attitudes (towards teamwork), self-efficacy, individual effectiveness, emotional exhaustion, depersonalization and perception of care. However, these training programs did not seem to succeed in reducing adverse outcomes, improving subjective workload, reducing length of stay, or reducing community discharge.

A downside of these high quality studies is that they often provide little information about the context in which the intervention was tested, making it difficult to determine if the intervention will also be effective in other settings. As interventions to improve team effectiveness are introduced in complex settings with many variables, research and practice would benefit from mixed-method approaches (Campbell et al., 2000; 2007; Creswell, 2003). Using both qualitative and quantitative research methods will help to (1) explain the findings, (2) contextualize the results and (3) build new theories (Brown et al., 2008). The authors also suggest assessing the effect of the intervention on different end points by linking the intervention to structure, process and outcome indicators. New research designs are also emerging, such as Stepped Wedge Trial Design and Evidence-based Co-design, which seem better suited to evaluate interventions to improve team effectiveness than a classic RCT due to the complex and dynamic setting in which such interventions are introduced (Brown et al., 2008b).

There are several gaps in the literature on interventions to improve team effectiveness. Little research has been conducted in long-term care and most studies focus on acute hospital care. Few studies exist on interventions to improve team effectiveness in mono-disciplinary teams in health care. We identified only four such studies in acute care and none in long-term care. More cohesion in outcome measures is needed, as well as replication of same-intervention studies to enable synthesis of findings across different studies. Finally, more high quality evidence needs to be provided using objective outcomes, especially related to tools and organisational interventions to improve team effectiveness.

Some limitations of this systematic review have to be taken into account when interpreting the results and recommendations. Our study was restricted to peer-reviewed articles. By not including books or 'grey' literature, we may have missed relevant publications. Our search was also restricted to a number of key words. They were, however, based on a preliminary search and corroborated during the main search by looking at key words in identified articles. Thus, it is possible, but unlikely that we have excluded relevant key words leading to important publications. However, Salas and colleagues have found similar results concerning team training (Salas et al., 2008; 2008b). A meta-analysis of research in other sectors than health care found team training to be useful for "improving cognitive outcomes, affective outcomes, teamwork processes and performance outcomes... team training accounted for approximately 12–19% of the variance in the examined outcomes" (Salas et al., 2008b, p. 926). Team training also seems to be effective 'across a wide variety of settings, tasks and team types' (Salas et al., 2008b).

For reasons mentioned above, policy-makers should be aware that there is still little high quality evidence available about the effectiveness of the aforementioned interventions, but most evidence points in the same direction. For teams in acute care, there is growing evidence that communication skills and coordination in high risk, complex medical departments can be improved by simulation training and training based on Crew Resource Management. As these are departments where errors due to miscommunication and poor teamwork can have serious consequences, which can lead to a high number of adverse events (Kohn et al., 1999), we advise policy-makers to stimulate the implementation of these training methods. Although the evidence for long-term care also seems to indicate that team training, has positive effects for multi-disciplinary teams in particular, the evidence is still too weak. More research needs to be conducted before any sound advise about the use of such interventions in long-term care can be given. Furthermore, policy-makers should make sure that, when implementing interventions, they also consult case studies, because they provide valuable insights in how to implement these interventions.

Finally, before an intervention is used, the specific circumstances of a team should be diagnosed. The right fit between the intervention and the problems, context and characteristics of a team are more important to improve team effectiveness than the underlying level of evidence.

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Chapter 3

Discrepant Perceptions among Surgical Team Members

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Abstract

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

Design: Questionnaire design

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

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

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

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

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

3.1 Introduction

The surgical team consists of surgeons, anaesthetists, operating theatre nurses and nurse anaesthetists and is a dynamic, multi-disciplinary team. In this article a surgeon is defined as: "a medical specialist who performs surgery: a physician qualified to treat those diseases that are amenable to or require surgery" ("Merriam Webster's Medical dictionary," 2007). Performing safe surgery relies on the ability of the team members to combine professional knowledge and technical expertise with non-technical skills (e.g. communication, teamwork, situation awareness, leadership, decision making) (Yule, Flin, Paterson-Brown, & Maran, 2006).

Many errors that occur in the operating theatre (OT) are attributed to the non-technical skills of the surgical team (Cuschieri, 2006; Flin et al., 2003; Flin et al, 2004; Flin et al, 2006; Helmreich, 2000; Leonard ett al, 2004; Makary et al, 2006; Mishra et al, 2008; Sexton et al, 2006; Yule et al, 2006). In order to work safely and effectively, with a minimum of technical errors, the non-technical skills, communication, teamwork and situation awareness are the most important (Flin et al, 2003; Leonard M et al, 2004; Lingard et al, 2008; Makary et al, 2007; Mishra et al, 2008; Undre et al, 2006; Yule et al, 2006.). In this context communication is defined as "skills for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete the tasks effectively" and teamwork is defined as "skills for working in a group context, in any role, to ensure effective joint tasks completion and team member satisfaction". (University of Aberdeen., 2006b) Furthermore, situation awareness is defined as "developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment, understanding what they mean and thinking ahead what might happen next". (University of Aberdeen., 2006b)

Communication failures have also been reported to contribute to accidents in other high-complex and high-risk industries. In aviation, communication failures between flight crew-members, rather than a lack of technical skills or malfunctioning of the airplane, were responsible for approximately 70% of accidents (Flin and Maran, 2004; Helmreich, 2000; Leonard et al, 2004; Mishra et al, 2008; Sexton et al, 2006).

Procedures in OT are complex and demand intense interaction between team members. Therefore, work processes should emphasise the interdependency of team members and support a good understanding of each team members' tasks, roles and responsibilities. This facilitates effective teamwork, ensures that action is linked to reflection and creates a culture that is open to change.(Edmondson, 2004; Leonard, Graham, & Bonacum, 2004; Mishra, Catchpole, Dale, & McCulloch, 2008; Nestel & Kidd, 2006; Undre, Sevdalis, Healey, Darzi, & Vincent, 2006) Surgical teams should be cohesive and have similar perceptions of communication and teamwork; otherwise they cannot collaborate effectively, establish common goals for improving team performance and ensure patient safety.(Leonard et al., 2004; Mills, Neily, & Dunn, 2008) The purpose of this study was to assess surgical team members' perception of their non-technical skills, specifically communication, teamwork and situation awareness. Research questions were aimed at identifying the category or categories on which team members differed most and where the largest differences in perception between the different disciplines existed. As these non-technical skills are

important for surgical teams to work safely and effectively, it is important to identify these discrepancies before introducing interventions for improvement and adjust implementation strategies accordingly.(Haynes et al., 2009; Makary et al., 2007; Makary et al., 2006; Mills et al., 2008; Thomas, Sexton, & Helmreich, 2003; Undre et al., 2006; Yule et al., 2006)

3.2 Methods

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

Questionnaire

The questionnaire elicited background information, such as date, details on the respondent (age category, gender and function within the hospital) and respondents' opinion on statements about communication, teamwork and situation awareness. The statements were

 Table 3.1 | Definitions for Communication, Teamwork and Situation Awareness (University of Aberdeen., 2006a, 2006b)

Subjects including number of statements in questionnaire

Communication: Skills for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete the tasks effectively.

C1–Exchanging information: giving and receiving knowledge and information in timely matter to aid establishment of a shared understanding among team members. (n=6)

C2–Establishing a shared understanding: ensuring that the team not only has necessary and relevant information to carry out the operation, but that they understand it and that an acceptable shared 'big picture' of the case is held by team member. (n=7)

C3–Co-ordinating team activities: working together with other team members to carry out cognitive and physical activities in a simultaneous and collaborative manner. (n=5)

Teamwork: skills for working in a group context, in any role, to ensure effective joint tasks completion and team member satisfaction. The focus is particularly on the team rather than the task. (n=11)

Situational Awareness: Developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment (patient, team, time, displays and equipment): understanding what they mean and thinking ahead what might happen next.

S1–Gathering information: seeking information in the operating theatre from the operative findings, theatre environment, equipment and people. (n=5)

S2–Understanding information: updating one's mental picture by interpreting the information gathered and comparing it with existing knowledge to identify the match or mismatch between the situation and the expected state. (n=2)

S3–Projecting and anticipating future state: predicting what may happen in the near future as a result of possible actions, interventions or non-interventions. (n=1)

based on two rating systems: the Non-Technical Skills of Surgeons (NOTSS) and the Anaesthetists' Non-Technical Skills (ANTS).(University of Aberdeen., 2006a, 2006b) Table 3.1 presents the definitions of categories and subcategories used in the questionnaire.

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

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

3.3 Results

Survey sample

The five hospitals that volunteered to participate comprised: one university hospital, three teaching hospitals and one general hospital. In total, 235 questionnaires were returned. Response rates per hospital ranged between 29% and 60%, with an average response rate of 39% (Table 3.2).

The respondents represented all disciplines directly involved in surgical procedures: 66 surgeons (and residents), 97 OT nurses, 18 anaesthetists (and trainee anaesthetists) and 40 nurse anaesthetists (for distribution between hospitals, see Table 2). Fourteen participants did not include their function and were therefore excluded from the study. Within all hospitals the surgeons (78.5%) were predominately male and most OT nurses (87.2%) were female. Within the other two groups, men and women were represented

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

Table 3.2 | Response to questionnaire

equally (50% of anaesthetists and 59% of nurse anaesthetist were male). No significant differences were seen for gender between hospitals.

Table 3.3 presents the statements most team members rated as inadequate and Table 3.4 presents the mean ratings, standard deviation and median per subcategory. Additionally, Table 3.5 presents the significant differences of the team members' ratings per subcategory using the Mann-Whitney *U* test. Here, application of the Bonferroni correction for multiple comparisons suggests an appropriate level of P < 0.008.

Table 3.3 | Statements within Communication, Teamwork and Situation Awareness rated inadequate by surgical team members

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

Communication

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

C1 | Exchanging information

Surgeons rated this subcategory as adequate, the mean rating was 3.95 (Table 3.4). The other team members rated this lower: mean 3.12-3.34. This difference of opinion between surgeons and other team members was significant (P<0.001, Table 3.5). No significant differences were found between the OT nurses and Anaesthesiologists (P=0.215), between the OT nurses and nurse anaesthetists (P=0.011), or between anaesthesiologists and nurse anaesthetists (P=0.677). All team members rated the statement "Anaesthetist/nurse anaesthetist communicating an update on the administered medication" as inadequate (Table 3.3).

	subcategory		Surgeon	Anaesthesiologists	OT nurse	Nurse Anaesthetist	Total
	C1	mean (STDEV)	3.95 (1.05)	3.26 (1.25)	3.12 (1.08)	3.34 (1.07)	3.41 (1.14)
tion	U1	median	4.00	3.00	3.00	3.00	
Communication	C2	mean (STDEV)	3.68 (1.14)	2.73 (1.15)	2.35 (0.99)	2.74 (0.97)	2.85 (1.19)
nmr	02	median	4.00	3.00	2.00	3.00	
Con	C3	mean (STDEV)	3.83 (1.16)	3.33 (1.32)	2.77 (1.25)	3.04 (1.23)	3.18 (1.31)
	03	median	4.00	3.00	3.00	3.00	
Team-work	т	mean (STDEV)	3.78 (1.07)	3.47 (0.99)	3.06 (0.99)	3.26 (0.89)	3.32 (1.04)
Team		median	4.00	4.00	3.00	3.00	
s	SA1	mean (STDEV)	3.84 (1.03)	2.84 (1.24)	3.15 (1.14)	3.14 (1.20)	3.30 (1.18)
ene	SAI	median	4.00	2.00	4.00	3.00	
Situation awareness	SA2	mean (STDEV)	4.35 (0.80)	4.11 (0.92)	3.91 (0.78)	4.05 (0.70)	4.07 (0.80)
oné	5A2	median	4.00	4.00	4.00	4.00	
tuati		mean (STDEV)	3.41 (1.23)	2.67 (0.89)	3.74 (0.97)	3.28 (0.63)	3.51 (1.01)
Sit	SA3	median	4.00	3.00	4.00	3.00	

Table. 3.4 Team members' ratings for the subcategories of communication, teamwork and situation awareness: Mean (on 1-5 scale, higher score = higher quality) standard deviation (STDEV) and Median

	Co	mmunica	tion	Team-work	Situa	tion awar	eness
Subgroups compared:	C1	C2	C3	т	SA1	SA2	SA3
Surgeon – OT nurse	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.170
Surgeon - Anaesthetist	<0.001	<0.001	0.001	<0.001	<0.001	0.146	0.025
Surgeon – Nurse Anaesthetist	<0.001	< 0.001	<0.001	<0.001	<0.001	0.001	0.237
Anaesthetist – OT nurse	0.215	<0.001	<0.001	<0.001	0.023	0.074	<0.001
Anaesthetist – Nurse Anaesthetist	0.677	0.811	0.079	0.005	0.055	0.389	0.350
OT nurse – Nurse Anaesthetist	0.011	< 0.001	0.013	0.001	0.919	0.174	0.002

Table 3.5 | Significant differences between surgical team members (Mann Whitney *U* test with Bonferroni correction)*

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

C2 | Establishing a shared understanding

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

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

C3 | Coordinating team activities

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

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

Teamwork

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

All respondents perceived themselves as team players, felt comfortable about expressing their opinion and perceived the OT nurse and nurse anaesthetist as team players. However, the OT nurses did not see the surgeon or anaesthesiologists as team players and rated some statements related to this subject as inadequate (Table 3.3). Most team members, except the surgeons, rated "Contentment with communication and teamwork in OT" as inadequate.

Situation Awareness

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

S1 | Gathering information

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

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

S2 | Understanding information

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

S3 | Projecting and anticipating future state

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

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

3.4 Discussion

The purpose of this study was to study the discrepancies in team members' perception of 1) communication, 2) teamwork and 3) situation awareness. Having a shared perception on what to improve and why, is a necessary precondition to learn collectively and will facilitate the implementation of quality improvement initiatives.(Carroll & Edmondson,

2002; Haynes et al., 2009; Makary et al., 2007; Makary et al., 2006; Mills et al., 2008; Thomas et al., 2003; Undre et al., 2006; Yule et al., 2006) Overall, this study showed a significant discrepancy in perception between the surgical team members in all three categories. Throughout the questionnaire, the surgeons rated most items as adequate (mean 3.41-4.35) in contrast to all other team members where more differences in opinion were found. All team members agreed on two statements being inadequate: "Preoperative briefings with the whole team on the procedure" and "Anaesthesiologists/nurse anaesthetist communicating an update on the administered medication". Pre-operative briefings create an opportunity, just before the start of the surgical intervention, to exchange information on the patient and on the surgical procedure with the whole team.

Within the category, 'communication' results showed a large variety in opinion between team members. The largest discrepancy was found in 'establishing a shared understanding', which is an important factor when performing complex procedures, such as surgery. All team members should understand and be well informed about the surgical procedure and about specific patient related subjects, such as allergies or co-morbidity. A lack in this 'shared understanding' among team members might result in adverse events.(Mills et al., 2008; Sexton et al., 2006) Errors are not always easy to solve, because usually they are complicated and rooted deeply in every day processes. Most team members experience a lack of communication on what to expect, whereas the majority of the surgeons' ratings on this subject were positive. In addition to that, surgeons do not recognise the error as a communication failure, in contrast to the other team members, which was confirmed in this study. Although human errors are inevitable, team members are reluctant to discuss failures. Surgeons might be hesitant to discuss failures because they find it hard to acknowledge that errors are made.(Wu, 2000) Other team members might be discouraged to speak up because of traditional hierarchical structures, authority, social barriers or differences in professional training and responsibility.(Edmondson, 2004; Makary et al., 2006; Thomas et al., 2003; Wu, 2000) Although there are fundamental differences like these between nurses and doctors, it is not fully understood yet why these discrepant attitudes exist. (Thomas et al., 2003)

The overall ratings concerning 'teamwork', also differed between surgical team members. Most surgeons and anaesthetists rated these as adequate. However, the majority of both nurses and nurse anaesthetists rated these as inadequate. Experiencing poor teamwork could lead to team members' withdrawal from discussions, but also to decreased job satisfaction and efficiency and finally result in communication failures and poor performance. In this situation, not hierarchical status seems to be of influence, but not taking time out to discuss complications as a team or to perform a thorough analysis of what went wrong and why. Research in aviation shows that, regardless of workload, poor performing teams spend only 5% of their time to discuss possible complications compared to 33% of time spend by effective teams (Sexton, Thomas, & Helmreich, 2000).

Most team members rated 'understanding information' one of the subcategories within 'situation awareness' as adequate. However, all team members, except the surgeons, rated 'gathering information' as inadequate. Room for improvement and time for a team discussion can only be created if team members share the same perception.(Makary et al., 2006; Mills et al., 2008)

The overall findings of this study are consistent with prior research. The most common pattern being that surgeons have a positive perception of communication and teamwork and that nurses have the most negative perception.(Flin, Fletcher, McGeorge, Sutherland, & Patey, 2003; Flin, Yule, McKenzie, Paterson-Brown, & Maran, 2006; Makary et al., 2006; Mills et al., 2008; Nestel & Kidd, 2006; Sexton et al., 2006; Thomas et al., 2003) OT nurses who have a poor perception of communication, might find it difficult to speak up and are afraid of confrontation. This could also withhold other team members from correcting errors before patients are harmed and inhibit discussing and learning from errors as a team.(Edmondson, 2004; Helmreich, 2000; Nestel & Kidd, 2006; Sexton et al., 2006; Thomas et al., 2003)

A limitation of this study was the number of centres involved; only five hospitals participated of the approximately 90 hospitals in the Netherlands (6%). However, these hospitals represent the whole spectrum of hospital types at a regional level and are comparable for quality of care. On the national list of quality indicators for patient care the volunteering hospital ranked from average to good, but changed positions annually when compared over the last five years.(H Pons, H Lingsma, & Bal, 2009)

Additionally, this study's overall response rate, was relatively low compared to other related studies. (Flin et al., 2006; Makary et al., 2006; Mills et al., 2008) Although the OT nurses' response rates were lower compared to Mills et al. (2008), the response rates for the surgeon and anaesthesia 'crew' were higher compared to Makaray et al. and Mills et al. (Makary et al., 2006; Mills et al., 2008) Overall, the sample is a good representation of the Dutch hospitals and of the population of surgical team members within the hospitals.

This study shows the difference in perception of surgical team members in relation to non-technical skills. Further research on patient safety should focus on team interventions for improvement that include technical as well as non-technical skills. As surgical procedures are complex and error prone, mastering non-technical skills is as important as mastering technical skills in order to perform safe surgery.(Institute of Medicine, 2001) These interventions should support the dialogue between team members, create a shared mental model and focus on team, process and system problems.(Cuschieri, 2006; Edmondson, 2004; Haynes et al., 2009; Helmreich, 2000; Leonard et al., 2004; Lingard et al., 2008; Makary et al., 2007; Makary et al., 2006; Sexton et al., 2006; World Health Organization, 2005; Yule et al., 2006) Interventions to improve communication and teamwork should thus include multiple objectives related to the team, the care process and to the support systems.

So far research shows very little evidence on positive results of team interventions on team effectiveness.(Buljac-Samardzic, Connie M. Dekker-van Doorn, Jeroen D.H. van Wijngaarden, & Wijk, 2009) There is emerging evidence however, that team interventions that include technical as well as non-technical skills might lead to better outcomes. (Haynes et al., 2009) If teams strengthen their ability to reflect collectively on problems encountered, it will improve learning from experience and create a shared understanding between team members. These are all necessary preconditions to prevent adverse

events.(Edmondson, 2004) Interventions like a pre-operative briefing and post-operative debriefing include these different aspects and might be successful and lead to improved team performance.(Haynes et al., 2009; Lingard et al., 2008; Makary et al., 2007; Makary et al., 2006; Sexton et al., 2006)

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Chapter 4

Introducing TOP*plus* in the Operating Theatre

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4.1 Introduction

The focus in healthcare is changing from cost-effective ways of delivering care to delivering care that is safe, has a high standard of guality and improves patient outcomes like a shorter hospital stay and less complications. In this respect, concerns about patient safety are rising worldwide. Different studies suggest that 30-40 per cent of patients do not receive care in compliance with current scientific evidence and, possibly even worse, 20-25 per cent of the care provided is not needed or potentially harmful (Grol 2001, Schuster et al., 1998), Although surgical safety knowledge has improved substantially, it is estimated that 3-16 per cent of all hospitalized patients are affected by adverse events and almost 50 per cent of these events occur during surgical care. involving all surgical disciplines (Cuschieri 2006, World Health Organization, 2008). The replication of the Harvard Medical Study in the Netherlands showed that 5.7 per cent of all patients hospitalized suffered from adverse events causing temporary or permanent disabilities and 4.1 per cent of all patients who die during hospitalization die because of these probably preventable incidents (de Bruijne 2007, Wagner and de Bruijne 2007). Inadequate anaesthetic safety practices, avoidable surgical infection and poor communication among team members are issues that are common, deadly and preventable problems in all countries and all settings (World Health Organization 2008).

It is suggested that half of adverse events can be prevented, provided professionals in healthcare accept that human error is inevitable, teams are willing to learn from mistakes and organisations are looked at from a systems perspective. In this context the team is a small separate unit of a larger organisational system in which management decisions and organisational processes are important factors in relation to patient safety. The lack of support (managerial as well as financial), inadequate training and staff or the absence of reliable management information systems can all be causes for latent failures that eventually lead to adverse events (see Figure 4.1).



Figure 4.1 | Causes for latent failures leading to adverse events (adapted from Reason 2005)

If a team works together effectively in the right working environment, it can avert a considerable proportion of life-threatening complications. 'Improve cooperation among team members' and 'Promote effective team functioning' are two recommendations of the Institute of Medicine (IOM) to achieve a healthcare system that is: *safe, effective, patient centred, timely, efficient and equitable* (Institute of Medicine, 2001). These recommendations support the creation of a system where it is easier 'to do things right than to do things wrong' and underscore the importance of teamwork and communication in relation to patient safety. This is especially true within a complex and critical environment like the operating theatre (OT).

Errors in OT might result in serious consequences for patients and families but also for healthcare professionals themselves and the entire healthcare organisation. Poor communication and collaboration between OT members, being one of the major causes for incidents, renders the team itself to be the most critical resource to improve surgical safety (Sexton et al., 2006). In addition to technical knowledge and skill, good communication and teamwork are critical for teams to be effective in complex and critical environments like the OT (Yule et al., 2006). Good teamwork depends on each individual team member having a better understanding of what others do, to anticipate the needs of other team members, adjust to each others actions and have a shared understanding of the procedure (Baker et al., 2006). Establishing a high level of situational awareness is one of the conditions for teams to work effectively. Yet, most teams in OT have had little team training and cannot rely on adequate work structures to improve effective teamwork and improve patient safety.

The aim of the project TOP*plus* is to improve situational awareness, decision- making, transparency and cooperation among team members; characteristics that are key in the requirements of the World Health Organization (WHO) Guidelines for Safe Surgery (World Health Organization 2008). Improvement of these characteristics helps individual team members to make the transition from autonomous professional to team player and overcome one of the barriers to achieve safe care. Healthcare professionals must be open to others with respect to problems and anticipate accordingly. This also requires looking at a care process as a system including other departments like the clinical ward (Amalberti et al., 2005). This in turn leads to reliable processes where a team of healthcare professionals work together for the benefit of the patient and *structurally* decrease the number of incidents and preventable deaths. It is at this specific team level where the proposed intervention TOP*plus* is situated, the level that is also the least well understood level of the structure of healthcare (Batalden and Splaine 2002).

4.2 TOPplus and Underlying Principles

TOP*plus* is based on the principles of crew resource management (CRM). CRM training encompasses a wide range of knowledge, skills and attitudes including communication, situational awareness, problem solving, decision-making and teamwork (also referred to as non-technical skills). In aviation, where links between teamwork and performance are paramount, CRM has successfully been used for teaching error management to flight crews, 'error management' meaning:

Using all available data to understand the causes of errors and taking appropriate actions, including changing policy, procedures and special training to reduce their incidence of error and to minimize the consequences of those that do occur. (Helmreich 1998, p. 1)

One of the underlying principles of error management is the recognition of the inevitability of human error and the adoption of a blame-free environment.

Most of the time commercial pilots fly as ad hoc teams and often work with unfamiliar team members, with different skills and knowledge and different tasks and responsibilities. circumstances that are similar to the multidisciplinary teams that work together in OT. Like flight crews, surgical teams need good, easy-to- transfer non-technical skills in order to work effectively.

As healthcare is a high risk and technically complex industry, cooperation between professionals is crucial to assure safety and reliability of care processes. Although interdependency is high and teamwork essential, teamwork is often poorly developed (Leggat 2007). One of the barriers for teamwork is partly due to the individual's formal education and training. Professional education forms a solid base for proficiency in technical knowledge and skills and standardization of processes, but also creates job boundaries and 'status' thus stifling communication (Boonstra 2004). Another barrier for teamwork has to do with the culture of the medical profession, like stress recognition. Healthcare professionals have a tendency to deny the influence of stressors such as fatigue, danger and personal problems on performances. Denial of these stressors leads to defensive reasoning, blaming the environment rather than reflecting critically on one's own work performance (Argyris 1991, pp. 99–109).

Another important contributing factor to teamwork is the organisational context in which the teams operate. This directly affects the design of teams and the training and resources available to them (Lemieux-Charles and McGuire 2006). The linkages between the different systems and levels must be seamless, timely, efficient and reliable (Nelson et al. 2002). One of the main contributors of effective teamwork in the organisational context is the influence of leadership (Mickan and Rodger 2005). Leadership at all levels of the organisation – senior leaders, team leaders as well as the front-line staff – plays an important role in the strategy for leading change and creating the desired culture (Pronovost et al. 2006).

The main factors influencing teamwork are these non-technical, behavioural skills rather than a lack of technical knowledge and skills. Teams make fewer mistakes when they know each other's responsibilities, are able to anticipate the needs of others, adjust to each others actions and have a shared understanding of a certain procedure (Baker et al. 2006). Non-technical skills, individual as well as team skills are directly related to failures and patient safety (Flin and Maran 2004). These skills are difficult to measure and difficult to change. However, there is emerging evidence that interventions, like

pre-operative briefings (also called 'time out') have a positive effect on teamwork climate and the reduction of incidents (Makary et al. 2006). In 2003, the Joint Commission on Accreditation of Health Care Organizations (JCAHO) introduced the Universal Protocol based on three primary components: (1) the pre-operative verification process, (2) marking the operative site and (3) taking a 'time out' immediately before starting the procedure (Joint commission on accreditation of Health Care Organizations 2003).

After introduction of the time out in the 'Eye Hospital Rotterdam' in 2004, wrong site incidents were reduced to zero. The introduction of a time out in Intensive Care Units (ICUs) at New York's public hospitals drastically reduced the number of serious infections (Hartocollis 2008). In a recent Canadian study it was concluded that inter-professional checklist briefings reduced the number of communication failures and promoted proactive and collaborative team communication (Lingard et al. 2008). Rather than introducing the whole CRM- concept including team training, development of checklists and a time out at once, it was decided to introduce the time out and a debriefing as the first step, called TOP*plus* (Time Out Procedure *plus* Debriefing).

TOP*plus*: Development and Introduction of a Time Out Procedure and Debriefing

TOP*plus* is designed to support team learning and engage the OT team in double-loop learning. Both the time out (briefing) and the debriefing put a strong emphasis on reflection, which is one of the main principles of adult learning. Leading to reflection *in* action and reflection *on* action, moving from single-loop learning to double-loop learning.

Double-loop learning occurs when an error is detected and corrected in ways that involve the modification of an organisation's underlying norms, policies and objectives (Argyris and Schön, 1978, pp. 2–3; Smith, 2001).

In case incidents occur because of a lack of technical skills or knowledge, or because of negligence, team members need their non-technical skills to solve the problem. The team member being 'lower' in the traditional hierarchy should know how to address the other team member who, in turn, needs to know how to react on suggestions for improvement. also, the team member higher in hierarchy should know how to address technical shortcomings from other team members in a positive way. all this implies the combination of highly specialized technical expertise with the ability to work effectively in teams, form productive relationships and critically reflect on and then change organisational practices (Argyris, 1991). Therefore TOP*plus* is team- and dialogue-based and involves the use of a structured communication protocol.

Registration of TOP*plus* provides structured and reliable information on incidents as well as on communication and teamwork, which is an important condition to support error management. The time out is the final step in a series of checks, which start when the patient leaves the clinical ward and is performed in OT just before incision. In the debriefing, just before closing the wound, incidents occurred during surgery are reported. These data provide a reliable base for a reporting system, which in turn provides the ability to learn from failures and enhance patient safety. If incidents are reported, analysis might show similarities and patterns in sources of risk that may otherwise go unnoticed.

This in turn leads to knowledge and actions for improvement: 'Ultimately it is the action we take in response to reporting – not the reporting itself – that leads to change' (World Health Organization 2005b, p. 3). According to the WHO (World Health Organization 2005b, p. 49), guidelines for safety reporting and learning system must:

- be safe for the individuals who report;
- lead to constructive response and meaningful analysis;
- have a solid base of adequate expertise and financial resources.

The reporting system must be capable of disseminating information on hazards and recommendations for changes.

To support TOP*plus*, a poster was developed to structure and support the time out and debriefing. This was based on The Universal Protocol of the JCAHO (Joint Commission on Accreditation of Health Care Organizations, 2003), the WHO recommendations on Safe Surgery (including their safety checklist) (World Health Organization, 2008) and expert opinions of the 'Eye Hospital, Rotterdam'. The aim of the TOP*plus* procedure was to include *all* members of the surgical team and double-check important factors related to the surgical procedure and patient characteristics. The poster was developed to structure the process, ensure the participation of all team members and improve the dialogue between team members. The objectives of TOP*plus* were:

- to reduce the number of incidents;
- to improve communication and teamwork;
- to reduce hierarchical structures.

Questionnaire: Communication and Teamwork

In order to measure the change in perceptions and opinions of team members on communication and teamwork, a questionnaire was developed comprising four teamwork characteristics: Teamwork and Communication, Decision-making, Situational awareness and leadership. The questionnaires' characteristics were based on the research on identification of non-technical skills and the development of behavioural markers for anaesthetist, surgeons and OT-teams (Fletcher et al. 2003, Undre and Healey 2006, Yule et al. 2006). The questionnaire 'Communication and Teamwork in Operating Theatre' consisted of 59 questions. Table 4.1 shows the design of the questionnaire. All questions had to be rated on a five-point scale, ranging from fully disagree to fully agree. At the end of each questionnaire, comments could be written down.

Team learning starts with dialogue, the capacity of team members to suspend assumptions and enter in a genuine 'thinking together' (Senge, 1990). A factor that might inhibit this kind of learning is the perception of communication and teamwork, which like the perception of leadership, varies considerably among the different team members. Where physicians rate teamwork as high, nurses at the same time perceive it as mediocre (Makary et al. 2006). A cross-sectional survey including physicians and nurses from teaching and general hospitals revealed that, unlike physicians, nurses reported that it is difficult to speak up, disagreements are not appropriately resolved, more input into decision-making is needed and nurse input is not well received (Thomas et al. 2003). All this might inhibit team learning and thus sustainable improvement and patient safety. Therefore, measuring the effect of TOP*plus* on improving communication and teamwork and the reduction of the hierarchical structures is as important as measuring the effect on the reduction of incidents. In the research final project fifteen hospitals are participating, following the protocol for implementation shown in Table 4.2.

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Number of questions	Subject
7	General information (age, sex, hospital, years working in function in particular hospital)
1	Who does the team regard as the leader during the surgical procedure?
53	'Communication and Teamwork' (based on the definitions of the NOTSS and ANTS rating systems) subdivided into:
18/11	- Communication and Teamwork: Skills for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete the tasks effectively.
8	 Situational Awareness: Developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment (patient, team, time, displays and equipment); understanding what they mean and thinking ahead what might happen next.
11	- Decision-making: Skills for diagnosing the situation and reaching a judgement in order to choose an appropriate course of action.
5	- Leadership: Leading the team and providing direction, demonstrating high standards of clinical practice and care and being considerate about the needs of individual team members.

Table 4.1 | Overview questionnaire Communication & Teamwork in Operating Theatre

Table 4.2 | Time frame TOPplus project

Month 1–2	Visit hospital to provide additional information about TOP <i>plus</i> Distribute questionnaire 'Communication and Teamwork in OT' (T0) (Week 1 – Distribution, Week 3 – Reminder, Week 4 – Closure)
Month 2	Introduction TOP <i>plus</i> in OT according to poster Perform TOP <i>plus</i> during 100 surgical procedures Analyse response questionnaire
Month 3	Analyse data and evaluate registrations of TOP <i>plus</i> Adapt poster to local context if necessary Present analysis of questionnaire (T0) and TOP <i>plus</i>
Month 4–6	Resume TOPplus in OT according to (adapted) poster
Month 7	Redistribute questionnaire 'Communication and Teamwork in OT' (T1) (Week 1 – Distribution, Week 3 – Reminder, Week 4 – Closure)
Month 8	Analyse data and evaluate registrations of TOP <i>plus</i> Analyse questionnaire T1 and compare to T0
Month 9	Present data on incidents and questionnaire

4.3 Material and Methods

Pilot TOPplus in Operating Theatre

The project was piloted at three locations: the ambulatory care department of an academic hospital, a teaching hospital and a community hospital. TOP*plus* consisted of

three interventions: (1) a questionnaire 'Communication and Teamwork in OT', (2) a time out and (3) a debriefing. The main objective of the pilot was to test the poster, which was designed to support the time out and debriefing procedures. The main objective of the questionnaire was to measure the effect of TOP*plus* on the perception of teamwork and communication of the individual team members. The first results of the questionnaire will be used for validation of the Dutch translation and will not be elaborated in this chapter.

The objectives of the pilot study were the following:

- Improve patient safety and efficiency during the surgical procedure. improve communication involving *all* team members.
- Test the design of the time out and debriefing: layout of the poster, structure and the designation of specific team members to certain questions and answers.
- Test the registration of incidents that occur during surgery.
- Measure how much time the time out and the debriefing take.

Implementation

Poster A feasibility study was initiated to test the design and the usability of the poster. In all three participating hospitals, the use of the poster was presented and explained to representatives of the OT team. They in turn explained the project's aim and use of the poster to all team members verbally by means of meetings and/or presentations. in addition, all participants received a letter with more detailed information.

The poster was developed based on literature and expert opinions (figure 4.2) (Joint Commission on Accreditation of Health Care Organizations 2003, World Health Organization 2008).

Participants were asked to comment on the layout and structure of the poster. Furthermore, they were asked to comment on the designation of the different team members to ask or answer specific questions. The questions were all related to the formal responsibility of each team member in the operative process. Participants were invited to propose suggestions for improvement.

The shaded bars and corresponding bullets preceding the questions indicated the team member intended to *ask* the question. The purpose of the questions was to engage the dialogue between the team members and was not to memorize the questions. The bullets at the end of each line indicated the team member(s) intended to *answer* the question.

The surgeon starts the time out. Then the anaesthetist or anaesthetic nurse starts with the first question: 'What is the name of the patient?' The surgeon is supposed to answer. Then the surgeon will ask the next question and so on according to the poster.

Time out The time out was initiated when all operating team members were present in OT, just before the first incision. Because the time out is a double-check, the patient did not have an active role, as he/she was already under anaesthesia or pre-medicated in addition to a regional block anaesthesia.



Figure 4.2 | TOPplus poster, first version tested during pilot

During the time out the anaesthetic nurse (demanding a special qualification, which is unknown outside the Netherlands) filled out a registration form, which included the following aspects:

- Did the designated team member ask the question?
- Did the designated team member answer the question?
- Were the questions asked as stated on the poster or in a different way?
- Did all team members participate? If not, please indicate which person did not.
- The time it took to perform the time out.

Debriefing The debriefing had to take place just before closing the wound. This particular moment in the surgical procedure was chosen because, in academic and most teaching hospitals, the supervising surgeon will leave the OT. The surgeon initiated the debriefing by asking: 'Were there any details to be reported?' All team members were invited to report incidents related to the operative process or related to communication and teamwork.
As in the time out, the anaesthetic nurse filled out the registration form. This form included the following aspects:

- the time it took to perform the debriefing;
- the remarks/incidents mentioned by the different team members.

4.4 Results

Implementation of TOPplus

This section represents the results of the pilot of the time out and debriefing in three participating hospitals during 308 surgical procedures (academic n=28, teaching n=180, community n=100).

The time out was performed and reported in 206 out of the 308 procedures. In reality the time out was performed during more procedures, but was not reported. No specific reason was given for not reporting the time out.

Did the designated team member ask the question? An important aspect was the layout of the poster. The layout was directly related to each person's tasks and responsibilities and was meant to involve the whole team in the discussion. Usually checks are performed individually and team members exchange little information, partly due to the strong hierarchical structure in OT. The time out is a relatively small intervention in the operative process but, because of this specific structure, a rather drastic one. Information from the team members directly involved provides important information on the feasibility of the project.

The designated team member asked most questions (Figure 4.3). Differences in a team member asking questions than the one indicated on the poster, were minor and improved during the course of the implementation process. If the designated team member did not ask the question, other team members took the initiative.



Figure 4.3. | Questions asked by team members as indicated on the poster

Did the designated team member answer the question? The designated team member answered most questions (Figure 4.4). In those cases where a team member other than the designated one answered the question, most of the time the surgeon answered. *Were the questions asked as stated on the poster or in a different way*? One of the pilot's objectives was to find out which layout would best support the time out and debriefing and support the involvement of the whole team. In one location, two versions of the poster were used: one version with unabbreviated questions (1) and a second version presenting short remarks (2), more resembling a checklist. It was expected that the questions in version 1 would be abbreviated to short remarks. However, the results (n=28) showed no significant difference in usage between the two versions. Both questions were asked and answered as indicated on the poster. In addition to the pilot in one location, representatives of the different OT teams were asked which poster they preferred. All OT teams in the participating hospitals decided to use the poster with the unabbreviated questions, as these full sentences would support the communication and dialogue within the team.



Figure 4.4 | Answers given by the team members as indicated on the poster

In most cases (n=160) questions were asked according to the poster, in 68 cases it was unknown and in 80 cases a different way of questioning was followed. During almost half of these, differences were reported. The most frequent ones were:

- The team members asking the questions were not reported, only the ones answering the questions (n=27).
- The questions were shortened (n=7).
- The content of the question asked was identical to the one on the poster, but the question was formulated differently (n=4).

Did All Team Members Participate? If Not, Please Indicate who Did Not? In 157 cases all team members participated in the time out. In 76 cases no additional information was given on team members' participation. In 101 cases where not all team members participated, the specific team member was reported (surgeon n=11, nurse n=14, anaesthetist n=61, anaesthetist in training n=1, anaesthetic nurse n=14). The high number of anaesthesiologists not participating (61 out of 101 cases) was mainly the result of working structures. This structure entails that he/she works in two OTs concurrently. A qualified anaesthetic nurse mans both rooms. Therefore, the anaesthesiologists did not participate in the time out because he/she was not present in OT at that specific moment.

How long does it take to perform the time out? The time out took an average of 1.6 minutes (95.58 seconds, see Table 4.3). When the time out took significantly more time, most incidents reported were related to instruments or material missing. There was no specific explanation found for the duration of the time out taking longer in the academic and the teaching hospital.

	Average (sec)	STDEV (sec)	n=	other	missing data
1. Academic	101.79	65.49	28	-	-
2. Teaching	98.61	67.19	122	4	54
3. Community	86.35	59.09	78	1	21
Total	95.58	63.92	228	5	75

Table 4.3 | Duration of the time out (in seconds)

How long does it take to perform the debriefing? The registration of the debriefing was carried out in the academic and community hospital. There is a significant difference in time/duration needed to perform the debriefing between the two locations (Table 4.4). The debriefing in the academic hospitals took twice as much time (52.2 seconds) as the debriefing in the community hospital (24.31 seconds). As with the time out no particular reason was indicated.

Average (sec)	STDEV (sec)	n=	other	missing data
52.22	28.33	28	-	-
-	-	-	-	-
24.31	31.04	70	9	21
	52.22 -	52.22 28.33 	52.22 28.33 28 - - -	52.22 28.33 28 - - - - -

What were the remarks/incidents mentioned during the debriefing? Several remarks and incidents were reported; the most reported ones are described below, subdivided into the categories used in the questionnaire.

- Communication and teamwork (n=44)
 - Improving communication between all team members, improving
 - Information on patient characteristics, surgical day schedule, necessary equipment and surgical approach (32 per cent of the remarks 'communication & teamwork').
 - Improve team spirit and teambuilding (20 per cent).
 - Show respect for your all OT-members and be honest (11 per cent).
- Situational awareness (n=30)
 - Improving information on the surgical day schedule, better preparation of surgery (including instrument set-up), improve written communication,
 - Introduce pre-operative team meeting (33 per cent).
 - Update on status of surgery (7 per cent).
 - Implement standards and protocols, including communicating this to all team members (7 per cent).
- Decision-making (n=1)
 - Improvements should be implemented faster.
 - Leadership (total 5 remarks)
 - Less hierarchy, more commitment, increase consultation and direct communication (60 per cent).

4.5 Discussion

The results of the pilot provided important information for implementing TOP*plus* on a wider scale and ensure that it supports its objectives. Some elements of the poster are still subject to discussion. The main conclusions are presented below. In general, four topics for discussion were reported:

- 1. The moment of the time out just before incision, rather than before administering total or local anaesthesia.
- 2. Performing a debriefing with patients under local anaesthetic.
- 3. Performing a time out and debriefing when three or more similar and relatively simple surgical procedures are scheduled successively.
- 4. The content of the time out being context specific (as expected).

The recently published 'Surgical Safety Checklist' of the WHO (World Health Organization 2008, p. 153) splits the checking process in three parts:

- Before induction of anaesthesia: including patient data confirmed by patient himself/ herself, surgical site, anaesthesia safety check completed? pulse oximeter on patient and functioning?, allergies?, difficult airway/ aspiration? and risk of blood loss?
- Before skin incision: similar to TOPplus.

 Before patients leaves OT: nurse verbally confirms name of procedure reported, instruments, sponge and needles correct?, correct labelling specimen?, equipment problems? and review by the whole team on key concerns for recovery and management of this patient.

TOPplus focused on Part 2. The hospitals that participated in the pilot are now analysing their pre-operative and post-operative process and adding checks related to these phases to their checks. Therefore, TOPplus acted as a catalyst for improving and checking the care process.

Topic 1: Performing a time out after the patient has been given a local or general anaesthetic and is ready for surgery, raised questions. Some incidents might result in postponement of surgery for one or two hours or even another day which might harm the patient, physically as well as mentally. However, one of the problems is the presence of the whole team as a requirement for the time out. Especially for the surgeons being present before anaesthesia as this means a drastic change in routine procedures. At the moment, in one of the hospitals a pilot is carried out to report incidents related to the moment of the time out just before incision.

Team members participating in the pilot suggested several solutions:

- Starting the time out before total or local anaesthesia is administered, with the whole team present including the surgeon.
- Starting the time out before total or local anaesthesia is administered, with the whole team present and one of the surgical staff members or one of the residents representing the surgeon.
- Starting the time out just before incision, but reducing the number of questions asked and developing multidisciplinary checklists carried out by two or more professionals during the pre-operative process.

Questions and answers indicated to be asked/answered by the anaesthetist should be adapted to the local situation. In case the anaesthetist is not present, because of different work structures, the anaesthetic nurse can take over.

Topic 2: Free exchange of information during the debriefing when patients are under local anaesthetic requires good and timely information to the patient and an open and blame-free culture, which takes longer to develop. TOP*plus* by itself is a relatively simple intervention and easy to introduce into daily routines but, in relation to professional and organisational culture, a rather drastic one. Although the first reaction was very positive, it took all participants four to six months to take the appropriate steps for communication with everyone involved and to establish the necessary commitment and support.

Topic 3: in those cases where four or more similar, small and routine surgical procedures were scheduled and the team remained the same, it was suggested to adapt the time out and debriefing:

- Before the whole session: Perform *one* overall time out, discussing surgical procedures and patients' characteristics with the whole OT-team and perform a reduced time out with every surgical procedure, just before incision.
- Perform one overall debriefing of all patients after all scheduled surgeries.

However, this subject is still open to discussion.

Topic 4: Some questions were considered irrelevant and some questions were not addressed in the time out, but perceived as being important in a specific local context. The questions asked during the time out and therefore stated on the poster, should be relevant to all team members. The most important adjustments were the following:

- Questions were adjusted to the ambulatory department such as the anaesthetic procedure, blood products ordered or ASA classification (Physical Status Classification of the American Society of Anaesthesiologists).
- Specific questions on subjects such as allergies, antibiotics or thromboprophylaxis were added according to the needs of the local OT teams.
- Sometimes questions were added to the poster because these were related to specific projects in the hospital such as infection prevention.

The ability to discuss the questions and adapt the content subsequently was much appreciated and is an important condition for establishing commitment and support of all parties involved. This is one of the principles of adult learning where personal involvement is crucial and in line with one of the basic rules of change management, to create powerful guiding coalitions:

Efforts that lack a sufficiently powerful guiding coalition can make apparent progress for a while. The organisational structure might be changed, or a reengineering effort might be launched. However, sooner or later, countervailing forces undermine the initiatives. (Kotter 1996, p. 6)

During the pilot, one adjustment to the poster was made. It concerned the registration of the incidents reported in the debriefing. Analysis of the incidents showed that a more detailed registration of incidents was necessary for adequate reporting. It was decided to create four categories: incidents related to surgery, anaesthesiology, materials and instruments and communication and teamwork (Figure 4.5). As mentioned before several initiatives were started by the hospitals to include checks during the whole care process.

4.6 Conclusion

Most professionals received the development of TOP*plus*, introducing a time out and a debriefing in OT, as a very good initiative. Especially the specific design of the time out (team-based and dialogue-based) and the objective to make it evidence-based created many positive reactions. The objective was to include two non-academic hospitals in the study. At this moment ten Dutch hospitals are participating in the project and a few more have shown interest.

Although results from the final research project are not yet available, some conclusions can be drawn from the pilot study. Conditions for successful implementation are:

 The ability to adjust the poster to the local context in regard to the questions as well as the designated team members is important for successful implementation, because ambulatory care, clinical care and some specific medical specialties have different



Figure 4.5 | Final version of the poster

requirements. The poster should provide a template including basic questions (an 'in addition to' format). Hospitals and departments should then add specific questions and topics relating to their local context and wishes. The questions on the poster should be 'owned' by all OT-team members.

- Good and timely information to the patient about the objectives of the time out and debriefing.
- Creating a blame-free and safe environment. This means that the registration of the incidents should be kept confidential and should be related to the kind of incidents and frequency and not to specific team members.

The precise moment of the time out and consequences for the questions asked is still open to discussion. These questions will be addressed in the final research project. There might be a concern about the time it takes to perform the time out and debriefing. One concern is related to the difference between the academic and community hospital. The second has to do with the total time it takes to perform the time out and debriefing.

A logical explanation for the difference in time between the two hospitals might be the number of people present in OT because of the teaching aspect. Another factor might be new residents joining the OT team rather frequently, as they change hospitals every few months during their medical specialist training. This might influence the time it takes for new work procedures like the time out to become a standard operating procedure. Finally, some hospitals used a different method of time recording during the time out. For example, when a specific instrument was not present, some hospitals recorded the time until the instrument was actually in OT, while others did not include this in their time recordings. Another explanation might be the fact that a correction for patient case-mix was not applied in the analysis. In general, 20–30 per cent of the patients, hospitalized in academic and maybe a little less in teaching hospitals, consists of tertiary referrals in general, including more complex patients where standard protocols are not applicable. Tertiary referrals are rare in community hospitals.

The total time it takes to perform both the time out and debriefing with every surgical procedure might become a concern. With an average production of 20,000-25,000 surgical procedures per annum, the total time adds up to quite an investment. Comparing the costs of the time invested in the time out and debriefing with the costs of incidents might help to overcome financial barriers. Healthcare associated infections in the United Kingdom are estimated to cost £1 billion (\in 1.26 billion) a year. In the United States, the estimate is between £2.3–3 billion (€3–3.7 billion) per year (World Health Organization 2005a). The average costs for a surgical site infection amounts to £5393 (€6780) (World Health Organization 2005a). Furthermore, a re-operation to restore iatrogenic ductal injury after a laparoscopic cholecystectomy costs 4.5-6 times the initial cost of an uncomplicated surgery (Savader et al. 1997). All these costs involve hospital budget. Besides, there are also costs involved for society, such as loss of wages of the patient and caretakers, additional treatment in an outpatient department and additional medication. Also, medical claims due to medical liability lead to cost increase. In conclusion, TOPplus is a feasible instrument which, once adapted to the local context, improves teamwork and communication and in the end improves patient safety. Although it requires some extra time, this will be compensated by fewer incidents in the end.

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Chapter 5

Participatory Design: Implementation of Time Out and Debriefing in the Operating Theatre

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5.1 Introduction

Healthcare is one of the most dynamic and expanding areas in the world. The number of chronically ill patients is increasing, leading to an increased demand for healthcare (Clemensen, Larsen, Kyng, & Kirkevold, 2007a). At the same time, (inter) national studies have shown that annually many medical errors occur. In 2000, it was estimated that 44 000 to 98 000 Americans die each year as a result of medical errors (Kohn, Corrigan, & Donaldson, 2000). In the Netherlands, this accounts for 1735 deaths annually (de Bruijne, Zegers, Hoonhout, & Wagner, 2007). Half of these (possibly preventable) medical errors occur in the operating theatre (OT) (Cuschieri, 2006; de Bruijne et al., 2007). The actual number of medical errors could even be higher, as errors are likely to be underreported (Leape, 1997; Verdaasdonk, Stassen, van der Elst, Karsten, & Dankelman, 2007).

Psychological and human factors research has shown that most errors are caused by defects in the system (Leape, 1997; Reason, 2000). Examples of these system defects are design failures (process, task and equipment design) and organization and environmental failures (psychological precursors, team building and training) (Cuschieri, 2006; Leape, 1997; Leonard, Graham, & Bonacum, 2004; Reason, 2000; Verdaasdonk, Stassen, Widhiasmara, & Dankelman, 2009; Vicente, 2006).

Today's OTs become even more complex systems that are comparable to other hightech, high-risk industries such as aviation, nuclear, oil and offshore industry (Helmreich, 2000; Mishra, Catchpole, Dale, & McCulloch, 2008; Sexton, Thomas, & Helmreich, 2000). The increased use of more complex equipment (instruments and apparatus) and the growing complexity and continuing developments in surgical procedures, demands that knowledge and skills of the entire operating theatre team (OT-team; surgeons, nurses, anaesthetists, assistants and residents) should increase accordingly (Cleary & Kinsella, 2004; Clemensen, Larsen, Kyng, & Kirkevold, 2007b; Healey, Undre, & Vincent, 2006; Makary et al., 2006; Undre, Sevdalis, Healey, Darzi, & Vincent, 2006; Verdaasdonk et al., 2007). Furthermore, the OT-team should be more actively involved during surgery (Healey et al., 2006; Undre et al., 2006).

Although other industries have already introduced quality systems decades ago, these existing systems have to be adapted for optimal use in the healthcare sector. Besides improving the safety of equipment, literature shows that many underlying causes of errors originate on the system's 'team level' (Healey et al., 2006; Mishra et al., 2008). Within the team level it is estimated that 70-80% of errors are caused by insufficient non-technical skills (e.g. communication, situation awareness, teamwork) rather than insufficient technical skills (e.g. knowledge of anatomy and pathology, dexterity, hand-eye coordination) (Cuschieri, 2006; Helmreich, 2000; Leonard et al., 2004; Makary et al., 2006; Mishra et al., 2008; Sexton et al., 2000; World Health Organization, 2008; Yule, Flin, Paterson-Brown, & Maran, 2006).

A proven method for improving these non-technical skills in aviation that has been applied in healthcare recently, is crew resource management (CRM) (Cuschieri, 2006; Helmreich, 2000; Leonard et al., 2004; McGreevy & Otten, 2007; Sexton et al., 2000). This CRM-concept encompasses a wide range of knowledge, skills and attitudes

including communication, situation awareness, problem solving, decision-making and teamwork. Furthermore, the CRM-concept also includes team training, simulations and development of checklists, briefings (time out procedure) and debriefings (Cuschieri, 2006; Helmreich, 2000; Leonard et al., 2004; McGreevy & Otten, 2007). Rather than introducing the whole CRM-concept at once, it was decided to introduce a Time Out Procedure *plus* a Debriefing procedure (TOP*plus*) as the first step (Leape, 1997; McGreevy & Otten, 2007).

The Time Out Procedure (TOP) is the final step in a series of checks, which starts when the patient leaves the clinical ward. This double-check is performed in OT just before incision with the whole OT-team being present.(Leonard et al., 2004; Makary et al., 2006) In the debriefing, just before closing the wound, 'incidents' occurred during surgery are reported (Leonard et al., 2004). These data provide a reliable base for a reporting system, which in turn provides the ability to learn from failures and enhance patient safety (Helmreich, 2000). If incidents are reported, analysis might show similarities and patterns in sources of risk that may otherwise go unnoticed (Leonard et al., 2004; World Health Organization, 2005(p.3)).

The final TOP*plus* will be supported by two applications: a Procedure Support Application for the TOP and a Feedback Application for the Debriefing (Figure 5.1). The Procedure Support Application should support the discussion within the OT-team of the double-check of patient and procedure related factors that are important to prevent errors. The Feedback Application should support the discussion and reporting of patient, procedure, team and communication related details. This Feedback Application should then sent (e.g. weekly) its feedback to the surgical staff.



Figure.5.1 | Overview of the applications to support the Time Out Procedure and Debriefing

Both applications aim to improve the non-technical skills 'communication' and 'teamwork' within the whole OT-team and reduce errors. The final applications will present their content and data by means of monitor screens in OT, enabling all team members to participate in both the TOP and Debriefing. As this user interface thus becomes the connection between man and instruments, it has to be designed adequately. Especially in OT, it is important that the interface is intuitive to the team members, i.e. does not take too much time to understand and only addresses relevant items that are necessary at a specific moment (Degani & Wiener, 1993; Johnson, Johnson, & Zhang, 2005). This makes the content of both applications very important (Degani & Wiener, 1993; Johnson et al., 2005; Verdaasdonk et al., 2009).

As all team members have to work with the applications, they should all be involved in the design process (Cuschieri, 2006; Verdaasdonk et al., 2009). Therefore, the 'Participatory Design' approach has been used. Participatory Design (PD) actively supports multi-disciplinary user participation and engagement into the design process, leading to a designed product that meets the users' specific needs (Namioka & Rao, 1996). Their input is important in order to reach good situation awareness on specifications of the design and the restrictions of the environment, enable development of realistic expectations and reduce resistance to change (Clemensen et al., 2007b; Namioka & Rao, 1996; Vimarlund, Eriksson, & Timpka, 2001).

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

5.2 Design of TOPplus

In order to design, test and evaluate TOP*plus*, the model presented in Figure 5.2 was followed (see following paragraphs).

Content

Time Out Procedure (TOP)

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

 Universal Protocol by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). The protocol was based on three primary components: (1) the pre-operative verification process, (2) marking the operative site and (3) taking a 'time out procedure' immediately before starting the procedure, verifying patient, side and procedure (Joint Commission on Accreditation of Health Care Organizations, 2003). Chapter 5 | Participatory Design: Implementation of Time Out and Debriefing in the Operating Theatre



Figure 5.2 | Model for designing, testing and evaluating TOP*plus* Source: Adapted from Eekels and Roozenburg (1991)

- Time out procedure of the 'Eye Hospital, Rotterdam'. This procedure was introduced in 2004 and is part of a series of checks. The time out just before incision entails verifying whether the patient is positioned on the right table, name and date of birth of the patient, patient's health status, operative side, procedure and whether all equipment and material is present. The introduction in 2004 of the time out reduced their wrong site incidents to zero.
- General Guidelines for designing checklist (Degani & Wiener, 1993).
- Opinions of experts: surgeons, nurse anaesthetists, an anaesthetist, scrub nurses, a human factors specialist/technician, head of the OT department, managers and researchers.

Furthermore, a taskforce was assembled; the design-expert-team. This team consisted of two surgeons, a nurse/ educational scientist, an anaesthetist, a psychologist, a

human factors specialist/ technician, heads of two OT departments and researchers. All members met during the kick-off meeting in September 2007 where the content of TOP*plus* was determined. Hereafter, the design-expert-team communicated mainly via email or meetings where most members were present. The researchers (LW, CD) coordinated this process.

Debriefing

Errors on incidents that occur during surgery are often not discussed as substantial pressure still exists to cover up mistakes (Sexton et al., 2000). However, in order to learn from errors made and prevent similar errors in the future, a debriefing was added to the procedure (McGreevy & Otten, 2007). For the design of a surgical debriefing little literature was available at the moment of design (McGreevy & Otten, 2007). It was decided with the design-expert-team to pilot the debriefing simply by asking, *"Were there any details to be registered"* and also ask for a summary of the details in the conclusion.

Design

Before designing the actual applications, the content was first structured in a poster. Advantages of this approach are that people feel less obstructed to change items (high adaptability), less costs are involved with restructuring elements and it is highly reliable (Johnson et al., 2005; Powsner, Wyatt, & Wright, 1998; Verdaasdonk et al., 2009). Furthermore, not all OT's have appropriate infrastructure to view the applications yet.

In September 2007, the basic TOP*plus* poster (Figure 5.3 was designed with the design-expert-team (Step 2, Figure 5.2) (Clemensen et al., 2007b). Here, the 'call-do-response' method, based on checklists used in aviation, was used (Degani & Wiener, 1993). Team members have to verify (cross-check) that an action was taken. This way all team members are involved and all items are checked systematically.

The coloured bars and corresponding bullets preceding the questions, indicated the team member who has to ask the question. The purpose of the questions was to engage in dialogue between team members and was not intended to memorise the questions (Degani & Wiener, 1993). The bullets at the end of each line indicated the team member(s) who should answer the question. The team members answering the questions are the ones responsible for specific tasks directly related to the surgical procedure. The anaesthetist and nurse anaesthetist were assigned to the same questions and answers. Due to Dutch working structures, the anaesthetist supervises two beds and in his absence the nurse anaesthetist takes over.

The colours used are the basic corporate design colours of the Erasmus University Medical Centre.

The TOP was initiated when all team members were present in OT, just before the first incision (Verdaasdonk et al., 2009). Because the TOP is a double-check, the patient did not have an active role, as (s)he could already be under anaesthesia or pre-medicated in addition to a regional block anaesthesia (Makary et al., 2006).

The Debriefing had to take place just before closing the wound, as in academic and most teaching hospitals the supervising surgeon will then leave OT. The surgeon initiated

the debriefing and all team members were invited to randomly comment (both positive and negative) on the surgical process, on communication and teamwork, the TOP*plus* procedure itself, or other striking events.

	Who should ask the question Who should answer t	he question
	×	TOPplus
Light blue	(su) → Start Time Out	Anest
Dark blue	Anest: A Name of the patient?	Su
	B Date of birth of the patient?	Anest
	C ASA-classification? >2 explain Will it influence the procedure?	Anest
	su: D How many packed cells are ordered?	Anest
Green	E Which procedure are we performing? According to which protocol? Is the patient positioned adequately? What are the critical moments? Which intra-operative measures are necessary?	Su
	Nu: F Which side will be operated on?	Su
	(a): G Which type of anaesthesia? Did the epidural work?	Anest
	Sector I function and the sector of the sector and the sector of the sector and the sector of the se	Anest
	(a): I Are anticoagulants administered? If yes, explain	Anest
	su: J Are instruments & apparatus in working order?	Nu Anest
	Anest → Start procedure	Nu Anest Su
	Debriefing	
	were there any details to be registered ?	Nu Anest Su
	See In conclusion: Summary	Su
	Erasmus MC	f uDelft
	Sugar Nu Scrub nurse / Circulating nurse Anaesthetist / Nurse Anaesthetist	Beitt University of Technology SGL Wauben & CM Dekker-van Doom Contact: La g1 wauben@tudett.nl

Figure 5.3 | TOPplus basic poster very first prototype

5.3 Materials and Methods: testing content and usability and evaluating PD approach

Participants

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

In each hospital the content of the poster was discussed with representatives of the OT-team; the hospital-expert-team (Clemensen et al., 2007b). This hospital-expert-team

could adjust the content of the basic TOP*plus* poster to local needs when considered necessary (Step 2, Figure 5.2). They, in turn, engaged their staff and explained the project's aim and use of the poster to all team members by means of meetings and/ or presentations. Furthermore, all participants received a letter with more detailed information. Each hospital decided, which department(s) would start the TOP*plus* project.

Method

In the third step – test (Figure 5.2) – each hospital had to perform the TOP*plus*, as described on the poster, for at least 100 surgical procedures. This testing had to be performed and supervised by each local hospital-expert-team itself. During the TOP*plus* the nurse anaesthetist observed and registered the following aspects:

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

Evaluation with the hospital-expert-team

In the fourth step – Evaluate (Figure 5.2) – the design's content and usability was evaluated with the design-expert-team and the hospital-expert-teams by means of interactive discussions. Additional comments and remarks were discussed. When considered necessary, the basic TOP*plus* poster and procedure were adapted, leading back to re-designing the TOP*plus* poster (step 2 Figure 5.2)

5.4 Results

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

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

Time Out Procedure (TOP)

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

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

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

 Table 5.1 | Participating departments, response and start date TOPplus

Duration TOP

On average, the TOP took 96 seconds (STDEV = 63 seconds) (A1: 97 \pm 56 sec; A2: 90 \pm 61 sec; T1: 99 \pm 67 sec; T2: 104 \pm 74 sec; C1: 86 \pm 60 sec).

Coordination of procedure by designated team member

This part of the registration form was completed for 596 procedures (partly) performed. Table 5.2 shows that in most cases, 57.9%-76.3%, the designated team member asked the questions. Differences in a team member asking a question other than the one indicated on the poster were minor and also improved during the course of the implementation. If the designated team member did not ask the question, other team members took the initiative.

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

Compliance with procedure as described on poster

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

- The questions were shortened or summarised (n=12),
- The surgeon asked and answered all questions (n=8),
- Some questions were skipped (n=7),
- The surgeon did not cooperate (n=6) and
- A different, not reported way was used (n=15).

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

Table 5.2 | Percentages of team members asking and answering the questions during the TOP

Participation of team members

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

Debriefing

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

Duration Debriefing

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

Only hospitals A1, A2 and T2 recorded if the designated team member asked and answered the questions. However, this part of the registration form was often (30.9-61.0%) not filled out (Table 5.3). The remaining data show that the designated team member asked and answered the questions.

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

Table 5.3 | Percentages of team members asking and answering the questions during the Debriefing

Coordination of procedure by designated team member

Remarks/incidents

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

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

Participatory Design: Implementation of Time Out and Debriefing in the Operating Theatre | Chapter 5

- Question E 'Which intra operative measures are necessary' is unclear (n=1).

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

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

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

Figure 5.4 presents the classification of the remaining 149 remarks. Fifty-one percent (n=76) entailed aspects relating to the non-technical skills communication and teamwork, leadership and situation awareness. The most frequent mentioned remarks are described below (for definitions see University of Aberdeen, 2006 (University of Aberdeen., 2006).

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

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



Figure 5.4 | Classification of the 158 remarks concerning the procedure (anaesthetic, surgical), the instruments or non-technical skills

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

As a first step in the PD-process, before starting TOP*plus* in OT, the basic TOP*plus* poster was discussed in interactive discussions with the hospital-expert-teams (Step 2, figure 5.2). All hospitals decided to use the poster in the pilot phase without any alterations.

Following the pilot, a report was drawn up, describing all relevant items as discussed in the paragraphs above. After testing TOP*plus*, interactive discussions were conducted with the hospital-expert-team, asking them if the results portrayed the situation accurately (Step 4, Figure 5.2). Most of the results were in line with their experiences. However, although they knew errors happened, team members were sometimes surprised by the amount of identical errors mentioned in the Debriefing.

Hospital	Question	T1	Т2	тз
\rightarrow	Start Time Out	1	\checkmark	\checkmark
Α.	Name of the patient?	\checkmark	\checkmark	\checkmark
В.	Date of birth of the patient?	\checkmark	Add: Patient ID number & date of birth; check with wristband	V
C.	ASA classification? ≥2 explain	\checkmark	\checkmark	\checkmark
	Will it influence the procedure?	\checkmark	Add: Allergies	Add: Blood type, rhesus factor, anaesthetic details
D.	How many packed cells are ordered?	х	\checkmark	Moved to C
Ε	Which procedure are we performing	\checkmark	\checkmark	\checkmark
	According to which protocol?	Х	Х	Х
	Is the patient positioned adequately?	\checkmark	\checkmark	\checkmark
	What are the critical moments?	\checkmark	\checkmark	\checkmark
	Which intra-operative measures are necessary?	\checkmark	Х	Х
F.	Which side will be operated on?	\checkmark	\checkmark	Moved to E
G.	Which type of anaesthesia?	\checkmark	\checkmark	\checkmark
	Did the epidural work?	Х	\checkmark	\checkmark
Н.	Are antibiotics administered? If yes, explain	\checkmark	\checkmark	Moved to C
I.	Are anticoagulants administered? If yes, explain.	Moved to C	\checkmark	Moved to C
J.	Are instruments & apparatus in working order?	\checkmark	\checkmark	\checkmark

Table 5.4 | Adaptations to basic TOPplus posters

√ question kept as if

X question deleted

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

The results showed that most questions were asked and answered as stated on the poster by the designated team member. The hospital-expert-teams of hospitals T1, T2 and C1 confirmed this, so there was no need to change the basic structure of the poster. However, the hospital-expert-team of hospital A (1&2) adapted the designated team member asking the questions, as they felt the current way of questioning/answering was counterintuitive and disruptive. It was decided to assign the nurse anaesthetist as designated team member for asking the questions. As a result, questions where the nurse anaesthetist was supposed to answer, the anaesthetist took over (see Figure 5.5).

Further evaluation of the remarks and incidents mentioned in the Debriefing resulted in deleting some questions, which were considered irrelevant and adding some questions



Figure 5.5 | Redesign TOPplus poster for hospital A1&2

which were not addressed in the TOP, but perceived as being important in a specific local context of hospitals T1, T2 and C1. The most important adjustments for hospitals T1, T2 and C1 are presented in Table 5.4.

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

Rather than developing pre-operative checklists, hospital A decided to split the TOP into two parts (Figure 5.5), as the results of the Debriefing showed that a significant part of the incidents (e.g. postponement of surgery, extra anaesthesia, repositioning the patient) could possibly be avoided if the TOP would take place before anaesthesia.

Finally, another interesting point discussed with the hospital-expert-teams was related to the registration of the 'incidents'. The recorded incidents showed that a more detailed registration was necessary for adequate action. Therefore, all hospitals adapted the registration, creating four categories, as these incidents were the most frequent reported: incidents related to surgery, anaesthesiology, materials & instruments and communication & teamwork Figure 5.5).

5.5 Discussion

In order to reduce incidents and improve non-technical skills it was decided to design and implement the TOP and Debriefing, one of the items of the CRM-concept, as the first step (Leape, 1997; McGreevy & Otten, 2007). This is important to create a fertile ground for other initiatives, such as team training and the introduction of checklist. Starting with TOP*plus* also provided team members with information about the whole peri-operative phase and created awareness about the gaps in information transfer between team members and departments.

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

The second aim was to test the design's content and usability. During the pilots a large amount of registration forms was not (completely) filled out. This was probably caused by the high workload of the nurse anaesthetists. However, the recorded data showed that the TOPplus poster design was mostly used as intended and most team members

participated in the process. Most hospitals only changed the order or the phrasing of the questions. However, hospital A also changed the designated team member asking the questions and the moment of performing the TOP. The second version of the TOP of hospital A seems similar to the first two parts, 'sign in' and 'time out, of the recently published 'Surgical Safety Checklist' of the WHO (World Health Organization, 2008).

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

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

During the Debriefing many details were (self) reported in contrast to the official error reporting systems, which only included incidents leading to direct patient harm. It seems that the threshold for reporting these details in the Debriefing was relatively low, partly caused by the 'pilot' character (without punishment) of the study (Leape, 1997). Performing a Debriefing is important, since this is the part in which (small) defects in the procedure can be expressed and reported, providing insight in the 'errors' made. Furthermore, reporting makes it more visible for other people and departments and it enables quantitative analysis (Cuschieri, 2006; World Health Organization, 2005). Reducing reported incidents could improve the operative process, as they often are relatively easy to solve, e.g. instrument related details, administration of antibiotics, surgical site infection (de Vries, Hollmann, Smorenburg, Gouma, & Boermeester, 2009; Haynes et al., 2009; Verdaasdonk et al., 2007).

In this study, most incidents mentioned during the debriefing were related to 'surgery', 'anaesthesia' and/or 'instruments'. Seeing that the TOP*plus* project focuses on reducing non-technical skills, 'team and communication' was added. The hospital-expert-teams and the design-expert-team therefore decided during the interactive discussions to add these four items to the Debriefing in order to remind the OT-team on reporting these incidents. The Debriefing is also comparable to the third part, the 'sign out', of the 'Surgical Safety Checklist' (World Health Organization, 2008). Moreover, future evaluation by means of case studies with the hospital-expert-teams will provide information if these

four items are sufficient for reporting incidents. However, the registration in this study already provided valuable input for designing pre- and postoperative checks. Therefore, TOP*plus* acted as a catalyst for improving and checking the care process.

The final aim was to evaluate whether PD was an appropriate method for designing the TOPplus. PD proved to support situation awareness on design's specifications and the restrictions of the environment and enabled the development of realistic expectations. Most professionals perceived the development of TOPplus as a very good initiative. Especially the ability to discuss the questions and adapt the content subsequently was much appreciated. Making small changes and making TOPplus, context-specific is an important condition for establishing commitment and support of all parties involved, as ambulatory care, clinical care and some specific medical specialties have different requirements.(Makary et al., 2006; Verdaasdonk et al., 2009) The poster and later the applications, should provide a template including basic questions (an 'in-addition-to' format). Hospitals and departments should then adapt the poster: add specific questions and topics relating to their local context and wishes. The questions on the poster should be 'owned' by all team members. However, the adaptations have to fit the original design: the TOP is a double-check, all team members have to be present and open questions have to be asked. Having a hospital specific design also contributes to a higher acceptance of this design. Other factors contributing to the acceptance is good communication (both presentations and documentation) before implementation and enthusiasm of local hospital-expert-teams. This resulted in a relative high rate of participation; only 13 team members did not participate during the pilot.

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

The content and usability of the TOP*plus* proved feasible. Designing the procedure and content by means of the poster first proved advantageous, as the low costs enabled a fast introduction of the TOP*plus*. Now the next step is to design the applications using the PD approach, starting with digitalising the poster's content for performing the TOP*plus* (Johnson, 2005). Expected advantages of digitalisation will be, the automatic registration of duration of the TOP and Debriefing, built in barriers that prevent the procedure to be started before all necessary information and equipment is available and (double) checked, integration with the patient's electronic patient records, improve data collection and the ability to design procedure specific TOPs and Debriefings (de Vries et al., 2009; Helmreich, 2000; van Lier, 2008; Verdaasdonk et al., 2009). However, the ultimate goal of this instrument is to reduce incidents in the peri-operative period and thereby improve patient safety. Chapter 5 | Participatory Design: Implementation of Time Out and Debriefing in the Operating Theatre

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Chapter 6

Adaptive Design: Theory-driven Implementation of Patient Safety Practices in the Operating Theatre

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6.1 Introduction

Patient Safety Practices (PSPs) are too often implemented without adaptations to address the needs of professionals or the characteristics of the local context (Bogner, 2003; Gennari, Weng, & Benedetti, 2005; Kohn, 2000; Leape et al., 2009; Vicente, 2006). PSPs are interventions, strategies or approaches used to prevent and mitigate unintended consequences of healthcare delivery and improve patient safety (Dy et al., 2011; Foy et al., 2011). PSPs are typically introduced by a small, disciplinarily limited group of professionals and consequently do not support all professional disciplines in their daily practices. As a result, PSPs are not always regarded as meaningful and are not fully adopted (Buchanan et al., 2005; Leape et al., 2009). Furthermore, the contextual features (organisational characteristics, policies or types of care) that influence the effectiveness of PSPs vary across healthcare settings and require different implementation strategies (Taylor et al., 2011). Most PSPs, involve changes in the clinical process and adaptation of individual work routines and behaviours (Batalden & Splaine, 2002; Foy et al., 2011). Changing behaviours involves learning new behaviours and unlearning old routines, which is often hampered by existing behaviours, such as hierarchical positions, fear of the unknown, or lack of awareness (Rushmer & Davies, 2004). Therefore, PSPs should be flexible and adaptable and include strategies for improving learning and unlearning.

Most initiatives to improve care delivery processes require a high degree of cooperation within and between teams (Berwick & Nolan, 1998; Bogner, 2003; Ferlie & Shortell, 2001). Most patients are now treated by multidisciplinary teams of professionals, supported by a team of administrative personnel and using sophisticated technology (Plsek & Greenhalgh, 2001). This requires the active engagement of *all* involved, to allow PSPs to be adapted to the organisational context and to the needs of healthcare professionals (Gennari et al., 2005; Keller, 2010; Plsek & Greenhalgh, 2001; Sjoberg & Timpka, 1998; Vicente, 2006; Weng, McDonald, Sparks, McCoy, & Gennari, 2007). Consequently, implementation strategies should include clinical, organisational and behavioural interventions and emphasise interdisciplinary collaboration (Dy et al., 2011; Foy et al., 2011).

Looking at existing theoretical concepts for implementation, many emphasise participation of professionals and discuss the impact of the organisational context (Bogner, 2003; Grol, 2002). Most concepts present facilitators and barriers, describe the steps for implementation and emphasise a system approach. However, these concepts provide little information on how to choose the right strategies or on how and when to include (particular) healthcare professionals. Also they mostly involve only a limited group of professionals in the design and implementation process. Furthermore, there is a real danger that by adapting PSPs, their essential features are lost and they become less effective. According to Greenhalgh et al. (2004), a more theory-driven, process-oriented, participatory approach is needed (Greenhalgh, Robert, & Bate, 2004). Foy et al. (2011) has recommended combining implementation strategies from different theoretical domains (Foy et al., 2011). Therefore, the present study combines two theoretical concepts: Participatory Design (PD) from Industrial Design Engineering to structure the design and implementation process and Experiential Learning (EL) from Organisational Learning to structure the learning process. PD engages a limited group of end-users in the design process in a structured, efficient and safe way, leading to an improved user-oriented design (Gennari et al., 2005; Pilemalm & Timpka, 2008; Weng et al., 2007). To expand the design process to a learning process for all professionals involved, PD is combined with EL. EL emphasises the value of learning cycles, where knowledge can be created and recreated through experience and reflection at individual and at team level. In this way professionals are able to adapt the PSP and make it effective in their own local situation (Kolb, 1984; Kolb & Boyatzis, 1999).

The aim of this study is to explore whether a model combining PD and EL supports the design, implementation and team learning process. This study focuses on the introduction of a PSP in hospital surgical care, namely the so-called Time Out Procedure combined with a Debriefing (TOP*plus*).

In surgical care, more than 50% of patients are harmed by preventable errors (Bruijne de, Zegers, Hoonhout, & Wagner, 2007; Cuschieri, 2006). Almost 70% of these errors, result from a lack of standardized procedures and protocols, inadequate coordination of care and poor communication and teamwork (Bogner, 2003; "Preoperatief traject ontbeert multidisciplinaire en gestandaardiseerde aanpak en teamvorming," 2007; Reason, 2000; Wolff, Boermeester, Janssen, Pols, & Damen, 2010). Previous research has suggested two specific procedures to increase safety in the operating theatre (OT): a Time Out Procedure (TOP), a double-check that takes place immediately before the surgical intervention and a Debriefing (plus) to be held before skin closure (de Vries et al., 2010; Haynes et al., 2009; Wauben et al., 2010). TOPplus is a complex intervention that affects professional behaviour and interferes with clinical processes. To improve adoption among team members, the implementation process should include design (and redesign) strategies and plans for experimenting, learning and making benefits observable (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004). Although introduction of TOPplus allows detection and correction of errors (single-loop learning), it may also necessitate changes in other clinical processes to prevent errors (double-loop learning) (Argyris, 1999a). Therefore, team learning is required.

6.2 Theoretical background

This study combines two theoretical concepts: PD - Participatory Design (Foy et al., 2011; Pilemalm & Timpka, 2008) and EL - Experiential Learning (Kolb & Boyatzis, 1999; Sjoberg & Timpka, 1998).

Participatory Design (PD) - Structure the Design and Implementation process

PD was developed to actively involve end-users in the design and decision-making processes (Gennari et al., 2005; Pilemalm & Timpka, 2008; Scott, Mannion, Davies, & Marshall, 2003; Scott, Mannion, Marshall, & Davies, 2003; Sjoberg & Timpka, 1998;
Weng et al., 2007). The PD process consists of four primary steps: Design, Test, Evaluate and Redesign. During this process, a small group of experts and end-users develops a prototype and another group of end-users is invited to provide feedback to improve the design and the usability of the product. To prevent the loss of essential features, experts safeguard the basic product criteria. For the time out procedure these included questions to prevent wrong side, wrong person and wrong surgical intervention. Research has shown that PD leads to more user-oriented designs and improves actual usage (Weng et al., 2007). Therefore, we assume that applying PD principles structures the design and implementation process of PSPs without sacrificing its essential features.

However, research has shown that the use of PD in healthcare fields is scarce and occurs only on a small scale, within specific units, with a limited number of professionals (Pilemalm & Timpka, 2008). In both Industrial Design Engineering and healthcare, professionals often encounter complex and unstable environments. Protocols help professionals to respond quickly and adequately to unforeseen changes, but compliance with new protocols and procedures can only be achieved if these procedures solve problems in the clinical process and if professionals are willing to change individual behaviours and work routines. Because new protocols implemented in one department or discipline might lead to unintended consequences for other departments or disciplines, all professionals should be involved in the learning process of the design and implementation iterations (Kolb, 1984; Pilemalm & Timpka, 2008).

Experiential Learning (EL) - Structure the Learning Process

Including all professionals in the learning process requires that special attention be paid to individual and team learning during PSP implementation (Carroll & Edmondson, 2002). To overcome resistance and improve adoption rates, extra time is needed to learn from experience and to be able to adapt PSPs to the local context (Shekelle et al., 2011; Wauben et al., 2010). EL emphasises experience, reflection and learning at the individual and organisational level (Kolb, 1984).

EL is defined as 'The process whereby knowledge is created through the transformation of experience' (Kolb & Boyatzis, 1999). EL includes four steps: Learn, Test, Evaluate, Reflect and Learn and Act. Users actively observe their experiences and determine whether and how the PSP improves patient safety and how it affects the work environment (Argyris, 1999b). Therefore, we assume that combining PD with EL principles improves the learning process of all professionals involved.

Adaptive Design (AD)

PD and EL are combined in a new implementation model called 'Adaptive Design' (AD) (see Table 6.1). The AD model blends design and learning cycles in which designers and professionals learn as a team and redesign TOP*plus* in iterations.

The Adaptive Design (AD) model is visualized in Figure 6.1. AD combines several design and learning iterations, each consisting of several steps involving three groups of participants.

 $Chapter 6 | {\it Adaptive Design: Theory-driven Implementation of Patient Safety Practices in the Operating Theatrem of Patient Safety Practices and Practic$

	Process	Participatory Design (PD)	Experiential Learning (EL)	Adaptive Design (AD)
ŝ	Adaptation/ Adoption	Adoption	Adaptation	Adoption & Adaptation
ss istic	Orientation	Product	Process	Product & Process
Process racterist	Design cycle	Structured	Unstructured	Semi-structured
Process characteristics	Knowledge	Objective	Subjective > created & recreated	Objective & Subjective > created & recreated
	End product	Final	Final (uncertain)	Provisional
Design process	Process Steps	Design Test Evaluate Redesign	Learn Experience Reflect & Learn Act	Design & Learn Test & Experience Evaluate & Reflect/Learn Redesign & Act
	Cycles	Iterative	Iterative	Iterative
	User participation	Small, ad hoc end-user group	End-users chosen at random from designated group	All end-users from designated group
u bu	Influence	Limited	No pre-set limits	Adaptable within pre-set limits
Desig	Acceptance	Early adoption	Adoption varies between end-users or user groups	Early adoption by small group, increasingly by more users, eventually by all end-users
	Learning	Participating user group	Individuals & teams from designated users	All users from designated group: individual, team & organisation
	End product	One end product for all end-users	End product might differ between end-users (user groups)	Provisional per user group, subject to change over time

 Table 6.1 | Design Process: Participatory Design – Experiential Learning – Adaptive Design



Figure 6.1 | Adaptive Design Iterations

Participants

In each hospital, three core groups are actively involved in the design and implementation process:

- the design expert team a small team of designers and key-users representing all disciplines in OT and well informed about national and international rules and regulations;
- the local expert team a group of users representing all disciplines involved in surgical care (surgical, nursing, anaesthesiology, managerial, support staff) and familiar with the local context;
- 3) all OT-team members all healthcare providers that are directly involved in surgical care.

Steps in each iteration

- 1a. DESIGN & LEARN. The hospital's local expert team functions as a steering group to provide the necessary information on the local context to adapt the prototype (if necessary). The design expert team safeguards the basic criteria.
- 1b. TEST & EXPERIENCE. The prototype is tested by a small group of users to obtain feedback on content and usability and possible changes required in clinical processes.
- 1c. EVALUATE, REFLECT & LEARN. The design expert team analyses the registered data and presents formal progress reports to the local expert team and all team members. Both teams look for additional information that requires revision of the basic criteria.
- 1d. REDESIGN & ACT. The design and local expert team discuss suggestions to redesign the prototype to ensure the best possible introduction and define evaluation criteria for the TEST & EXPERIENCE step in the second iteration.

To ensure structural evaluation of the procedure following the second iteration, a patient safety committee is involved in the decision-making process and replaces the design expert team.

6.3 Methods

This study is a multiple-site study that uses participatory action research to explore the application of the Adaptive Design model with the design and implementation process of TOP*plus* in OTs of hospitals in the Netherlands. Hospitals were not pre-selected, but joined the project voluntarily over time (2008-2009). Fourteen hospitals were included in this study: four university hospital locations (U1-4), five teaching hospitals (T1-5) and five general hospitals (G1-5). They represent the three main types of Dutch hospitals. The four university hospital locations were regarded as separate hospitals because they differed in size, patient population, type of care provided and in autonomy in policies, working procedures and budget.

Participatory action research permitted the improvement of PSPs and the gathering of empirical data in each iteration, both of which contribute to building a scientific body of knowledge (Bowling, 2002; Trondsen & Sandaunet, 2009). In participatory action research, the researcher has a dual role. At the university hospital locations, the researchers (CD/LW) were actively involved as project leaders and thereby attained a better understanding of the problems and professionals involved. In the other hospitals, the researchers were active as researchers and project advisers.

The TOP*plus* study included four main phases: 1) the start-up, 2) the pilot to test the prototype with one or two disciplines during one hundred surgical interventions, 3) implementation on a small scale and 4) implementation hospital-wide. A basic TOP*plus* poster (the prototype) was developed to support team members in performing the TOP*plus* in OT (see Figure 6.2).



Figure 6.2 | Basic TOPplus poster (prototype)

Preceding the first iteration, a presentation was given providing background information on patient safety issues, the TOP*plus* procedure and the project. All users received written information about TOP*plus* by mail and e-mail. In some hospitals, the researchers also met with team members on the work floor.

Extra pilots and adaptations to the poster or adding specific evaluation criteria were discussed and applied when necessary. Two hospitals (U3, T1) were used as pilot locations to test the AD model and the prototype. After the initial pilot, posters and evaluation forms were tested again in each participating hospital and adapted to the local context in two or more iterations. To test actual usage and usability of the prototype, four levels of influence were identified: basic criteria, content, process and layout.

Levels of Influence

To visualize the users' influence, the authors developed a model representing the levels of influence based on (Verschuren & Hartog, 2005) (Figure 6.3).





The level of basic criteria comprised items that should be addressed in the TOP to guarantee patient safety. These items were in line with national and international rules and regulations set by professional organisations, such as the World Health Organisation, the Joint Commission or by scientific professional associations (Weiser et al., 2010; Wolff et al., 2010). As TOP*plus* was a team intervention, it was also decided that all professional team members directly involved in the surgical intervention should be present. Prior to each iteration, developments at national and international level were checked to see if the basic criteria needed adaptation.

The content level consisted of questions to exchange critical information about the patient and the surgical intervention. Designated team members would ask or answer questions. At each iteration team members were invited to give feedback and add, delete or rephrase questions, or change the designated team member asking or answering questions.

At the process level, the design and local expert teams decided at which moment in the surgical intervention the TOP and Debriefing should be carried out. Again, at each iteration team members could propose changes. At the start of the project the design expert team determined the layout level of the posters. Colours, structure and font were functional: the colours represented the different medical disciplines, the structure supported the procedure and the font should be easy to read from a distance. Following each step, users were free to change the layout. All changes were based on consensus after discussing the analysed data from the iterations with the local expert team.

Data Collection and Analysis

Applying the AD model to TOP*plus* resulted in several iterations (Figure 6.1). Preceding the development of the first iteration (the start-up), the design expert team outlined the prototype for TOP*plus* using expert opinion and the relevant literature to determine which items should be included in the procedure (see Figure 6.2)(de Korne et al., 2011; Wolff et al., 2010). For the design of the prototype, see Wauben et al. (2010) and Dekker et al. (2009) (Dekker - van Doorn et al., 2009; Wauben et al., 2010). To improve communication and teamwork, requirements to emphasise the team aspect of TOP*plus* were established.

During each iteration, data were gathered on actual usage and usability of TOP*plus* at the four levels of users' influence:

- 1. Basic criteria: items added because of external guidelines, regulations or local needs;
- Content: the sequence of questions, questions added, deleted, or rephrased, the team member designated to ask/answer the questions and items discussed in the Debriefing;
- Process: changes in the surgical care process and its effect on documents or systems;
- 4. Layout: colours, font or size of the poster.

To measure all <u>adaptations</u> in the TOPplus procedure and in the surgical process during each iteration, (paper) evaluation forms were developed. In the first iteration, testing the prototype in one hundred surgical interventions, detailed information was gathered on the alterations to adapt TOPplus to the local context. Information included:

- Date and the surgical intervention
- Content of TOP*plus*: were all questions asked and answered, by the designated team member conform to the poster, or by one of the other team members
- Presence and active participation of each team member, if not why
- Duration of both TOP and Debriefing
- Moment in the per-operative process the time out procedure and debriefing were performed
- Incidents that occurred during the per-operative procedure. Initially incidents included four categories: incidents related to the surgical intervention, to the anaesthetic procedure, to lacking or defect of material or instruments and to communication and teamwork
- Extra remarks or suggestions for improvement of the content and process of TOP*plus*, could be added

All incidents were included in the formal reports and clustered in the four categories, but in this stage not analysed. The data about incidents gathered during the iterations

was meant to create awareness and decrease resistance. During the following iterations registration included again the date and the surgical intervention, if TOP*plus* was performed according to the redesigned procedure, if all team members participated and if not why, the duration of both procedures, incidents in the four categories and additional remarks and suggestions.

All data were self-reported and manually registered by one of the OT-team members (in most hospitals by the nurse anaesthetist) during or directly following the surgical intervention. The researchers (CD/LW) gathered and analysed the data. To validate the data and initiate the discussion between team members, both the data and the analysis were presented to and discussed with the local expert teams and in most hospitals with all team members, following each iteration. The number of feedback moments, depended on the number of iterations needed for adaptation and full implementation. Again all team members were invited to provide feedback. To inform each involved in the design and implementation process, formal progress reports presenting all data and the analysis were distributed in hard copy and/or e-mailed to all professionals. Possible adaptations that would improve the procedure were discussed and, if approved by the majority of team members, implemented. Adaptations related to a specific discipline, e.g. Ear Nose Throat (ENT) surgery or Ophthalmology, were discussed with that discipline and the involved OT-team members. The adaptations were then tested in a new iteration.

As one of the researchers (LW) redesigned the posters to adapt the procedure as a result of the team discussion in the implementation process, all alterations to TOP*plus* and inclusion of more disciplines were carefully monitored

To measure <u>adoption</u> of the design and implementation processes across hospitals, data were gathered to determine if TOP*plus* was implemented hospital-wide in all OTs, with each surgical intervention and according to the protocol with all team members present and actively participating and not as a tick box exercise. In each hospital, the following data were gathered: the sequence and duration of the iterations, the participation of the disciplines involved and implementation hospital wide.

6.4 Results

Fourteen hospitals introduced TOP*plus* in their OTs. Almost all of the hospitals adapted TOP*plus* at the content, process and layout levels, but little was changed at the level of basic criteria. The results are described at each level of influence; the basic criteria, content and process of TOP*plus* and the lay out of the poster and for each iteration.

Results at the Basic Criteria Level

In the first iteration (during the first one hundred surgical interventions), all team members accepted the basic criteria without deleting or adding items. In the second iteration, one hospital (G5) decided to change the TOP format. Rather than asking each other questions, the surgeon and anaesthesiologist informed the other team members about the patient, the surgical intervention and the anaesthetic intervention. Other team

members were invited to crosscheck and ask for additional information, thus keeping the team dialogue intact. In the four university hospitals (U1-4), the criterion 'with all team members present' was adapted by adding that the resident performing the surgical intervention could represent the staff surgeon provided he/she was actively involved in the intervention.

Results at the Content Level

Alterations following the first iteration were limited to the TOP (see Table 6.2). Some questions were irrelevant for small surgical interventions and were deleted, e.g. for ambulatory care 'Did the epidural work?' was deleted, as this kind of anaesthetic procedure is never used in ambulatory care. Some questions were added because of the complexity of the surgical intervention (e.g. 'Are co-practitioners informed?'), the large number of people present in OT (e.g. 'Does everyone know each other?'), or because the patients were included in a research project (e.g. 'Is this a study patient?').

Following the second iteration, to improve patient handover from OT to recovery, three hospitals (T4, T5, G5) added additional questions to the debriefing about post-operative care addressing 'postoperative orders' or 'additional diagnostic lab work'. With complex interventions, team composition may change during an intervention. Because nurses are always present, three hospitals decided that the nurse anaesthetist (T4, G5) or circulating nurse (U4) would ask all of the questions.

Questions		Start-up	Iteration 1	Iteration 2
Questions reordered in	ТОР	U1, U4, G4	U1, U3, T3, T4, T5, G1, G4	T4, T5, G5
	DEB	-	G4	-
Questions added in	ТОР	U1*, U4*, T4*, T5, G2, G4, G5	U1*, U3*, U4, T2*, T3*, T4*, T5*, G1*, G2*, G3	U4, T4*
	DEB	U1, U4, T4	U1*, T2, T3, T5*	T4, T5, G5*
Questions deleted in	ТОР	U1*, U2*, U4*	U1*, U2*, U3*, T2*, T3*, T4, T5, G1*, G2, G3*, G4*, G5	G5*
	DEB	-	U2, G4	G5*
Questions rephrased in	ТОР	U1*, U4*, T4*, T5*, G4, G5	U2*, U3*, T2*, T3*, T4*, T5*, G1, G3*	U4, T4*, G5*
	DEB	-	Т3	T4*, G5*
Procedure				
Designated team member	TOP	U4*	U1*, U3*, U4	U4*, T4*, G5
asking question in	DEB	U4	U1, U3	T4
Designated team member	TOP	U4*	-	U4, T4, T5
answering question in	DEB	U4*	-	T4, T5

Table 6.2 | Hospitals making alterations at the Content Level

*Hospitals making more than one alteration

TOP: Time Out Procedure

DEB: Debriefing

Results at the Process Level

Alterations at the process level were primarily related to the time at which the TOP was performed. Some team members stated that performing the TOP just before incision was too late. Errors like wrong patient or wrong site should be detected and corrected before induction. To perform the TOP before induction was difficult, as it interfered with existing surgical routines, such as early-morning patient handover. To solve this problem, the four university hospitals decided that the residents could replace the surgeon. Nine hospitals (U2, U4, T1, T2, G1, G2, G3, G4, G5) adapted the pre-operative process by adding a pre-anaesthesia check, conducted by two of the team members (G1, G2). Five hospitals (U1, U3, T3, T4, T5) decided to perform the TOP before induction and introduced a second comprehensive TOP just before skin incision. The children's hospital (U1) decided to perform the TOP without the patient because it would be too stressful for children. All adaptations were regarded as good solutions that better fit local needs without endangering patient safety.

Experimenting with 100 surgical interventions in the first iteration resulted in more comprehensive TOPs for small surgical interventions requiring only local or regional anaesthesia (G4), ophthalmology, ear, nose and throat (ENT) surgery (U1, U2, T1, T2, T3, T4, G2, G3) and ambulatory care (U3).

In the second iteration, hospitals U1 and U4 introduced a TOP to structure patient handover from the clinical ward to OT. ENT specialists in hospital U1 implemented another initiative that introduced two new TOPs provided the OT-team did not change: 1) TOP-5, to discuss five small consecutive interventions and 2) a comprehensive TOP, in which only the intervention, the surgical site and patient identification were checked again just before each intervention.

The implementation of TOP*plus* in OT also initiated discussions with other medical disciplines. These resulted in new TOP*plus* procedures for similar complex interventions with other medical disciplines, such as intervention cardiology, intervention radiology, oncology (chemotherapy) and obstetrics. TOP*plus* implementation also inspired the design and implementation of a checklist covering all of the critical steps in the surgical care path (U1, U2, U3, U4, T1, G1).

Results at the Layout Level

Only four hospitals made changes at this level. Over time, the TOP*plus* layout became almost standard. Following the first iteration, U1 combined the pre-anaesthesia TOP and the pre-incision TOP, performed in two different rooms, into one poster. For each room the other TOP was de-emphasised (smaller and grey font). Hospital U2 combined the basic TOP*plus* and the TOP*plus* for small interventions into one poster. Following the second iteration, T4 and T5 adapted the layout and colours to correspond to the hospital's corporate house-style.

User Participation & Duration of implementation

User participation varied between hospitals: six hospitals initially implemented TOP in all surgical disciplines (U2, U3, U4, T3, G4, G5), seven hospitals (U1, T1, T2, T4, T5, G2,

G3) in one surgical discipline and one (G1) in two disciplines. Ultimately all end-users were actively involved in the design and implementation process. However, the time to include all users varied (see Figure 6.4).



Figure 6.4 | Time for each of the four phases in each participating hospital

The whole project included four phases: the start-up, the pilot to test the prototype with one or two disciplines, implementation on a small scale and implementation hospital-wide. The TOP*plus* study itself included only the last three phases.

The largest differences were found in the period preceding the pilot, the start up phase. Three hospitals (U2, U3, T3) spent a significant amount of time discussing the project getting the means and support. Only one hospital (G3) stayed within the initially planned time of one to two months. Although, the three hospitals that spent the most time before starting the pilot were large hospitals, much time was also spent by two of the smaller hospitals. One large academic hospital spent less time (U1). The duration of the first iteration was almost the same for all hospitals. Teams tested the prototype with one hundred surgical interventions and data were gathered in one week. The next phases, implementation on a small scale and hospital-wide implementation, varied per hospital. Some hospitals decided not to start on a small scale, but to involve all OTs at once. Others decided to successively include different disciplines over time. Most hospitals completed the iterations to implement TOP*plus* hospital-wide within one year. For the whole design and implementation process (from start-up till hospital

wide implementation), the university and teaching hospitals required an average of 12.8 months and 10.6 months respectively and the general hospitals required an average of 8.2 months. Most hospitals needed at least three iterations to adapt TOP*plus* to the surgical disciplines or the type of care provided (clinical or ambulatory). The following topics were discussed mostly: whether to perform the TOP before or after induction, the necessity of having all team members present for both the TOP and Debriefing and whether and to what extent TOP*plus* could be adapted to meet local needs.

6.5 Discussion

The aim of this study was to explore whether Adaptive Design, a combination of PD and EL, supports the design, implementation and team learning process of TOP*plus*. The results showed that each hospital adapted TOP*plus* to its own needs and context. Adaptations were primarily made at the content, process and layout levels. The basic criteria remained essentially unaltered. All of the hospitals succeeded in implementing TOP*plus* with all surgical disciplines in all OTs.

Only recently, experts in the field of patient safety acknowledge the importance of understanding both contextual and psychological factors that influence implementation of PSPs (Foy et al., 2011; Kaplan et al, 2011; J. C. Ovretveit et al., 2011). Foy et al. (2011) suggested combining different theoretical domains to successfully implement PSPs. However, little or no research is available on the theory-driven design and implementation of PSPs. Research in this field has focused primarily on behavioural aspects and is rarely combined with theories related to contextual factors (Foy et al., 2011; Perkins et al., 2007).

Combining Participatory Design and Experiential Learning principles into the Adaptive Design model appeared to be successful for implementing TOP*plus*. The design cycles facilitated team discussion and promoted the active participation of all professionals through experimentation and learning in a structured way. The formal reports provided objective information and data transparency and created awareness about the number and the kind of errors that occurred during surgery. Both the structured approach and the objective information flow with the formal reports stimulated team members' willingness to participate and improved adaptation and adoption. Changes to TOP*plus* were easy to track, as one of the researchers (LW) would redesign the posters used and design of new procedures for other disciplines took place in close cooperation with the researchers (CD/LW). The researchers role was limited to asking clarifying questions (e.g. which items need to be addressed and by whom, or adding new team members as the perfusionist with thoracic surgery) and adapting the poster and the evaluation forms accordingly.

The learning cycle established by Adaptive Design deepened the team learning process, from single-loop learning by adding or deleting (irrelevant) questions to TOP*plus* to enhance error detection, to double loop learning by initiating additional interventions to prevent errors from occurring. For instance, performing the TOP before induction was a major decision for the surgical staff because it meant adapting their

long-standing early-morning patient handover (Argyris, 1999a, 1999b; Rushmer et al, 2004). The data gathered with each iteration, including duration and the incidents during the per-operative process, helped in the decision-making process. Adaptations were implemented step-wise and re-evaluated with each iteration. Implementing TOP*plus* with one or two disciplines at a time increases motivation and adoption (Greenhalgh, Robert, Macfarlane, et al., 2004; Resar, Rozich, Simmonds, & Haraden, 2006). In some hospitals, the local expert team decided to include all disciplines in the pilots. Although this did not affect the AD design iterations, it did sometimes increase the time needed for an iteration so all users could experiment, provide feedback and become involved in the decision-making process.

The iterative process of adaptation and engaging professionals supported and facilitated adoption. Professionals valued the possibility to be able to adapt the procedure step by step, which made it feel like an initiative of their own. When professionals are allowed to experiment and the results are visible and the new procedure is perceived as practical, resistance decreases (Greenhalgh, Robert, Macfarlane, et al., 2004; ledema et al., 2009; Molleman, Peters, Hosman, & Kok, 2005; J. Ovretveit, 2009). To create 'a fertile ground for change', it is important to put the professional in the lead, provide frequent structured feedback and actively involve all team members (Berwick & Nolan, 1998; ledema et al., 2009).

Differences in the duration of the project were partly by choice. Some hospitals decided to start with all disciplines at once, while others took a stepwise approach. The time it took to start with the pilot mainly differed because of the level of support that was already available in a specific hospital for introducing TOP*plus*.

This study has certain limitations. Voluntary participation and the supportive nature of the project might have influenced the results positively, but did not guarantee actual participation of all professionals. Working with many hospitals simultaneously and being actively involved as researchers was time consuming and resulted in delays to follow up on questions and to provide feedback. The time required by each hospital to complete the project is not predictable. Barriers that emerge during the course of the project might require an extra iteration. However, this is exactly the aim of AD, it is not "... a simple *linear process done to people*" but a strategy to encourage team members to decide what works best in their local context, based on evidence (J. Ovretveit, 2009). Another limitation was the dual role of the researchers, which challenged the researchers' ability to remain objective. To prevent bias, member checks were done during each iteration in each hospital by presenting the data and the analysis and discussing these with the local expert teams and in most hospitals with all team members.

A third limitation is the lack of a control group. However, we explicitly used participatory action research to explore if and how Adaptive Design could be effective, find out what would work and what not and validate the method used. The experience and scientific knowledge gathered in this study, allows better matching of groups in future research with an experiment and control group.

The impact of TOP*plus* might be greater and more lasting than can be demonstrated in this research project and, over time, may result in more changes at the system level (Ferlie & Shortell, 2001). It is important to obtain a better understanding of the impact of similar PSPs on clinical as well as behavioural aspects. Future research should use a longitudinal approach to measure results over time and include a multi-level analysis.

Participatory action research permits the accumulation of a significant amount of knowledge and experience, identifying which adaptations are generalizable with slight alterations and which are highly context specific. It provides insight into the factors that prevent and facilitate PSP implementation and how they can be resolved or exploited. In 56 interviews, which the researchers (CD/LW) conducted in six hospitals following the project, it was confirmed that especially the step-wise introduction, the involvement of all professionals and the objective data were highly appreciated. Compliance to the TOP was almost 100%, to the Debriefing almost 60% (forthcoming article). Since PSPs, but also the organisational context differ in size, character or complexity and over time other confounders might influence the results, it is important to carefully structure and monitor the implementation process and adapt the steps in the iterations when necessary. Every hospital has its specific local circumstances that need to be taken into account and only surface in the process of implementation. The Adaptive Design model provides a structure for successful implementation.

 $Chapter 6 | {\it Adaptive Design: Theory-driven Implementation of Patient Safety Practices in the Operating Theatrem of Patient Safety Practices and Practic$

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Chapter 7

Time Out Procedure in the Operating Theatre: Arguments for Improved Teamwork

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Abstract

Objective: Measure the effect of the introduction of a team-based combined time out procedure and debriefing on surgical team members' perception of: Communication, Teamwork, Situation Awareness, Decision-making and Leadership.

Background: In surgical care, a large percentage of preventable complications are caused by inadequate non-technical skills, such as poor teamwork and communication breakdowns. Research suggests that team interventions, like a time out procedure with a focus on the process of care, support these skills, improve team performance and ultimately improve patient safety.

Methods: In a pre-post study design (T_0 - T_1), perception of team members of Operating Theatres (OT) in 13 Dutch hospitals was measured, using a questionnaire comprising 62 items (statements) on relevant non-technical skills and additional questions on respondents' characteristics. Participating OT-team members were: surgeons, anaesthesiologists, OT-nurses and nurse anaesthetists. Statistical analysis included testing for reliability (Cronbach's Alpha) and for comparison and significant differences between T_0 and T_1 (Mann Whitney-U).

Results: T_0 resulted in an overall response rate of 44% (n=725) and T_1 in 36% (n=554). Especially perception of 'Communication' and 'Decision-making' were rated significantly higher at T_1 . The items 'discussing the surgical intervention pre-operatively with the entire team', 'performing debriefings with the whole team' and 'checking whether the team is ready to start' showed the highest increase in ratings (P<0.001). OT-nurses showed the most significant increase in ratings (33 items), nurse anaesthetists the least (12 items).

Conclusion: A time out procedure and debriefing in OT, designed and implemented as a team procedure improves perception of important non-technical skills.

Keywords: Patient Safety, Human factors, Non-technical skills, Multidisciplinary teams, Surgical Team Checks

7.1 Introduction

In surgery, complications are common and a large percentage is preventable (Kohn, 2001). Although surgeons are highly trained and educated, inadequate non-technical skills, such as poor communication and teamwork, often undermine the effectiveness of surgical care (Catchpole, Giddings et al. 2007). Mastering both technical and non-technical skills is an important condition to create a safe and reliable work environment (Undre, Sevdalis et al. 2006, Makary, Mukherjee et al. 2007).

Surgical care is complex and high risk provided by multidisciplinary teams, involving medical specialists, nurses and administrative support staff. With some surgical disciplines, allied healthcare professionals with a technical background join the team. This multidisciplinary team has a shared responsibility to secure the well-being and safety of each patient (2009). Inadequate non-technical skills, such as a lack of information sharing or communication breakdowns, are directly related to patient safety and might lead to a higher risk for complications or sometimes even death (Mazzoco, Petitti et al. 2009). 'Communication', 'Teamwork', 'Situation Awareness', 'Decision-making' and 'Leadership' are identified as important non-technical skills to decrease preventable errors and improve team performance (Leonard, Graham et al. 2004, Mishra, Catchpole et al. 2008). These skills are vital and enable teams to create the right environment to discuss problems encountered, which in turn supports shared decision-making and learning collectively (Edmondson 2004, Lemieux-Charles and McGuire 2006). However, attaining these skills as a *team* is difficult. In practice, surgical teams mostly work in changing team compositions and team members have different perceptions of each other's roles, tasks and responsibilities within the team. This undermines good communication and coordination of tasks within the surgical team (Undre, Sevdalis et al. 2006).

Research suggests that team interventions with a focus on the clinical care process support teams in attaining those necessary non-technical skills to improve team effectiveness (WHO 1988, Buljac-Samardzic, Dekker-van Doorn et al. 2010) Work processes should support communication and teamwork among team members and emphasize the interdependency of team members (Sexton, Makary et al. 2006). Several studies indicate that the introduction of a time out procedure in the operating theatre (OT) helps to improve teamwork and reduce errors (Lingard, Regehr et al. 2008, de Vries, Hollmann et al. 2009, Haynes, Weiser et al. 2009, Norton and Rangel 2010). However, most studies measured the effect on medical errors right after or a few months following implementation and not over a longer period of time. To find out if the effect on improved teamwork is sustainable, more time is needed. Literature suggests that to reduce resistance and scepticism and improve acceptance of new work procedures, it is important to use a 'bottom up' approach and to include all relevant professionals in the design and implementation process (Greenhalgh, Robert et al. 2004) (Wilkinson, Rushmer et al. 2004).

The aim of this study is to measure the effects of a combined Time Out Procedure and Debriefing (TOP*plus*), 12-18 months after implementation in OT, on team members' perception of the non-technical skills: 1) Communication, 2) Teamwork, 3) Situation

Awareness, 4) Decision-making and 5) Leadership. TOPplus was designed and implemented engaging all professionals involved in surgical care.

TOP*plus*: Time Out Procedure (TOP) and Debriefing (*plus*) Based on literature and expert opinion a Time Out Procedure (TOP) and Debriefing (*plus*) were developed. Both were designed and implemented as team procedures, inviting all team members to actively participate in these procedures. To improve implementation, the procedures were adapted to the local hospital context stepwise and in close collaboration with all team members from all relevant disciplines. With each step in the design and implementation process more professionals and disciplines were invited to participate and provide feedback, so TOP*plus* could be adapted to their specific needs (Dekker - van Doorn, Wauben et al. 2009, Wauben, Dekker-van Doorn et al. 2010, Taylor, Dy et al. 2011).



Figure 7.1 | Basic TOPplus poster

7.2 Methods

Study design and sample

This study used a pre-post study design. The setting consisted of OTs in 13 Dutch hospital locations, which volunteered to participate: three university hospital locations (U1-3), five teaching hospitals (T1-5) and five general hospitals (G1-5). Together these hospitals represent the main types of hospitals in the Netherlands and cover approximately 15 percent of all Dutch hospitals.

Data collection

Perception of OT-team members on 'Communication', 'Teamwork', 'Situation Awareness', 'Decision-making' and 'Leadership' was measured preceding the introduction of TOP*plus* in OTs (T_0) and 12-18 months following implementation (T_1). The whole project took almost four years; the first hospital started early 2008 and the last hospital finished late 2011. The time from the start of the project towards full implementation of TOP*plus* hospital-wide in all OTs differed per hospital.

The questionnaire was based on two validated observational rating systems developed by the University of Aberdeen: the Non-Technical Skills of Surgeons (NOTSS) (University of Aberdeen. 2006) and the Anaesthetists' Non-Technical Skills (ANTS) (University of Aberdeen. 2006, Mills, Neily et al. 2008) (See Table 7.1). The questionnaire comprised 62 statements (items) to measure the respondent's opinion on non-technical skills and additional questions to obtain background information, such as date and respondent

Category & definition	Sub-category
Communication Skills for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete the tasks effectively.	C1: Exchanging information C2: Establishing a shared understanding C3: Coordinating team activities
Teamwork Skills for working in a group context, in any role, to ensure effective joint tasks completion and team member satisfaction.	No sub-category
Situation Awareness Developing and maintaining a dynamic awareness of the situation in theatre based on assembling data from the environment, understanding what they mean and thinking ahead what might happen next.	S1: Gathering information S2: Understanding information S3: Projecting and anticipating future state
Decision-making Skills for diagnosing the situation and reaching a judgment in order to choose an appropriate course of action.	D1: Considering options D2: Selecting and communicating option D3: Implementing and reviewing decisions
Leadership Leading the team and providing direction, demonstrating high standards of clinical practice and care and being considerate about the needs of individual team members.	L1: Setting and maintaining standards L2: Supporting others L3: Coping with pressure

Table 7.1 | Definitions of categories and subcategories used in the questionnaire (University of Aberdeen.2006a, 2006b)

characteristics (age category, gender, function within the hospital, years working in function and years working in that particular hospital). The items were randomly distributed over the questionnaire using a five-point Likert scale ranging from '1' (strongly disagree) to '5' (strongly agree). All professionals directly involved in surgical care in OT were invited to fill out the questionnaire, thus including four groups of professional disciplines: surgeons, anaesthetists, OT nurses and nurse anaesthetists. In this article, the surgeon is defined as: "a medical specialist who performs surgery: a physician qualified to treat those diseases that are amenable to or require surgery" (Merriam-Webster.com. Merriam-Webster, n.d. Web. 30 July 2014. <http://www.merriam-webster.com/dictionary/ surgeon>). The questionnaires were anonymous to team members' name, but not to team members' function or hospital. All data were analysed confidentially.

Data analysis

Statistical analyses were performed using IBM SPSS Statistics Version 19.0.0 for Mac. Reliability of scales was tested using Cronbach's Alpha. A distinction was made between five subscales: 18 items Communication ($\alpha T_0/T_1=0.88/0.86$), 11 items Teamwork ($\alpha T_0/T_1=0.78/0.77$), 8 items Situation Awareness ($\alpha T_0/T_1=0.57/0.64$), 11 items Decision-making ($\alpha T_0/T_1=0.86/0.88$) and 14 items Leadership ($\alpha T_0/T_1=0.82/0.85$). Although Situation Awareness' Cronbach's Alpha was low, it is still acceptable, as a Cronbach's Alpha from 5 to 7 is acceptable for scales with less than 10 items (Field, 2005). Comparisons between T₀ and T₁ for all OT-team members per statement were performed using the Mann-Whitney U-test to test for significant differences, making P<0.05 statistically significant.

7.3 Results

Survey sample

Table 7.2 shows the respondents and their characteristics. In each hospital, all four groups of professionals participated in the project and filled out the questionnaires. The 'surgeons' and 'residents' represent the following surgical disciplines: General Surgery, Gynaecology, Ear Nose Throat (ENT), Urology, Plastic Surgery and Orthopaedics.

With a total of 725 respondents, the T_0 resulted in an overall response rate of 44% ranging from 29% to 74% between hospitals. Sixty-three respondents did not provide information about their function or belonged to other groups than the four groups of professionals in a surgical team and therefore excluded from analysis (see Table 2). T_1 resulted in an overall response rate of 36% (n=554), ranging from 14% to 90% between hospitals. The non-response analysis showed that the underlying reason for a low response differed per hospital. According to the OT-manager of one of the teaching hospitals, the low response with the second measurement (T_1) was related to an overload of questionnaires from other projects at that particular moment and in one of the other teaching hospitals, the group of nurse anaesthetists refused to participate in T_1 because of poor communication wit the surgical staff (oral communication). At T_1 , 35 respondents

							F	Function								
	Send out	ا بە	Surgeons & Residents	ons & ents	OT Nurses	ses	Anaesthesiologists & Residents	ologists & ents	Nurse ana	Nurse anaesthe-tists	Miscellaneous	snoəu	Total received	ceived	Respo (% of tot	Response rate (% of total received)
Hospital	٤	F	2	F	۴	F	2	F	2	7	TO	F	2	F	2	F
5	80	80	8	13	21	10	9	9	15	12	2		52	41	65	51
U2	180	180	SS	24	27	24	7	5	6	20	0	4	78	77	43	43
ខា	74	77	9	5	10	9		-	5	4	10	8	31	24	42	31
F	150	150	15	18	18	12	4	2	10	8	7	-	54	41	36	27
12	65	30	ო		18	27	4		÷		e		39	27	60	06
٤	154	154	22	10	18	5	6	ę	5	ę	-		55	21	36	14
T4	160	160	33	27	33	21	6	5	28	21	15	б	118	83	74	52
T5	355	277	24	25	50	30	9	7	18	24	÷	12	109	98	31	e
61	130	130	œ	œ	21	7	ę	ę	5	4	-		38	22	29	17
G2	85	85	9	10	26	29		ę	7	10	4		43	52	51	61
G3	80	80	5	2	14	14	-	ę	÷	£	0		33	24	41	30
G4	50	50	4	12	13	7		2	5	4	e		25	25	50	50
G5	77	77	1	7	22	5	e	ı	12	9	0	-	50	19	65	25
Total	1640	1530	178	161	291	197	52	40	141	121	ន	35	725	554	44	36
Gender: Female			35	40	266	173	22	16	70	64						
Male			143	119	21	20	29	24	70	57						
Unknown			,	7	4	4	۰	ı	۲							
Average years in functions - STDEV	n functions - S		10.8-8.9	11.3 -8.9	14.3-9.7	14.6-9.8	10.5-7.8	13.9-9.4	14.5-10.3	16.0-10.6						
Average years in hospital - STDEV	n hospital - STI		8.7-8.1	9.1-8.0	9.7-8.1	11.0-8.4	7.9-6.3	9.0-7.8	12.7-9.7	14.2-10.2						
Age: 18-25			-	-	39	25	-	ı	6	8						
26-35			35	32	86	59	7	4	35	29						
36-45			60	43	78	52	24	16	38	24						
46-55			48	59	62	44	14	10	45	47						
56-65			33	24	17	12	5	6	13	11						
Unknown			-	2	6	5	-	-	-	2						

Table 7.2 | Respondents and characteristics

Table 7.3 Mean, STDEV and Mann-Whitney U test for 59 statements concerning non-technical skills (A-symp. Sig. (2-tailed))	erning non-technical sk	cills (A-symp. Sig. (2	-tailed))	
statements		Fun	Functions	
		Mean (STDEV) *₌	Mean (STDEV) *=P≤0.05; **=P≤0.001	
	Surgeons &	OT nurses	Anaesthetists &	Nurse
	Residents		Residents	Anaestheti

	Surgeons & Residents (SURG)	OT nurses	Anaesthetists & Residents (ANEST)	Nurse Anaesthetists
Ι	T0 (sd)	T0 (sd)	T0 (sd)	T0 (sd)
	T1 (sd)	T1 (sd)	T1 (sd)	T1 (sd)
C1-Exchanging information (n=6):				
C1.1. ANEST / Nurse Anaesthetist keeps SURG informed on administered medication during surgery	2.68 (1.124)	2.38 (0.910)	2.02 (0.860)	2.54 (0.937)
	2.84 (1.055)	2.49 (0.930)	2.70 (0.823)**	2.50 (0.886)
C1.2. SURG communicates if surgery is not going to plan	4.15 (0.771)	3.20 (0.836)	2.52 (0.896)	2.99 (0.945)
	4.23 (0.577)	3.48 (0.678)**	3.43 (0.813)**	3.10 (0.760)
C1.3. ANEST communicates if surgery is not going to plan	3.61 (0.988)	2.91 (0.876)	3.21 (0.893)	3.12 (0.932)
	3.71 (0.979)	3.16 (0.774)*	3.72 (0.793)*	3.12 (0.885)
C1.4. I feel uncomfortable addressing the SURG directly C1.5. I feel uncomfortable addressing the ANEST directly C1.6. ANEST provides info about changes in patient's condition as they occur	su	su	SU	su
C2-Establishing a shared understanding (n=7):				
C2.1. SURG communicates planned procedure to team	4.32 (0.802)	2.90 (0.913)	2.41 (0.804)	2.65 (0.965)
	4.54 (0.537)*	3.66 (0.745)**	3.60 (0.841)**	2.98 (0.961)*
C2.2. SURG communicates planned actions to team	4.13 (0.868)	2.93 (0.855)	2.71 (0.893)	2.64 (0.928)
	4.37 (0.621*)	3.48 (0.761)**	3.40 (0.744)**	2.92 (0.862)*
C2.3. ANEST communicates planned procedure to team	3.55 (1.138)	2.53 (0.889)	3.42 (0.848)	3.20 (0.945)
	3.84 (1.044)*	3.03 (0.898)**	3.80 (0.648)*	3.24 (0.884)
C2.4. ANEST communicates planned actions to team	3.49 (1.134)	2.56 (0.862)	3.73 (0.795)	3.29 (0.875)
	3.79 (1.059)*	2.95 (0.883)**	3.75 (0.630)	3.23 (0.847)
C2.5. Surgery is discussed pre-operatively with entire team	2.73 (1.060)	1.84 (0.828)	1.58 (0.637)	1.70 (0.870)
	3.86 (0.980)**	3.21 (1.020)**	3.43 (0.984)**	3.03 (1.056)**
C2.6. Debriefings (post-operatively) are performed with entire team, discussing what problems occurred	3.11 (1.079)	2.10 (0.905)	1.81 (0.908)	2.09 (0.824)
	3.87 (0.897)**	2.95 (1.071)**	3.13 (0.966)**	2.71 (1.068)**
C2.7. Communication in OT is clearly audible and well articulated	su	su	SU	SU

statements	Functions Mean (STDEV) *=P⊴0.05; **=P⊴0.001	≤0.05; **=P≤0.001		
	Surgeons & Residents (SURG)	OT nurses	Anaesthetists & Residents (ANEST)	Nurse Anaesthetists
	T0 (sd)	T0 (sd)	T0 (sd)	T0 (sd)
	T1 (sd)	T1 (sd)	T1 (sd)	T1 (sd)
C3-Coordinating team activities (n=5):				
C3.1. SURG checks pre-operatively whether entire team is ready to start	3.91 (1.073)	2.31 (0.993)	2.08 (1.055)	2.48 (1.150)
	4.32 (0.676)**	3.17 (0.966)**	3.50 (0.906)**	2.95 (1.007)**
C3.2. ANEST checks pre-operatively whether entire team is ready to start	3.15 (1.183)	2.16 (0.879)	3.12 (1.022)	2.45 (1.031)
	3.60 (1.154)**	2.60 (0.976)**	3.62 (0.963)*	2.76 (0.954)*
C3.3. Surgery is stopped when asked by OT nurse	3.02 (1.146)	2.17 (0.989)	2.27 (1.026)	2.36 (1.033)
	3.27 (1.177)*	2.51 (1.032)**	2.67 (0.828)*	2.57 (0.985)
C3.4. In an emergency situation I will speak up, regardless of who might be affected C3.5. Surgery is stopped when asked by ANEST	รม	su	รม	SU
Teamwork (n=9)				
T1. I am satisfied with communication & tearnwork in OT	3.72 (0.928)	2.48 (0.830)	2.67 (0.810)	2.53 (0.948)
	3.99 (0.753)*	3.16 (0.831)**	3.58 (0.931)**	2.90 (0.942)*
T2. SURG is a true team player	3.94 (0.845)	2.78 (0.787)	2.76 (0.857)	2.57 (0.782)
	4.11 (0.808)	3.09 (0.759)**	3.21 (0.704)*	2.73 (0.831)
T3. OT nurse is a true team player	4.15 (0.736)	3.80 (0.638)	3.50 (0.810)	3.61 (0.779)
	4.15 (0.752)	3.93 (0.633)*	3.73 (0.838)	3.81 (0.724)*
T4. Nurse Anaesthetist is a true team player	3.95 (0.850)	3.48 (0.782)	3.87 (0.661)	3.72 (0.721)
	4.02 (0.783)	3.71 (0.690)**	4.03 (0.726)	3.83 (0.738)
 T5. I address the SURG by his/her first name T6. I address the ANEST by his/her first name T7. I prefer to agree with other team members than to voice a different opinion T8. I am a true team player T9. ANEST is a true team player 	З	SU	SU	SU

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statements	Functions Mean (STDEV) *=P⊴0.05; **=P⊴0.001	.05; **=P≤0.001		
•	Surgeons & Residents (SURG)	OT nurses	Anaesthetists & Residents (ANEST)	Nurse Anaesthetists
	T0 (sd)	T0 (sd)	T0 (sd)	T0 (sd)
	T1 (sd)	T1 (sd)	T1 (sd)	T1 (sd)
S1–Gathering information (n=5):				
S1.1. Relevant patient data are discussed pre-operatively with entire team	3.09 (1.148)	1.93 (0.934)	1.94 (0.916)	1.99 (1.018)
	4.14 (0.784)**	3.12 (1.099)**	3.63 (0.925)**	3.11 (1.072)**
S1.2. During surgery, SURG asks the anaesthetic team repeatedly for update on patient's condition	3.61 (1.006)	2.87 (0.896)	2.29 (0.879)	2.46 (0.917)
	3.57 (0.926)	2.88 (0.834)	2.83 (0.958)*	2.34 (0.781)
S1.3. I check if specific equipment and surgical instruments are available and ready for use, pre-operatively	3.48 (1.084)	4.12 (0.537)	2.75 (1.366)	4.02 (0.945)
	3.98 (0.926)**	4.34 (0.505)**	3.30 (1.244)	3.98 (0.831)
S1.4. I check all relevant patient data in OT, pre-operatively	4.48 (0.746)	4.00 (0.753)	4.39 (0.682)	4.41 (0.639)
	4.63 (0.535)	4.16 (0.675)*	4.63 (0.489)	4.54 (0.501)
S1.5. With each surgery I know its guidelines/protocols	SU	ns	SU	SU
S2-Understanding information (n=2):				
S2.2. Working in this hospital is like being part of a large family	4.35 (0.771)	4.11 (0.716)	4.28 (0.688)	4.05 (0.734)
	4.50 (0.616)	4.29 (0.632)*	4.32 (0.904)	4.21 (0.654)
S2.3. I always ask questions when I feel there is something I do not understand	SU	ns	SU	SU
D1-Considering options (n=4)				
D1.1. When making choices during surgery, SURG asks for opinion of other team members	3.00 (0.994)	2.66 (0.879)	2.19 (0.886)	2.57 (0.899)
	3.31 (0.946)*	2.74 (0.777)	2.67 (0.869)*	2.42 (0.717)
D1.2. When making choices during surgery, ANEST asks for opinion of other team members	2.78 (0.963)	2.36 (0.864)	3.06 (0.968)	2.90 (0.930)
	3.01 (0.925)*	2.44 (0.823)	3.17 (0.775)	2.74 (0.824)
D1.3. Pros and cons of surgical approach are discussed pre-operatively with all relevant team members	2.37 (0.961)	1.71 (0.756)	1.54 (0.576)	1.67 (0.815)
	3.10 (1.106)**	2.53 (0.979)**	2.88 (0822)**	2.41 (0.939)**
D1.4. Guidelines regarding surgery are discussed pre-operatively with entire team	2.75 (1.065)	2.21 (0.785)	1.81 (0.715)	2.09 (0.827)
	3.35 (1.041)**	3.01 (0.894)**	2.90 (0.841)**	2.78 (0.931)**

	,			
statements	Functions Mean (STDEV) *=P≤0.05; **=P≤0.001	0.05; **=P≤0.001		
	Surgeons & Residents (SURG)	OT nurses	Anaesthetists & Residents (ANEST)	Nurse Anaesthetists
	T0 (sd)	T0 (sd)	T0 (sd)	T0 (sd)
	T1 (sd)	T1 (sd)	T1 (sd)	T1 (sd)
D2-Selecting and communicating option (n=5)				
D2.1. When suspecting conversion, SURG communicates this to anaesthetic team	4.21 (0.827)	3.32 (0.816)	3.24 (1.012)	3.32 (0.939)
	4.45 (0.634)*	3.59 (0.740)**	3.79 (0.811)*	3.52 (0.872)
D2.2. When deviating from original plan, SURG explains chosen option	4.15 (0.856)	3.11 (0.883)	2.60 (0.913)	2.86 (0.983)
	4.32 (0.619)	3.35 (0.827)**	3.33 (0.694)**	2.89 (0.883)
D2.3. When deviating from original plan, ANEST explains chosen option	3.38 (1.094)	2.78 (0.881)	3.35 (0.890)	3.49 (0.852)
	3.77 (0.995)**	2.92 (0.909)	3.76 (0.675)*	3.36 (0.827)
D2.4. It is explained to entire team why a contingency plan has been adopted	3.49 (1.061)	2.56 (0.947)	2.58 (0.936)	2.51 (0.907)
	3.88 (0.837)**	2.92 (0.863)**	3.28 (0.905)**	2.79 (0.896)*
D2.5. Decisions are clearly communicated to entire team	3.80 (0.903)	2.44 (0.821)	2.73 (0.940)	2.54 (0.909)
	4.10 (0.686)*	2.90 (0.795)**	3.25 (0.927)*	2.68 (0.767)
D3-Implementing and reviewing decisions (n=2)				
D3.1. SURG updates team on progress of surgery	3.90 (0.812)	3.02 (0.852)	2.42 (0.915)	2.66 (0.901)
	4.03 (0.822)	3.31 (0.762)**	2.85 (0.770)*	2.72 (0.798)
D3.2.1 call for assistance if required	ns	ns	SU	us
L1-Setting and maintaining standards (n=2)				
L1.1. I clearly follow OT protocol L1.2. I introduce myself to new/unfamiliar team members	SL	su	SL	SU
L2-Supporting others (n=5)				
L2.1. SURG gives me constructive criticism where necessary	4.11 (0.840)	3.16 (0.907)	2.88 (1.041)	2.75 (1.008)
	4.05 (0.742)	3.37 (0.872)*	3.36 (0.986)*	2.80 (0.928)
L2.2. ANEST gives me constructive criticism where necessary	3.75 (1.127)	2.75 (0.997)	3.74 (0.966)	3.67 (0.825)
	3.78 (0.964)	2.77 (1.018)	3.69 (0.850)	3.50 (0.754)*

Table 7.3 | Mean, STDEV and Mann-Whitney U test for 59 statements concerning non-technical skills (continued)

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statements	Functions Mean (STDEV) *=P⊴0.05; **=P⊴0.001	≰0.05; **=P≤0.001		
	Surgeons & Residents (SURG)	OT nurses	Anaesthetists & Residents (ANEST)	Nurse Anaesthetists
	T0 (sd)	T0 (sd)	T0 (sd)	T0 (sd)
	T1 (sd)	T1 (sd)	T1 (sd)	T1 (sd)
L2.3. SURG ensures delegation of tasks is appropriate	4.06 (0.818)	2.98 (0.853)	2.47 (0.915)	2.84 (0.877)
	4.21 (0.637)	3.35 (0.793)**	3.45 (0.795)**	3.04 (0.851)
L2.4. ANEST ensures delegation of tasks is appropriate	3.63 (0.958)	2.98 (0.797)	3.44 (0.801)	3.29 (0.940)
	3.95 (0.676)*	3.26 (0.781)**	3.84 (0.638)*	3.34 (0.812)
L2.5. I give credit for tasks performed well	SU	su	su	SU
L3-Coping with pressure (n=7)				
L3.1. SURG emphasises urgency of situation when there is an emergency/	4.37 (0.752)	3.35 (0.867)	3.15 (1.036)	3.24 (0.936)
critical situation	4.41 (0.671)	3.59 (0.807)*	3.60 (0.900)*	3.32 (0.868)
L3.2. ANEST emphasises urgency of situation when there is an emergency/ critical situation	4.14 (0.936)	3.34 (0.892)	4.24 (0.716)	3.92 (0.771)
	4.32 (0.759)	3.60 (0.780)*	4.32 (0.721)	3.84 (0.778)
L3.3. SURG makes appropriate decisions under pressure	4.31 (0.662)	3.71 (0.599)	3.22 (0.659)	3.52 (0.679)
	4.36 (0.580)	3.86 (0.561)*	3.73 (0.652)*	3.47 (0.747)
L3.4. ANEST makes appropriate decisions under pressure	4.15 (0.706)	3.73 (0.592)	3.78 (0.553)	3.80 (0.662)
	4.26 (0.671)	3.91 (0.542)*	4.00 (0.667)	3.78 (0.713)
L3.5. In emergency situation I take responsibility for the patient L3.6. SURG continues to lead the team through the emergency L3.7. ANEST continues to lead the team through the emergency	SL	ñ	٤	S

C= Communication S= Situation Awareness D= Decision-making L= Leadership

did not belong to one of the four groups of professionals in a surgical team, or did not fill out their function and were thus excluded from the study.

All disciplines were represented at all sites and comparable to surgical teams in other OT-settings national as well as international. Women were overrepresented among OT-nurses and the surgeons were mostly male. Within the group of anaesthetists and nurse anaesthetists, male/female were equally represented.

Perception non-technical skills

Table 7.3 shows the P-values, the mean values and the standard deviation at T_0 and T_1 of all statements concerning non-technical team skills. Three items appeared to be irrelevant in some hospitals and were excluded from the final analysis: two items were related to the resident and anaesthetist in training and are not relevant for general hospitals, one item was related to conversion (changing from endoscopic to open surgery) and were not applicable for all surgical disciplines.

In total, 39 items (66.1%) were rated significantly higher at T_1 compared to T_0 by at least one discipline: 11 items by all four disciplines, 5 items by three disciplines, 14 items by two disciplines and 9 items by only one discipline. Twenty items (=33.9%) with high ratings at T_0 scored similar high ratings at T_1 . One item - L2.2: ANEST gives me constructive criticism where necessary - scored significantly lower at T_1 (P=0.027) by one discipline, the nurse anaesthetists.

Especially the categories Communication and Decision-making were rated significantly higher at T_1 . Within the category Communication, the items 'discussing the surgery pre-operatively with the entire team (C2.5)', 'performing debriefings with the whole team (C2.6)' and 'checking whether the team is ready to start (C3.1-2)' showed the highest increase in ratings (P<0.001). The anaesthetists' ratings (mean) related to discussing the surgical intervention pre-operatively increased from 1.58 to 3.43. Within the category Decision-making, the items concerning 'discussing pros and cons of the surgical approach with all relevant team members (D1.3)' and 'discussing the guidelines (D1.4)' were rated significantly higher (P<0.001) with all four disciplines. Again, the anaesthetists' ratings 'discussing the pros and cons' increased most: from 1.54 to 2.88. Within the subcategory Leadership L1, mean ratings were high, but statistical analysis showed no significant differences, which was expected as similar high ratings were already found at T_0 (>3.92).

The group of OT-nurses showed the most significant increase in ratings (33 items), followed by the anaesthetists (29 items) and the surgeons (21 items). The least significantly increased ratings were found within the group of nurse anaesthetists (12 items).

7.4 Discussion

The aim of this study was to measure the effects of the introduction of a team-based time out procedure and debriefing (TOP*plus*) in OT on team members' perception of the non-technical skills that are critical to provide safe care. The assumption that this

introduction would improve perception (Wauben, Dekker-van Doorn et al. 2011), was to a great extent confirmed by our findings. Significant improvement within all disciplines was found with items in all categories and subcategories except in the subcategory Leadership L1, which already received high ratings at T_0 . As this subcategory mainly refers to norms and values of professional behaviour, in following protocols and guidelines, high ratings at both T_0 and T_1 were expected.

Significant increase in ratings for all disciplines was found in 11 out of 59 items in the questionnaire, the majority (n=7) within Communication and Teamwork. These results are in line with earlier research findings that show that the use of a surgical safety checklist not only reduces the number of incidents in surgical care (Lingard, Regehr et al. 2008, de Vries, Hollmann et al. 2009, Haynes, Weiser et al. 2009), but also improves non-technical skills, especially communication skills (Norton and Rangel 2010, Helmio, Blomgren et al. 2011, NHS 2011). In this study, the most significant effects of TOPplus were found within the group of OT-nurses (33 items) and the least significant effects were found within the group of nurse anaesthetists (only 12 items improved significantly). These results might also be a reflection of the non-response of the nurse anaesthetists because of poor teamwork in one of the participating hospitals (T_2). The overall lower ratings by the nurse anaesthetists could be due to strong hierarchical structures in OT ^{33, 40}. In the additional comments in the questionnaire, some respondents (n=11) explained that sometimes they found it difficult to take their role and speak up which depended on the surgeon or anaesthesiologist they were working with that day. The nurse anaesthetists also rated one item (L2.2 anaesthetist giving constructive criticism) significantly lower, but in the additional comments by the respondents no specific explanation was found.

As expected, all disciplines seemed to have experienced a significant improvement in non-technical skills. The most significant improvements among all disciplines were found within the category 'Communication'. Items that improved significantly were directly related to exchanging critical information with each other just before surgery and right after surgery before the patient leaves OT. Timely sharing of critical information, just before and right after surgery, supports team performance and improves patient safety (Awad, Fagan et al. 2005). It enables team members to anticipate unforeseen changes in the surgical procedure during surgery and take appropriate action to prevent errors from occurring in the postoperative process (Davies, 2005). Other studies have shown that reflection as a team on what went wrong and why may lead to process redesign and clarified responsibilities and thus structurally decrease the number of workarounds and improve patient outcomes (Edmondson, Bohmer et al. 2001, Aston, Shi et al. 2005, Awad, Fagan et al. 2005, Weaver, Rosen et al. 2010).

The most significant effects measured at T₁ were related to discussing the patient, the procedure and possible complications that might occur during surgery with the whole team pre-operatively. Within the category 'Decision-making', all team members scored significantly higher on two items: 'discussing pros and cons of the surgical approach' and 'discussing the guidelines' with the whole team pre-operatively. Research shows that surgeons use different decision-making strategies to solve problems that occur (intuitive, rule-based, analytical or creative) as opposed to other OT team members who

work mostly rule-based (Flin, Youngson et al. 2007). As this leaves little or no time to take preventive measures for other team members, it is important to discuss options at the appropriate moment before surgery (Flin, Youngson et al. 2007). Although this might not influence decision-making directly, exchanging critical information improves situation awareness among team members and encourages speaking up intra-operatively. In addition to the necessity of being well informed, good communication and teamwork are also important because the surgical team is not only separated from the anaesthetic team by professional domain, but during surgery also physically by large sterile drapes, which complicates communication. This physical separation during surgery makes oral communication before and during surgery vital for patient safety as timely and accurate information will increase team members' awareness and support pro-active behaviour (Wauben, Dekker-van Doorn et al. 2011).

Communicating critical information about the patient and the surgical procedure before the surgical intervention and discussing problems that occurred intra-operatively in the debriefing, also enables team members to detect errors before harm is done and to act proactively to prevent complications later in the post-operative trajectory (Edmondson, 2004). By discussing patients and possible complications as a team, OT-team members become more open to each other and accept that human error is inevitable but manageable. If problems are discussed without blaming individual team members, a more open and more effective improvement climate of psychological safety can be established and errors are considered as learning opportunities (Tucker and Edmondson 2003).

The fact that participation was voluntary might have influenced the ratings of the participants in a positive way. That we measured perception of behaviour and not observed behaviour might raise questions too. Although this study would have benefitted from aggregation to team level and matching of respondents, aggregation to team level and matching is difficult as often OT teams are ad-hoc and turnover in OT is high (Makary, Sexton et al. 2006). Even if teams are stable, team members work in different shifts, 24/7 and rarely work with the same team members. Therefore, it is important to feel safe and comfortable independent of team composition. Although generalising the conclusions is difficult, the results and the lessons learnt provide other hospitals with valuable information for implementation of similar procedures.

By now a time out procedure and debriefing are mandatory in the Netherlands, but are not always performed as a team procedure. A time out procedure and debriefing can also be limited to (double) checks by one or two disciplines. Although this ensures that all information, documents and instruments are available and working, it is often perceived as a 'tick box procedure' (Walker, Reshamwalla et al. 2012) and does not improve communication among all team members. A time out procedure as such is not enough to ensure patient safety. Research in other areas (e.g. hand hygiene), has shown that implementation of simple safety guidelines, rules or procedures is difficult (Erasmus, Daha et al. 2010). The time out procedure and debriefing as described in this study are not a cookbook recipe, but a team procedure, adapted to the specific local context (patient, surgical intervention or organisation) to exchange critical information with *all* team members in a structured way to provide safe care. During the design and

implementation process of TOP*plus*, teams also received feedback on the registered data on a regular basis, which supported team reflection. Our research shows that there is room for improvement. In conclusion, the team approach and the clear structure of exchanging information in TOP*plus* encourages team members to ask for additional information, to speak up and to discuss problems as a team.

To gather evidence on sustainability, it is advised to measure a combination of outcome measures over a longer period of time: team members' perception of communication, changes in the surgical care path at process, structure and system level and patient reported outcomes related to medical conditions.

Future research should focus on projects where team interventions and safety procedures to improve teamwork and communication are combined with an additional team intervention, e.g. the introduction of dedicated teams. Dedicated teams are teams that stay 'fixed' during the day, where team members work together during different interventions and creates opportunities to work and learn together to build a safe work environment for patients and professionals (Walker, Reshamwalla et al. 2012). A combined approach might reinforce the effect on team performance, improve sustainability and lead to continuous learning and improvement (Edmondson, 2004; Stepaniak, Vrijland, de Quelerij, de Vries, & Heij, 2010; Weaver et al., 2010). Learning collectively and taking appropriate action to structurally improve care processes, including changing policies and procedures, create a clinical microsystem where team members work together to improve patient safety now and in the future (Helmreich, Merritt, & Wilhelm, 1999; Mohr, Batalden, & Barach, 2004).

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Time Out Procedure in the Operating Theatre: Arguments for Improved Teamwork | Chapter 7

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Chapter 8 Multi-site Stud

Multi-site Study: The Role of Process Orientation

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8.1 Introduction

Over the last decades, patient safety has been one of the main priorities in health care organisations (Shekelle et al., 2011). Patient safety focuses on reducing hazards and risks of injury or harm to patients (Emanuel et al., 2008). Reason (1995) was one of the first to acknowledge the importance of looking at health care from a systems perspective in relation to patient safety. He argues that errors at the 'sharp end' of the health care organisation, more specifically the physician-, nurse-patient interaction, might be the result of flaws somewhere else in previous steps in the care process. In other words, active human failures are not the main cause, as hazards for patient safety are often embedded in the process and structure of health care delivery. Identifying these so-called latent failures or system errors is one of the key issues in improving patient safety (Reason, 1995). However, in the dynamic and complex setting of healthcare conditions change over time, which makes identification of latent failures not a one-time effort but a continuous process (Hofinger, 2009).

Although most errors are inconsequential, some might mature in significant adverse events. System flaws such as deficient reporting systems, low quality of communication, or inconsistencies in postoperative recovery instructions might result in an adverse event and unavailability of patient information in cancelation of surgery and unnecessary readmissions (Croskerry, 2000). Especially patients hospitalised for a surgical intervention are subject to harm (Bruijne de et al, 2007; Cuschieri, 2006; Kohn, 2000). Research shows that almost half of the incidents occur in the operating theatre (OT) and 70% of these are caused by inadequate communication (Cuschieri, 2006; Mills et al, 2008). In a study in 6 hospitals, 149 errors were registered during 650 surgical interventions. Eighteen of these errors were so-called 'risk-sensitive events' and cause harm to patients if undetected (Wauben et al., 2010).

As human errors are inevitable, organisational systems should have defences, barriers and safeguards in place to detect failures and mitigate their effects before harm is done (Reason, 2000). According to Cartey et al (2001), two kinds of measures are necessary, viz. reactive and proactive measures (Carthey et al, 2001). Reactive measures to 'detect and correct' errors before harm is done and proactive measures to prevent errors from occurring by anticipating what might go wrong and have the right procedures in place to act immediately and adequately, e.g. extra material or a different protocol in case complications do occur (Carthey et al., 2001). Studies presenting research on interventions based on a systems approach and which are more process-oriented show positive results in improving patient care (Carroll et al, 2012; Espinosa et al, 1997; Nelson et al., 2002). Even small interventions like structured handovers or the introduction of ward rounds improve communication and thus team effectiveness (Dutton et al., 2003; Graham et al., 2013; Halm, 2013; Montague et al, 2004).

To reduce errors in the operating theatre a Time Out Procedure (TOP) and a Debriefing (*plus*) were developed and implemented, based on the concept of Crew Resource Management (CRM) (Makary et al., 2006). CRM is a management concept developed and

successfully used in the airline industry to reduce errors due to failures of communication, decision-making, leadership and teamwork (Helmreich, 2000).

To facilitate design and implementation of TOP*plus* and engage all professionals involved to adapt TOP*plus* to the local context, we developed a new model for implementation: Adaptive Design. Adaptive Design combines methods and strategies from Participatory Design to structure the design process and Experiential Learning to structure and support the team learning process. Adaptive Design includes three or more iterative cycles, each consisting of four steps in which professionals designed, tested, evaluated and learned and redesigned the TOP*plus* procedure to improve usability and adoption. In each cycle, data were gathered to adapt TOP*plus* to the professionals' own local context, which in most hospitals also varied between departments or disciplines.

The objective of TOPplus is to improve communication and teamwork to timely detect and correct errors and to prevent errors from occurring in the future. The exchange of information in the time out procedure and the discussion in the debriefing should also raise awareness and questions about the underlying causes of errors. Teams are expected to be able to differentiate between errors that occur because of wrong behaviour (active failures) or errors with a more structural character because of faulty processes and procedures (latent failures) (Reason, 2005). Information gathered during the debriefing might thus become the trigger for further exploration. This will reveal the interdependence between the team members, the teams and the daily care process of the surgical patient in the clinical microsystem, which in turn is embedded in the larger healthcare system. To explore causes of errors detected in OT improves multidisciplinary teamwork across disciplinary boundaries. To get engaged in a double-loop learning process and learn as a team, active participation of all team members with TOPplus is paramount to effectively improve patient safety. Creating awareness about the consequences of errors earlier in the surgical care process among all involved, might result in improvements in procedures and systems at the structural level of the health care organisation. If improvements are embedded in the structures of the health care organisation, initiatives may become more sustainable and improve patient safety in a more fundamental way and longer lasting (Hovlid et al, 2012).

The aim of the multi-site study was to explore the effects of TOP*plus* in OT on daily work processes at operational level and possible effects on procedures and systems at structural level of the organisation. It is expected that the introduction of TOP*plus* leads to process improvement in OT to reduce preventable errors by learning as a team, but also improves team learning across disciplinary boundaries and leads to improvements at structural level (Bogner, 2003; Kolb, 1984; Pilemalm & Timpka, 2008).

8.2 Methods

Design

The study was designed as an exploratory multi-site study using semi-structured interviews. In total fourteen Dutch hospitals participated in the TOP*plus* study to de-

sign and implement TOP*plus* in OT to improve the perception of communication and teamwork between OT-team members. The effect of TOP*plus* on changes in processes at operational or structural level was studied in six of the participating hospitals: two university hospitals, two teaching hospitals and two general hospitals, thus representing the three hospital types in the TOP*plus* study.

Operationalisation

To operationalise the difference between the process and structural level, the Clinical Microsystems (CMS) Framework was used which looks at healthcare organisations from a systems perspective. All characteristics of the CMS were related to either the process or the structural level (see table 8.1). This Framework was used because it has a special focus on patient safety and includes the clinical unit where the actual care is delivered, the so-called Clinical Micro-System (CMS) and the organisational system that supports and surrounds it (Battles, 2006; Mohr, Batalden, & Barach, 2004). Also, the CMS framework has been used successfully within different health care settings to measure the results of Patient Safety Practices (PSPs) at different system levels (Nelson et al., 2008).

The topic list for the semi-structured interviews was developed by relating the characteristics of the CMS to relevant aspects for the Operating Theatre (see table 8.2). Additional topics were added to identify to what extent TOP*plus* was used as intended in the different settings, viz. engaging all team members actively in a team dialogue, information was gathered on the actual usage of TOP*plus* in OT and adherence to the TOP*plus*-protocol. At the end of each interview, team members were asked which characteristics of TOP*plus* were most helpful in facilitating team discussions. As a result, the topic list included questions on TOP*plus* as a daily routine procedure (when, with whom and how) and questions related to the impact of TOP*plus* at process and at structural level (where, what and how) (see Table 8.2).

Data Collection

In each of the six hospitals, data were gathered through semi-structured interviews, using the topic list to identify possible changes in clinical processes and in organisational structures. As effects might be found throughout the whole surgical process, members of OT-teams as well as members of the management and support staff (as informed observers) were interviewed. In total 55 interviews were carried out: 8 surgeons, 9 anaes-thesiologists, 12 OT-nurses, 11 nurse anaesthetists, 2 perfusionists, 6 administrative staff members quality, safety and innovation, 6 OT-managers and 1 manager patient care (see Table 8.3). Most hospitals were represented by at least one surgeon, anaesthesiologist, scrub/circulating nurse, nurse anaesthetist, OT manager, administrative staff member and if possible a senior manager.

Through semi-structured interviews, information was gathered on changes in the surgical care process, including the pre- and post-operative pathway and on changes in support systems or structures across disciplinary boundaries. Additional general information included hospital size, organisational structure, quality indicators, possible

Process & Structure Framework (Battles, 2006)	Clinical Microsystem Characteristics (Mohr et al, 2004)	CMS definitions
Process	Process Improvement	An atmosphere for learning and redesign is supported by the continuous monitoring of care, use of benchmarking, frequent tests of change and a staff that has been empowered to innovate
Process	Information and Information Technology	Information is THE connector – staff to patients, staff to staff, needs with actions to meet needs Technology facilitates effective communication and multiple formal and informal channels are used to keep everyone informed all the time, listen to everyone's ideas and ensure that everyone is connected on important topics
Process	Performance Results	Performance focuses on patient outcomes, avoidable costs, streamlining delivery, using data feedback, promoting positive competition and frank discussions about performance
Structure	Organisational Support	If a practice is part of a larger healthcare system, the larger organisation looks for ways to support the work of the practice and other microsystems
Structure	Patient Focus	The primary concern is to meet all patient needs – caring, listening, educating and responding to special requests, innovating to meet patient needs and smooth service flow
Structure	Community and Market Focus	The practice is a resource for the community, the community is a resource to the practice; the practice establishes excellent innovative relationships with the community
Structure	Leadership	The role of leaders to balance setting and reaching collective goals, empower individual autonomy and accountability, through building knowledge, respectful action, reviewing and reflecting
Structure	Education and Training	All CMS-practices have responsibility for ongoing education and training of staff and for aligning daily work roles with training competencies Academic CMS have the traditional responsibility of training students
Structure	Staff focus	There is selective hiring of the right kind of people The orientation process is designed to fully integrate new staff into culture and work roles Expectations of staff are high regarding performance, continuing education, professional growth and networking
Structure	Interdependence	The interaction of staff is characterized by trust, collaboration, willingness to help each other, appreciation of complementary roles, respect and recognition that all contribute individually to a shared purpose

 Table 8.1 | Clinical Microsystems Framework (Mohr et al., 2004) related to critical elements of structure and process in a healthcare system (Battles, 2006)

accreditation and hospital policies related to quality and safety. The interviews were conducted in duo's, with one of the main researchers (CD or LW) and a student assistant present or in case a student assistant was not available, the two main researchers. All interviews were recorded.

Process & Structure Framework (Battles, 2006)	Clinical Microsystem Characteristics (Mohr et al, 2004)	Interview topics			
Process	Process Improvement	 Improvements in the peri-operative procedure Changes in handovers pre- and postoperatively in the operating theatre with admission and discharge New processes to prevent incidents in OT, e.g. extra checks on material and instruments, air-way management 			
Process	Information and Information Technology	 Registration of incidents in e.g. patient records or registration systems in OT Linking registration of incidents in OT to hospital reporting systems Adaptation or development of digital reporting systems, local or hospital-wide 			
Process	Performance Results	 Work processes adapted because of the introduction of TOP<i>plus:</i> Influence on the number or the kind of incidents In the surgical pathway, including the pre- and postoperative surgical pathway from admission to discharge With other minimal invasive interventions, e.g. interventions cardiology Any other adaptations/changes in processes because of TOP<i>plus</i>, e.g. streamlining the process with the laboratory Any other process changes to prevent incidents or streamline patient flow (assigning tasks and responsibilities) 			
<u>Structure</u>	Organisational Support	 Facilitators and that helped with implementation Support of the leadership (senior managers and board) 			
Structure	Patient Focus	 Active participation of patients in the TOP<i>plus</i> procedure Engaging patient in TOP<i>plus</i> Informing patients about TOP<i>plus</i> (verbally, written, flyers) 			
Structure	Community and Market Focus	 Information sharing or collaboration with external partners (e.g. other healthcare providers of Patient Associations) Publications in local or regional journals/magazines or any other public channels 			
Structure	<u>Leadership</u>	 Influence of TOP<i>plus</i> on chances in leadership style Positive reinforcement to discuss remarks or suggestions for improvement Influence of TOP<i>plus</i> on improved shared decision-making and shared goals 			
Structure	Education and Training	 Information to new employees Instructing/training new employees on the job 			
Structure	Staff focus	 Roles and responsibilities redefined in functional profiles Positive feedback to employees about results Common objectives, shared goals defined 			
<u>Structure</u>	Interdependence	 Incidents and actions for improvement on agenda of regular team meetings Structural collaboration with other disciplines and departments 			

Table 8.2	Topic list effect of	TOPplus on proces	s and structure le	evel of the healthcare system
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Interviewees	Hospitals							
	A Univ. Hospital	B U.H.	C Teach. Hospital	D T.H	E General Hospital	F G.H	Total	
Surgeon	2	1	1	1	1	2	8	
Anaesthesiologist	2	1	2	2	1	1	9	
Scrub Nurse/ Circulating Nurse	2	2	2	2	2	2	12	
Nurse Anaesthetist	2	2	2	2	2	2	11	
Perfusionist	-	2	-	-			2	
Administrative staff Quality-Safety-Innovation	1	1	1	1	1	1	6	
OT manager	1	1	1	1	1	1	6	
Manager Patient Care				1			1	
Total	10	10	9	10	8	8	55	

Table 8.3 | Study population: Hospitals and participants per discipline

Data analysis

The interviews were transcribed verbatim and first coded thematically by the two main authors (CD and LW) using the characteristics of the CMS framework and the topics from the topic list. An excel database was developed to link each relevant quote to a specific theme/topic. The authors started by analysing 20 interviews together, to esthablish a common frame of reference. The remaining 35 interviews were divided between the two authors. Afterwards both authors crosschecked the database. Then open codes were added based on the data, by both authors together. This involved a more detailed categorisation of the effects of the TOP*plus*. The final step was to see how these categories were related to either the process or the structural level or both. For instance, information on registration of incidents might only take place at process level. Especially when the registration of the incidents is not integrated in a reporting system as part of a larger safety management system, the information will be lost. This step was carried out together by both authors.

8.4 Results

The results will be presented in three different sections. Section 1 is about the actual usage of TOP*plus* in the operating theatre which includes: a) implementation of TOP*plus* with every surgical procedure, b) compliance to the TOP*plus* protocol: dialogue-based and participation of all team members, c) registration of TOP*plus* (written or digital) in existing patient records or in other reporting systems. Section two presents the changes that were made at process level as a result of the TOP*plus*: a) the clinical micro-systems viz. the organisational front line units, b) procedures, documents and systems that shape and enhance the process of daily care delivery (e.g. patient records, administrative

systems or incident registration systems) and c) the clinical work systems where professionals interact and work as a team and d) the patient. Section 3 describes the changes that have been made at the structural level: a) the macro organisation (policies, systems and procedures) that influences all other structures and processes in the health care system, b) the educational system for healthcare professionals and newly hired ones and c) the built or physical environment that surrounds the professionals (Battles, 2006).

Implementation and usage

Usage of TOPplus was verified to make sure that TOPplus was performed as a dialoguebased team procedure and with every surgical intervention and results could be related to TOPplus. In all six hospitals the TOP was adopted as a daily routine procedure, performed with the whole team present in most hospitals, with all surgical interventions and as intended, dialogue-based according to the TOPplus-protocol. In three hospitals, several interviewees added that although all team members were present, sometimes only the surgeon and the anaesthesiologists were actively involved in exchanging information. According to one of the surgeons: "Usually the surgeon and the anaesthesiologist or nurse anaesthetist. Usually there is a circulating nurse present, but he or she does not actively participate in the procedure." The debriefing was accepted as a routine procedure, but in most hospitals not with every surgical intervention and not with all team members present. In the teaching and general hospitals the nurse anaesthetist often replaced the anaesthesiologist, who was preparing the next patient for surgery. In all but one hospital TOPplus was registered: in most hospitals with a tick box in one of the electronic reporting systems used in OT and in one hospital in regular medical, nursing, or patient records. Sometimes the incidents mentioned in the debriefing were registered as well. No large differences were found between hospitals. Some interviewees mentioned that in case of emergencies the TOP was not performed or only the most critical information was double-checked: "In a digital anaesthesiology reporting system we register if the time out procedure and the debriefing are performed and problems/ incidents that occurred intra-operatively are registered in special pre-programmed fields." (nurse manager) The evidence gathered in every iterative cycle during the implementation and the team discussions that followed, triggered discussions with other disciplines and departments. The discussion about the problems encountered in OT deepened insight and showed the interdependency and interrelatedness with other departments, leading to changes at process level.

Changes at process level

At *process* level, several improvement initiatives were mentioned. In all six hospitals, implementation of TOP*plus* resulted in an improved structured handover between the clinical unit and the OT-team and in the introduction of a checklist covering all handovers in the surgical pathway from admission to discharge. The ability to gradually adapt the procedure to the local context, helped to make TOP*plus* a meaningful improvement. According to one of the anaesthesiologists: *"Without the TOP procedure, I won't start any anaesthetic procedure."* Results were also found in registration of TOP*plus*.

Existing electronic systems e.g. systems to document information on the surgical intervention (operative notes), or separate reporting systems were adapted to register TOPplus. To register more specific information, such as instruments missing or defect. or communication failures, in some hospitals additional item sections were added to the electronic system. In two other hospitals, regular team meetings were used to discuss the information derived from the debriefing. One of the nurse anaesthetists elucidated the procedure as follows: "Structural incidents and possible actions for improvement are discussed in team meetings. The first few months TOPplus was discussed with every team meeting." In two hospitals, one of the team members was made responsible to check all technical equipment and material in the operating theatre (e.g. screens, OT-table, air management systems) before the start of the daily OT-program. Other team members would double-check instruments (OT-nets) and material to be used in the elective surgical procedures of that day. One of the nurse anaesthetists mentioned that during the team discussion it was decided to work with dedicated teams in one of two operating theatres that were primarily used by one or two surgical disciplines. As it was one of the initiatives directly related to the feedback on incidents registered in the debriefing, they started a research project to evaluate the introduction of the dedicated teams. At the time of the interview, the first results were visible. He further explained that each of these operating theatres has a fixed team that discusses the surgical program, the patients and the surgical interventions for that day, before the start of the program with all team members present. During the day, the team performs TOPplus with every surgical intervention and takes coffee breaks and lunches together. Responsibility for the whole program is shared as a team. "In my opinion, the largest gain is the increased awareness and shared responsibility towards the patient's safety. We used to have separate teams of OT-nurses and nurse anaesthetists, but more and more we work as one team." (nurse anaesthetist)

Results were also reported in improved collaboration with other departments. Handovers between the surgical and the clinical department were restructured. Items were added to improve safety and detect errors and tasks and responsibilities clarified and assigned to the team members involved. In one hospital, new arrangements were set up with one of the facility departments to improve process of sterility assurance. "*Recently one of the team members of the Sterile Processing Department was made responsible for processing all our orders*", one of the OT-nurses explained.

Changes at structure level

Results at *structure* level included not only changes in the educational system and (re) allocating tasks and responsibilities among the professionals involved in surgical care, but also changes in procedures to improve patient information. In two hospitals, patients were actively engaged in the TOP*plus* procedure by stating their name, date of birth and possible allergies. In most hospitals, the patients received oral information about TOP*plus*. In some cases information was provided on the website or in a brochure with general information about the surgical procedure. Communication about TOP*plus* by a publication in the hospital magazine was found in most hospitals, but very few initiatives

were found to inform associated health care providers about TOP*plus,* e.g. general physicians. Two hospitals published an article in a local newspaper.

In three hospitals, communication and teamwork were added as a separate nontechnical skill to the functional profile and used when hiring and assessing new employees. According to one of the nurse anaesthetists: "When hiring new employees who will join the team, I will ask probing questions about these skills. Although there is a shortage of specialised nurses, you want to maintain quality." In some hospitals, communication skills were integrated in clinical educational or training sessions. In all hospitals, new employees received information and instruction on TOPplus. One of the surgeons explained: "We are taking our whole staff to one of the oldest attraction parks, to train communication skills."

Few changes were found in the leadership role. OT-managers would encourage OT team members to take initiative and speak up and team leaders or one of the team members would take the leadership role. "Especially (name) the OT manager, but also the team leaders from the OT-nurses and nurse anaesthetists and the staff member on quality, continually emphasised the essence of TOPplus." (perfusionist)

Visible and active support of the managers at strategic level was lacking in most hospitals. As one of the surgeons stated: "I don't think we received any support from the organisation, no certainly not." According to one of the nurse anaesthetists: "I do think that they (the organisation) find it important, but I never experienced any support." In two hospitals, interviewees were positive about the leadership role. "A committee on policymaking, presided by the hospital board is supervising the project." (staff member) In one of the hospitals, the hospital board decided to sanction negative behaviour. If staff members refused to comply to the TOPplus procedure, refusal resulted in a yellow card and the next time in a red card. In case of a red card, they had to give an explanation for their behaviour to the hospital board. Almost all interviewees saw improved teamwork and team spirit as a result directly related to the introduction of TOPplus. They valued taking responsibility as a team, being well informed about the surgical procedure and being more aware of each other's contribution to the surgical process. In one hospital, team members mentioned that the introduction of TOPplus also smoothened the flow of the surgical process during the day. According to one of the nurse anaesthetists: "Team members report errors immediately and act adequately to solve the problem, which shortens the delay in the pre-operative process. It has streamlined and structured the process, which in turn has shortened the whole process." And, "Absence or delay of one of the team members, a common problem in OT, hardly ever occurs anymore."

When asked which characteristics of TOP*plus* facilitated team discussion, the interviewees most valued by contextualisation, i.e. the possibility to adapt TOP*plus* to their own clinical practice step by step (n=33). Twenty-nine interviewees (n=29) mentioned the positive influence of the poster in A1 format on the wall of every OT. The poster showed all questions indicating roles and responsibilities for each team member, thus engaging all team members to participate in the discussion. One of the scrub nurses emphasised the importance of the poster as follows: "A poster that large puts you right on the spot and really helps. It is hanging there and you can't get around it." The time

out procedure, performed with the whole team also created a 'formal' moment to ask for some more explanation about certain subjects. Some interviewees (n=19) mentioned the importance of having one of the team members as "the clinical champion" who would encourage discussion and could be one of the medical specialists but also one of the OT-nurses. *"It does help if one of the medical specialists encourages other staff members, but most of the support came from one of our own OT-nurses, who is also team leader."* (scrub nurse)

All in all, the results show that the introduction of TOP*plus* not only helped to timely detect and correct errors, but also stimulated improvements at process and at structural level to prevent errors from reoccurring.

8.5 Conclusion and discussion

In all six hospitals, the time out procedure was implemented as a routine procedure; with the necessary adaptations to make it fit the local context. The use of the Adaptive Design approach in which each team member participated in adaptation and adoption seemed to be successful as an implementation strategy. However, the debriefing was not fully implemented. Although each hospital has implemented the debriefing in OT, it is not used during each surgical intervention or during each type of surgery. Introducing the debriefing seems more complicated because it has a bigger impact on OT processes, as not all OT members are always present throughout the end of the surgical intervention. For example, the anaesthesiologist usually leaves before wound closure to prepare the next patient for surgery and sometimes the staff surgeon leaves the closure of the wound to the resident.

Overall, it can be concluded that the implementation of TOP*plus* has resulted in both process and structural improvements in all six participating hospitals. However, improvement initiatives at process and structural level that included more departments and disciplines and thus more teams varied between hospitals.

Subjects for discussion

Adaptive Design and the learning process

The time out procedure is first of all introduced as a way to improve single-loop team learning in OT, by helping teams to detect and correct mistakes just before the surgical intervention to prevent harm. However, combined with a registration system and the introduction of moments for team reflection as part of the implementation strategy, it evolved into a tool that also stimulates double-loop team learning. It helped OT teams to prevent mistakes from occurring by identifying and correcting underlying causes. The registration of the mistakes identified during the time-out procedure also helped them convince others, that changes in procedures and structures were required. Yet, teams were not always successful in convincing others to participate. Some changes that

needed to be made, such a digital registration system integrated in a safety management system hospital wide, also require management support and budget, which are not always available.

The introduction of TOP*plus* in OT as a team intervention triggered discussions between professionals in those frontline units that were part of the care trajectory of the surgical patient, which starts with the clinical unit where patients were admitted and prepared for OT. In all six hospitals, the effect of TOP*plus* was visible organisation-wide, at operational process level and in processes and procedures at the structural level of the hospital organisation. Using the Adaptive Design methodology as an implementation strategy helped to structure the learning process and made adaptation and adoption step by step a natural process. The iterative cycles made it possible to adapt the implementation process to the learning process of the professionals involved and focus on problems they encountered.

The discussions between team members helped to gain insight in the interrelatedness and interdependency not only between team members, but also with other disciplines and other departments. The first discussion between team members concerned their own processes and functioning, which resulted in actions to monitor the safety of the patient while in the OT-department. Actions were diverse and ranged from introduction of extra checks on material and instruments and improved post-operative instructions to prevent errors, to assigning tasks and responsibilities to certain team members. As team members gained a more accurate and deeper understanding of the problem, the next step was the discussion with the clinical team that prepared and delivered the patient to the OT-department. This discussion resulted in restructured handovers and in a checklist for the surgical patient covering the whole surgical pathway and introduced hospital-wide in all hospitals. The implementation of the checklist, including the stopping rules with critical handovers hospital-wide, was supported by policies to stimulate adherence to the stopping rules. The policies included providing information about the content and the aim of TOPplus to new employees and in one of the hospitals also sanctions if professionals refused to comply.

The open and flexible character of both TOP*plus* and the Adaptive Design methodologies used, allowed the researchers to monitor and anticipate the needs of the professionals and to take more time for the team discussion. If needed, the researchers performed extra analyses on the data gathered, or added extra iterative cycles to pilot improvement actions to experiment and learn. In one hospital, data were analysed to explore if performing the time out procedure before induction could prevent errors. The pilots focused on specific problems and failures to design actions for improvement that would fit the local context of that hospital. The focus on their own problems deepened the team learning process in a natural way, experimenting and learning while working and with all disciplines involved. This continuous learning process improved adaptation and stimulated initiatives across departmental boundaries, as shown in this study. The system approach and process orientation used in TOP*plus* encouraged multi-disciplinary discussions, gradually involving more disciplines and in the end produced a positive "ripple" effect throughout the whole organisation (Waring et al, 2006).

The role of board members and senior managers

In all hospitals many different professional disciplines, managers and support staff became involved and created productive partnerships, but the managers at strategic level and hospital board members were mostly absent. There was no doubt that the hospital board approved of the TOP*plus* project, but very few of them were visibly involved. Only in two hospitals, the interviewees were positive about the board's leadership role. Managers at strategic level and members of hospital boards should take an important role in patient safety initiatives. They can oversee the whole project and support and guide it by e.g. developing vision and strategy, setting aims related to quality and safety and communicate these to all involved. One of the aims should focus on the creation of continuous learning opportunities for all concerned, to fill the gap in knowledge and skills of patient safety issues, (Conway, 2008).

Process-orientation and reporting systems

The TOPplus study showed the importance of a system and process-oriented approach. At the start of the project, it was expected that TOPplus would improve communication and teamwork, but no assumptions could be formulated on the extended effect of TOPplus across the organisation. In many hospitals, the traditional functional organisational structure is still the guiding principal and often a barrier for real change (Leape et al., 2009). Recently more and more hospitals are moving away from this structure to a more patient-centred organisational structure. In patient-centred hospitals, the guiding principle for the organisational structure is process orientation where processes and departments are organised around care processes (Vos et al., 2011). Process orientation improves the coordination of patient care and improves fact-based learning from incident reporting systems. Reporting systems with a focus on reporting adverse events produce outcome information, which contributes to external reporting on indicators but does not solve process or system failures. Voluntary reporting systems, like TOPplus, focus on reporting incidents and errors and provide process-information that helps to analyse the problem, assess the risks and design actions to prevent errors from occurring (Nuckols et al, 2009). At the same time, the focus on the process "How and why did it happen" contributes to the creation of a blame-free, non-punitive culture which is the foundation for patient safety (Wolf and Hughes, 2008).

Voluntary reporting systems, as an integral part of improvement initiatives, produce a large amount of information. Evidence-based knowledge related to processes contributes to the creation of evidence-based practices, by monitoring how implementation takes place and to differentiate between context-related elements and elements that are generalisable (Cuschieri, 2006). Studies similar to TOP*plus* that include the Adaptive Design methodology, gathering evidence in iterative cycles to experiment and learn, provide an opportunity to build a coherent body of knowledge that is evidence-based, valid for practitioners and researchers and scientifically justifiable. When we are able to combine efforts from multidisciplinary teams with experts from different backgrounds, different health care fields and different scientific domains, we might be able to oversee

the whole healthcare chain. Thus, deepen our understanding about its interrelatedness and interdependency and improve implementation of evidence-based practices.

Limitations and final conclusion

One of the limitations of the study was the fact that the interviews were conducted in just six hospitals and only in the Netherlands. However, they do represent the three main types of hospitals. Another limitation is the role of the two main researchers, who were both researcher and project advisor and one of them (CD) project manager at the university hospitals. To prevent bias a rigorous theoretical framework was used. If results are generalisable cannot be concluded from this study. However, it seems that most findings are not so much related to the characteristics of specific hospitals, but to the multi-professional character of operating theatres, which are embedded in larger organisational systems.

The TOP*plus* study showed how individual learning can be changed to team learning and single-loop learning cycles to double-loop learning cycles to change supporting procedures, structures and sometimes even organisational policies. The question remains if the Adaptive Design methodology also provides a structure that invites professionals to get engaged in a *continuous* learning process, in a triple-loop or higher-order learning process and a continuous strive for excellence.

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9.1 Review and general conclusions

The overall aim of this thesis was to find an answer to the question: *How to design and implement a team intervention to improve communication and teamwork in the operating theatre*? Thereby building on the theoretical notion that improved communication and teamwork are strong predictors for a positive patient safety culture (El-Jardali, Sheikh et al. 2014). A positive patient safety culture creates a positive non-punitive climate to discuss errors and encourage team learning, without being hindered by hierarchical structures and disciplinary boundaries and by biases within the health-care system (Leape, Berwick et al. 2009). Patient safety needs rules, regulations and measurement systems to assure safe care, but also a culture of trust, reporting, transparency and discipline. In a blame-free culture errors are perceived as an opportunity to learn as a team and take appropriate action to prevent errors from recurring (Hutchinson, Young et al. 2009). However, in many health-care organisations the functional structure based on medical disciplines is counterproductive to openness and trust. Although organisational culture is hard to change, it can be transformed under the right circumstances and by the right initiatives (Schein 1999, Hudson 2001, Schein 2002).

To gain more insight in existing evidence and scientific arguments for the decision to use implementation of a time out procedure and debriefing as a team intervention, one of the authors joined a systematic review study. In the study, the research team focused on team interventions to improve team effectiveness. (Chapter 2).

Little scientific evidence was found at a high quality level (Grade 1 or 2), but a few studies showed some evidence with indications that team interventions based on concepts such as Crew Resource Management (CRM) improve communication and teamwork. The latter also contribute to the creation of an open and blame-free environment. CRM, successfully used in aviation, is a management and not only a philosophical concept that also includes processes and procedures to "live" safety as a team. CRM requires work processes that support team reflection and discussion and creates an open atmosphere where team members can exchange critical information, speak up and voice concerns. Briefings, time out procedures and debriefings were found to be promising procedures to improve communication and teamwork that are essential team skills to improve patient safety (Kosnik, Brown et al. 2007). A time out procedure is a double check and a final step in a series of checks in the preoperative process just before surgery. In this study the time out procedure (TOP) was combined with the debriefing (plus) and designed as a dialogue-based team procedure, to be performed with the whole team present. The purpose of the time out procedure is to timely detect and correct errors and to exchange and discuss critical information about the patient and the surgical procedure prior to the surgical intervention. In the debriefing the team reflects on the surgical procedure, discusses and registers errors and defines postoperative orders for safe patient handoff to the recovery.

After identifying the appropriate intervention the next challenge was to find a successful design and implementation strategy for TOP*plus* and turn these procedures, often perceived as a tick box exercise, into meaningful improvements and evaluate the

outcomes on patient safety practices in the operating theatre. To measure the influence on perception of communication and teamwork of surgical team members, preceding and following introduction of TOP*plus*, a questionnaire was developed (Chapter 3). In a study in five hospitals, prior to implementation of TOP*plus*, the results of the questionnaire showed significant differences in perception among all surgical team members. The largest discrepancies in perception were found between the surgeons and the other team members. Surgeons were significantly more positive about communication and information gathering than other team members, which might indicate different levels of situation awareness among all team members. Shared situation awareness is an important precondition to anticipate unforeseen situations peroperatively and provides safe care. Almost all team members rated routine briefings and debriefings as inadequate, but the lowest ratings were found for anaesthesiologists, nurse anaesthetists and OT-nurses. In the ratings of the fifteen hospitals that ultimately participated in the project, the differences in perception between team members and high and low ratings were similar (Chapter 7). These results showed that there was room for improvement.

To identify an appropriate design and implementation strategy for TOPplus a pilot study was carried out. With a small team of medical and scientific experts a prototype of a time out procedure and debriefing was developed and tested on design and content (Chapter 4). The first design resulted in a combined Time Out Procedure (TOP) and Debriefing (plus), a structured communication protocol, which included all items that are critical to provide safe care. TOPplus was designed as a multidisciplinary procedure to discuss all items as a team, with all team members directly involved in the surgical intervention. Questions and answers were assigned to specific team members. TOPplus was visualised in a large poster (A1-format) and colour-coded, each colour representing one of the professional disciplines, i.e. the surgeon, the anaesthesiologist, the operating theatre nurses (circulating nurse and scrub nurse) and the nurse anaesthetist. The poster also presented the debriefing, which in the prototype included only two items: a question to discuss details and a summary. In the summary one of the team members would recapitulate the items the whole team agreed upon to be registered in a separate document. From the start of the project the presence of the whole team with the time out procedure and the debriefing appeared to be problematic. To exchange critical information about the patient and the procedure is vital for safe surgery. However, to be present in the operating theatre early in the morning with the first time out procedure appeared to be problematic and created resistance. It posed a problem especially for the surgical discipline as it interfered with the long existing daily routine of patient handover. Following a discussion it was decided that the resident could replace the surgeon, provided he or she was directly involved in the surgical intervention.

In a pilot in five hospitals, the TOP*plus* prototype was tested during hundred surgical interventions and incidents that occurred were discussed and registered (Chapter 5). Using Participatory Design (PD), a design method that originates from Industrial Design Engineering to engage end-users in the design process, all team members were encouraged to participate in the design and implementation process and to provide feedback on the content and the process of TOP*plus*. The results of the pilot provided relevant

information on the content and the usability of both time out procedure and debriefing and on the importance of using PD to engage professionals in the design and evaluation process. The registration of incidents during the pilot phase increased awareness of team members about errors that occurred during surgery and reduced resistance. Inviting professionals to participate and provide feedback supported the discussion among team members and improved adaptation to the local context. Two topics were found to be important to further develop and implement TOP*plus:* the presence of the whole team with both time out procedure and debriefing and the adaptation of TOP*plus* to the local context. The latter made it necessary to include more professionals in the design process to address specific critical items, that are related to the patient, to the surgical intervention, or to the physical work environment. Depending on the complexity and diversity of the local context teams needed more time for reflection and discussion and to experiment and learn as a team.

To put more emphasis on the learning aspects Participatory Design was combined with Experiential Learning as an implementation strategy, which resulted in a new model with iterative design cycles called Adaptive Design (Chapter 6). Experiential Learning emphasises the team learning process in iterative cycles (Plan-Do-Study-Act) to create and recreate knowledge based on experience. Each cycle includes four iterations, i.e. design, apply, evaluate and reflect and redesign. With each cycle more professionals were included in the design and redesign process to adjust TOP*plus* to their local context. If needed, extra cycles were added to focus on specific multidisciplinary processes across departments and disciplinary boundaries. Applying Adaptive Design created and more time *and* more moments to reflect as a team, to detect and correct errors before harm is done and prevent errors from recurring. Thus creating learning cycles leading from single-loop learning (detection and correction) to double-loop learning (prevention).

To measure if implementation of TOP*plus* improved perception of nontechnical skills of surgical team members a pre- and post-study was carried out in fifteen hospitals (Chapter 7). The questionnaire "Communication & Teamwork in the Operating Theatre" was distributed preceding introduction of TOPplus (T₀) and following its final implementation hospital-wide in all operating theatres of each participating hospitals (T₁). The second measurement showed significant improvements in communication and decision-making with all surgical team members and most team members rated execution of TOP*plus*, with active participation of all team members in several design and redesign cycles, showed to have a positive effect on team members' perception of communication and teamwork. Discussing problems encountered in the operating theatre as a team initiated the dialogue with other disciplines and departments, leading to improvements pre- and postoperatively in the surgical pathway.

To explore the effects of TOP*plus* across the functional departmental boundaries and the disciplinary silos within the hospital system, a multi-site study was carried out in six of the participating hospitals, using semi-structured interviews based on the framework of the Clinical Micro System (Chapter 8). The clinical microsystem (CMS) represents the clinical unit with its processes where the actual care is delivered and professionals of different disciplines provide care to a defined group of patients. The CMS also includes all supporting staff and the necessary technology and information to support the process of health-care delivery. The CMS framework provides a practical tool to look at health-care delivery and at organisational learning, thus including the process and structure level of the health-care system. The results showed improvements at both levels in all six hospitals. At process level, improvements found in all hospitals included extra checks on materials and instruments, improved multidisciplinary patient handovers and the development of a multidisciplinary checklist following the surgical patient from admission to discharge. Improvements at structural level were diverse, ranging from clarification of tasks and responsibilities for each surgical team member and improved registration and reporting systems, to extra educational activities for team members. In some hospitals new employees would receive detailed information about the TOP*plus* process and its underlying principles. In one hospital discussion between team members resulted in establishing dedicated, fixed teams in specific surgical areas such as minimal invasive surgery.

Overall, the whole stepwise process of design, test and evaluation, redesign and implementation of TOP*plus*, gradually engaging more professionals and disciplines in the project, improved communication and teamwork among team members and facilitated its adaptation and adoption. It also enhanced the team learning process to improve patient safety in a more sustainable way through improvements in the supporting structures of the hospital system, e.g. team training or installing incident reporting systems. All fifteen hospitals implemented TOP*plus* in every operating theatre in the hospital. Over the last two years, the researchers received and are still receiving, requests to redesign the poster or design a new poster for other disciplines, e.g. intervention radiology, intervention cardiology, psychiatry and very recently obstetrics.

9.2 Discussion

This research project was based on the hypothesis that the best learning opportunities are in and around the workplace. More than ever teams need time to reflect and react while working to anticipate unexpected changes in the complex and dynamic work environment of health-care delivery. Although health care has improved immensely in treating patients with the introduction of innovative procedures and new medication, this has also increased the number of disciplines involved and the risk of errors, which can be human or system related. In contrast to human failures, which are inevitable and difficult to manage, system or organisational failures are to some extent manageable. Errors can be reduced by redesigning organisational processes and by designing in barriers to prevent errors from occurring. To improve processes and procedures in a more sustainable way teams need time to reflect, experiment and learn. However, team learning requires a certain attitude from individual professionals, teams and organisations. It requires individual leadership based on expertise and knowledge and not on hierarchical function and depends on mutual trust and respect between team members.

Team learning also needs an organisational environment and structure that supports and encourages team learning. In most hospitals, however, the focus is on improving efficiency, reducing costs and gathering information for external reporting systems. That is why this study focuses on process improvement to prevent errors and at the same time on improvement of communication and teamwork between team members as a precondition for team learning to improve patient safety. In this paragraph, we will discuss the lessons learned about implementing innovations and iterative learning by professionals in daily practice adapting and adopting TOP*plus*, facilitated through the use of methods from participatory action research.

9.2.1 Adaptive Design as a participatory and iterative research design

The slow progress in patient safety is to a certain extent due to the persistence of hierarchical structures and poor communication and teamwork, but also to the lack of high-guality evidence of successful implementation of patient safety practices (Riesenberg, Leitzsch et al. 2010). Most studies present low-grade evidence and provide only an overview of the intervention and its results. Often, outcomes, anticipated or unintentional, are not explained and a detailed description of the context and its influence on the design and implementation process is lacking (Leape, Berwick et al. 2009, Shekelle, Pronovost et al. 2011). Participation of professionals in the identification of relevant problems and in the design and implementation process is essential. The complexity and diversity of the organisational context in health-care require different research designs and methods to capture the process of design and implementation of patient safety practices. This study demonstrates that theoretical insights from social sciences, system design or human factor theory provide a better understanding of human and organisational factors involved. The multidisciplinary perspective in this study improved the research process by providing directions and instruments to design, select, evaluate and redesign patient safety practices.

This study presented several methodological challenges to be solved and it was expected that over time during the study problems would emerge that were not quite predictable. Questions or problems that emerged might call for additional iterative cycles, additional research questions or the use of a different instrument to gather data. Building upon the principles of Participatory Action Research we developed Adaptive Design (see Chapter 6), as our own research method to introduce and implement TOPplus. Adaptive Design can be characterised by 'research in action', it is participative (engaging participants in the research activities) and runs parallel alongside actions to improve processes. It requires close collaboration between participants, in this study medical professionals and scientific experts and a combination of different theoretical domains if necessary. This enabled us to adapt the sequence or the number of steps to broaden the scope of the study. It also created the possibility to add extra cycles or additional instruments whenever suitable to support the communication in the multidisciplinary teams in the surgical pathway across disciplinary and organisational boundaries. Learning to improve safety in health-care practices needs to take place within this complex system and with participation of all involved. In order to improve sustainability learning also needs to take place at three levels, i.e. individual, team and organisational (Freeth and Reeves 2004).

In a study like this, with an open and exploratory character, the steps in the research process are not as well defined and prescriptive as in quantitative studies, e.g. randomised controlled studies. It requires a flexible and open attitude from the researchers. Based on the results of each step, extra pilots were introduced and new research questions emerged. If required, a research method was introduced different from the one initially planned for in the research proposal. Adaptive Design proved to be an appropriate and useful method for the implementation of TOP*plus*. It empowered professionals in adjusting their work environment to meet their needs. It supported shared decision-making grounded in their daily work environment and adoption of TOP*plus* as their own innovation in their own practice. For the researchers it provided a structure to deepen their insight in and learn more about specific contextual aspects in relation to TOP*plus*. The evidence gathered in this study was not only valid for participants, but at the same time justifiable as a *scientific* result. Benefitting from a multidisciplinary theoretical basis, we feel that this research design has helped to obtain improved scientific results and gain better insights into the nature of change.

As a research method Participatory Action Research is sometimes criticised. The criticism concerns among others the unclear research goals, the single case approach and the instruments used, which might all influence the objectivity of results. (Munn-Giddings, Hart et al. 2005). To prevent problems related to the objectivity and the scientific validity of results, Adaptive Design includes rigor in methods used and preferably more cases or sites to compare results. With TOP*plus* the goal of the study was clear: implementation of a team intervention to improve communication and teamwork between surgical team members in the operating theatres. To make results between hospitals comparable, the intervention, the evaluation forms, questionnaire and topic list were identical and used in all fifteen hospitals. The questionnaire was based on validated instruments and analysed with statistically valid methods.

The criticism also concerns the hierarchical power within organisations, which might inhibit active participation of low ranking participants. As hierarchical barriers were identified as one of the underlying causes of poor communication and teamwork, special attention was paid to include everyone involved. All professionals and support staff directly involved in the surgical procedure were included, irrespective of hierarchical or functional status and provided input, verbally in meetings or written by means of the questionnaire and received the same reports with feedback. This study shows that active engagement of all involved is important and leads to improvement at process level and structural level. To include just a small team of professionals might limit the results of the innovation to certain processes or structural levels within the health-care organisation (Kahn and Chovanec 2010). Although, the success of Adaptive Design can certainly be contributed to the simplicity and adaptability of the TOP*plus* procedure, but the main reason for that success can be found in the method itself.

9.2.2 Learning to improve safety

Learning to improve safety in health-care practices needs to take place within that practice and with participation of all involved (Freeth and Reeves 2004). The main challenge in this study was to overcome the resistance to change and engage professionals in the discussion about errors and how to improve safety. There is a widespread belief that health care professionals should be infallible and are supposed to perform at a high level of professional competence, no matter what circumstances. Errors are often perceived as individual failures or incompetence and difficult to discuss as a team, thus creating a culture of "blaming and shaming". This hinders the ability to learn, individually, as a team and as an organisation. Our research demonstrated that Adaptive Design and TOP*plus* helped to overcome this barrier.

To improve patient safety through process improvement involves organisational learning and in this study it involved team learning. To prevent errors in the preoperative process team members needed to get engaged in a learning process to discuss errors detected in the time out procedure before surgery and to take action. However, introducing this kind of learning in health-care is difficult, especially because learning is closely tied to professional education and the professional discipline. During the formative years in professional education, but also with continuing education as practicing professionals, formal learning often occurs outside the work environment. Learning is mostly an individual process, with a focus on technical skills and not always directly transferrable to their daily complex and dynamic multidisciplinary work environment. As a result, health-care professionals do not learn to communicate and collaborate with professionals from other disciplines and do not develop a common language to solve problems at team or organisational level. However, in daily practice professionals from different disciplines work together in teams to provide care to individual patients. Problems encountered while working need quick and adequate solutions. This kind of learning, defined as single-loop learning, meaning reflection in action, is adequate to solve these problems and correct errors before harm is done, but not enough for sustainable improvement. Problems encountered often need multidisciplinary solutions, in other words, team learning. To prevent errors from recurring in the future team members need more time for reflection and discuss the problems in depth as a team to find adequate and creative long-term solutions. Therefore, a different type of learning is required.

The monodisciplinary character of professional education also affects the work environment of health care organisations. Departmental boundaries are defined by medical disciplines and create monodisciplinary silos with monodisciplinary work processes, which means that professionals not only learn in silos but also work in silos. The first cycle in the TOP*plus* study, testing the prototype on content and usability, helped to overcome barriers to change. The insight gained in errors created a sense of urgency and awareness about the multidisciplinary character of work processes in the operating theatre and the interdependency between team members. The structured feedback on the incidence, the nature of errors that occurred and the simplicity of the procedure stimulated discussion with the whole team. For instance, with respect to missing patient verification, the operating theatre team members clarified tasks and responsibilities to restructure the patient handover, by adding a specific item on patient identification or making the ward nurse present at the handover responsible for the pre-operative checks carried out on the clinical ward. The results of the second cycle showed an immediate decrease in the number of patients admitted to the operating theatre without patient identification and thus the chance of wrong patient errors. The whole process decreased the resistance to report and discuss errors and improved collaboration with the clinical ward team.

Solutions often included changing multidisciplinary processes and collaboration with different professionals and departments at all levels throughout the whole system. In other words, identifying sustainable solutions requires double-loop learning, i.e. reflection on how processes are organised and interrelated or reflection *on* action (Schon 1984). Our data, gathered in the iterative cycles, showed that most errors were neither related to individual failures nor to violations, but to system failures in the health care delivery process. They were also not incidental but errors with a more structural character. This made it easier for professionals to discuss these errors, to speak up and voice concerns. It opened up the team discussion to find solutions, decreased hierarchical and disciplinary barriers and improved good communication and teamwork. The positive results from the iterative cycles also initiated a discussion with technical experts from the IT department to develop an adequate registration and reporting system. This makes it easier to capture near misses and not only decreases errors but also helps to create an open and blame-free culture as a precondition to learn from errors as a team and improve patient safety (Firth-Cozens 2001, Edmondson 2004).

The introduction of TOP*plus*, accompanied with Adaptive Design methods, helped to create a supportive work environment and, being dialogue-based, contributed in a natural way to the creation of an open and blame-free culture. In most hospitals, the whole process of fully implementing TOPplus took one to two years and in some hospitals even longer. Even professionals that strongly opposed the project admitted that it did help to improve their surgical process. As one surgeon commented: "It does not feel safe anymore to perform surgery without doing the time out first!" It took a lot of energy and perseverance of each team that initiated the discussion around patient safety, but as Hudson (2001) stated:

"The road to safety may seem long and hard and appear to wind, but the destination makes it well worthwhile" (Hudson 2001).

9.3 Limitations

Because of its flexible and open character, Adaptive Design is a useful research method for studies in a dynamic and complex environment with a large variety in contextual aspects that might influence the objectives of the study and the research methods used. For the TOP*plus* study Adaptive Design appeared to be a valuable and appropriate method to apply. During the TOP*plus* project, however, there were some limitations related to the role of the researcher and to the exploratory character of the study that made it difficult

to be specific in terms of outcomes. Questions were also raised about the influence of cultural differences on the method or the instruments used and, consequently on the validity and effectiveness of Adaptive Design in different organisational cultures. In some cases where hierarchical differences are prominent, the participation of professionals might be limited to a small group of 'preferred' professionals.

The dual role of the researcher in Adaptive design, i.e. working as a researcher but also being actively involved in the implementation process, might raise questions about the validity of the research process. One of the researchers was also responsible for the implementation of TOPplus in the operating rooms in the four university hospitals in this study. To safeguard the objectivity of the study, however, the researchers used validated questionnaires and introduced a number of cross-checks. Four independent researchers cross-checked the data related to incidents and member checks were done with all professionals that participated in the study, each of whom received full reports with detailed information. In addition, the two researchers that carried out the study had a different scientific background, viz. one with a background in Industrial Design Engineering and the author of this thesis in Nursing and Organisational Learning. Inclusion of more organisations in the TOPplus study also helped to reduce the risk of becoming subjective and increased the scientific validity of results. All hospitals were required to follow the research protocol and monitor the inclusion criteria. As a result, one hospital was excluded from the study because the guestionnaire was distributed too late, following the introduction of TOPplus and not before as required.

The second limitation is that some uncertainty about the outcomes remains. The study clearly showed that, according to the respondents, the introduction of TOP*plus* improved communication. It also showed how improvements were made to prevent incidents from recurring and how the use of Adaptive Design seems to have stimulated the implementation process. However, statistical evidence about the effects of the implementation of TOP*plus* on the number of incidents is still lacking. This is mainly related to the fact that measuring incidents is problematic, because it depends on the willingness of professionals to report these. This willingness only improves when safety awareness improves and a blame-free culture exists.

The question remains about the ability to generalise our findings. A different organisational culture but also cross-national cultural differences might be of influence on the effectiveness of action research. Cross-national cultural differences become visible in cultural traits and are far deeper ingrained in individual or group behaviour and thus also deeply ingrained in organisational behaviour. Differences as power distance, individualism versus collectivism, or being more competitive versus being focused on harmonisation need to be taken into consideration when choosing a specific research method and the instruments used. Despite these arguments, Adaptive Design might still be a valuable research method to use. In studies that focus on change and continuous improvement like TOP*plus* methods like Adaptive Design that combine quantitative with qualitative research methods, that are more formative and evaluative, are appropriate and valuable (Ovretveit 2009).

9.4 Perspectives for clinical practice

The TOP*plus* study demonstrates that a multifactor approach, using implementation strategies that address clinical processes as well as behavioural aspects, helps to overcome resistance and increases adoption of patient safety initiatives. This study also shows that the implementation strategy should focus on creating learning opportunities, learning as a team, discussing problems encountered and improving shared decision-making.

At the start of the implementation process, it is important to address the scope of a problem within the local context. How serious is the problem, how many times does it occur and what are the consequences? Gathering concrete evidence about the frequency and the nature of the problem helps to adapt the intervention and to overcome resistance. One of the reasons this study focused on the operating theatre was the availability of scientific evidence about preventable errors (Bleich 2005, Langelaan, de Bruijne et al. 2013). The first step in the TOP*plus* study was to gather evidence about incidents in each of the participating hospitals to gain insight in the local situation. Even within the same location, with every new discipline or team, it might be necessary to repeat this first step.

The use of a systems approach helps to adapt the intervention by identifying its interrelatedness with other care processes. The experience of the team members in contextualisation using Adaptive Design methods reduces most barriers for implementation of patient safety initiatives. The objective of TOP*plus* was to implement a team intervention in the operating theatre to improve patient safety. As many errors identified in the operating theatre result from process or system failures in the pre-operative trajectory, a systems approach was required. In addition to discussing system failures, it initiated the discussion about so-called defences in the surgical pathway to prevent human failures. In the TOP*plus* study, this concerned the introduction of so-called "stopping rules" at critical patient handovers in the surgical pathway. Using a systems approach and Adaptive Design methods put the focus of the study on individual and team responsibilities and not on hierarchies. The challenge is to shift from "who did it" to "how did it happen" (Walton 2006).

Time should be spent to discuss the objective of the project and inform teams about the methods used in Adaptive Design. Professionals need the assurance that the information they provide is paramount for decision-making and in adapting the innovation to their clinical practice. During the TOP*plus* project much time was spent on team meetings. Team members then discussed the results between the iterative cycles to redesign TOP*plus* and improve usability within their specific context. Extra team meetings need to be organised or extra cycles added, whenever necessary.

The last perspective for clinical practice concerns professional education. To create awareness about the multidisciplinary character of health care services delivery and the interdependency between team members, it is recommended to introduce interprofessional education in the initial curricula of health-care professionals. Socialisation processes acquired during the early years of professional education have a strong influence on individual behaviour later in professional practice. Therefore, it is recommended to design and to introduce multidisciplinary educational activities in the initial curricula. Patient safety is a current and interesting subject to explore for these activities. In addition, multi-professional educational activities should also be organised within clinical practice. It is important to learn and continue to learn and therefore educate and train professionals and support staff, including care managers and governors. Education and training should include patient safety issues and protocols professionals can use to prevent errors and instruments or tools to analyse near misses and errors, to learn from.

Although the TOP*plus* study has not produced all the results we expected, it did initiate the first step in a process to change the organisational culture. A change from a culture where hierarchal functions are dominant and errors are perceived as individual failures to a culture of openness, where reporting near misses and errors is routine and learning from errors is valued and rewarded (Firth-Cozens 2001, Edmondson 2011). A process like that, requiring a change in procedures and a change in behaviour, will take a lot of time, energy and perseverance from all involved, throughout the whole organisation. This leads us to the last subject in discussing future perspectives: health-care governance.

A subject that has not been addressed in the TOPplus study and now very topical, is health-care governance and the role of board members and Chief Executive Officers (CEO's) in relation to guality and safety. Improvement in guality and safety needs to take place at all four interrelated levels of the health-care organisation: individual, team and organisational and external stakeholders. TOPplus was limited to the individual and team level of the organisation, but to realise real and sustainable change the strategic organisational level should be actively involved. Hospital board members and CEOs should take responsibility and play an active role in major improvement programmes addressing guality and safety. Active leadership, such as executive leadership walk rounds and providing resources (e.g. IT-support, material or extra educational activities on patient safety issues for all involved) improve quality and safety and reinforce implementation of patient safety practices. Although participation of board members is highly recommended by national and international institutions on patient safety, our study showed that in many cases active participation is lacking. According to Conway (2008), problems identified impeding board members' engagement were: illiteracy on quality and safety, the absence of an agenda to improve quality and safety and accountability (Conway 2008). Moreover, in many health-care organisations a long-term vision and strategy are lacking because of budgetary problems most hospitals are facing (Bodenheimer and Fernandez 2005). Strategies to improve engagement should focus on these subjects and gather evidence on the impact of governance on quality and safety at organisational level. More and better-structured information is needed to design evidence-based strategies and systems and CEOs and board members should expand their expertise to use these to reinforce patient safety initiatives (Millar, Mannion et al. 2013). In this respect, the role of CEOs and hospital boards in relation to patient safety issues is still an immature research field and needs a distinctive body of knowledge and a methodology that is suitable for this domain. Governing institutions outside the hospital organisations, like quality assurance institutions or national inspectorates, should change their role from prescriptive and corrective to monitoring the results and supporting implementation of best practices. They should also develop evidence-based multidisciplinary guidelines with professional organisations and reinforce structural reporting, not to design ranking systems, but to create a learning environment, stimulate the exchange of best practices between hospitals and encourage a continuous endeavour for excellence.

9.5 Perspectives for research

Future research should focus on improvement initiatives that aim to design and implement multidisciplinary processes to improve quality and safety. Similar to TOP*plus*, these projects should also support the creation of a non-punitive culture and a learning environment. One of the subjects most discussed in the TOP*plus* study were the pre- and postoperative handovers in the surgical pathway. Although improvements were introduced, scientific evidence about the results and the essential components of handovers is still lacking (Cheung, Kelly et al. 2009, Manser, Foster et al. 2013). Questions to be addressed include among others which elements are crucial for patient safety to make the handover effective and efficient, what would be the best moment in the surgical pathway to discuss these items and who should be involved?

An interesting subject to focus on is the daily ward round, when a multidisciplinary team visits the patient and discusses the patient's condition, laboratory results and possible actions to review and plan patient care. Ward rounds are complex multidisciplinary clinical activities to provide safe care for patients and require effective communication between team members. Like TOP*plus*, ward rounds provide an excellent opportunity to learn as a team and include patients in the discussion. Similar to handovers, research should focus on the structure of the ward round and how it can be improved. What should be discussed, who should be involved and what are the responsibilities of each team member (Mohan and Caldwell 2013)?.

TOP*plus* includes a time out procedure and a debriefing. Our research shows that by now the time out procedure is introduced as a daily routine procedure and mostly performed as designed, with the whole team. However, the debriefing part of TOP*plus* needs more attention. A follow-up study in five hospitals showed that the low compliance was mainly caused by lack of attention of the surgical team, lack of time and lack of feedback on actions taken and results. Suggestions to improve compliance and make the debriefing meaningful were the following: adaptation of the timing of the debriefing following termination of anaesthetic procedure and assign responsibility for certain subjects (surgical, anaesthetic, instruments and material) to individual team members. Research on performance and compliance following introduction of these improvement measures will provide useful information about which item contributes most to improving effectiveness of the debriefing.

Another subject that requires further research is related to the feedback on the results following each iterative cycle in the Adaptive Design model. Not only because the debriefing lacked feedback, but also to find out if different forms of feedback improve

compliance and lead to more improvement actions. With TOP*plus* the feedback was provided following every cycle that differed in length between hospitals. Some hospitals were productive in their decision-making process and quickly entered the next cycle, however, in some hospitals each cycle would take more time. The next step in the TOP*plus* study could be the introduction of a feedback cycle every two or four weeks, studying the effect on shared decision-making and adoption. A stepped wedge design would provide an appropriate research design to include more sites at different time intervals, gathering insight in contextual aspects that are specific in a certain context and those that can be generalised (Brown, Young et al. 2014, Guzman, Fitzgerald et al. 2014). Gradually more articles are published in high impact medical journals that question the applicability and effectiveness of RCTs and promote innovative qualitative research methods that focus on quality improvement, learning and change (Bate and Robert 2006, Tunis, Benner et al. 2010).

Last but not least, an important and actual subject to explore is patient engagement. What is the role of the patient in patient safety initiatives? Handovers and ward rounds provide an excellent opportunity to study the role of the patient in clinical activities as well as in research projects. Active engagement of the patient in safety practices and active engagement as a partner and stakeholder in research projects might lead to improved outcomes, not only for the patient but also for the health-care organisation (Berger, Flickinger et al. 2014). Patients are getting more and more involved in shared decision-making and redesigning health-care delivery, already pointing to a future role of the patient as a member of his own care team, possibly even with specific responsibilities for his own treatment process. Laws are issued to safeguard patient information and informed consent and national and international patient organisations are involved in the development of policies and guidelines to improve health-care delivery. However, scientific evidence on patient participation, on how to involve patients and identification of valid measurable results is lacking and very much needed (Domecq, Prutsky et al. 2014).

To conclude this discussion, based on the results of this study it is strongly advised to use a multifactor approach in studies addressing design and implementation of Patient Safety Practices. This implies the combination of research methods from different theoretical domains, e.g. health-care technology and behavioural sciences, composing a multidisciplinary research team and using the Adaptive Design methodology and strategies to support, structure and monitor the implementation process.

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Summary

Since the publication of the Institute of Medicine study "To Err is Human" ten years ago, followed by "Crossing the Quality Chasm" two years later, patient safety has become a concern for all involved: patients, healthcare professionals and healthcare organizations. Over the last ten years, significant improvements were made and many innovative initiatives resulted in improved patient safety. However, research shows that preventable medical errors, also called Adverse Events (AEs) still occur. Causes of errors are diverse and range from technical and organizational factors, to human and patient factors. In many health care studies on patient safety, human factors e.g. communication and teamwork, are identified as the main contributors to the causation of AEs. A significant part of AEs is found in acute care hospitals and most of these errors in surgery and more specifically in the Operating Theatre (OT). Errors as wrong patient, wrong procedure and wrong site, often result in severe consequences for patients. To improve communication and teamwork and decrease the number of errors and prevent errors from occurring is one of the biggest challenges in OT.

Research on patient safety in surgical care shows four areas that complicate implementation of patient safety initiatives: 1) the complex and dynamic character of surgical care, which makes processes in OT difficult to manage and vulnerable to human error, 2) the professional silos and independent medical departments that make team cohesion and information-sharing at system level, across disciplines and departments difficult, 3) the organizational culture that needs to change from a punitive "blame and shame culture", to a "safe culture", without hierarchical barriers, where errors are perceived as opportunities to learn from and 4) the ability to learn as a team.

This thesis focuses on a Time Out Procedure (TOP) and debriefing (*plus*) to improve communication and teamwork of multi-disciplinary teams in the operating theatre (OT) to enhance patient safety. In a time out procedure critical items related to the patient or the surgical intervention are double checked to prevent errors from occurring. In the debriefing incidents or complications are discussed to prevent errors from occurring post operatively.

A basic multidisciplinary surgical team includes at least five team members: the surgeon, the anaesthesiologist, the scrub nurse, the circulating nurse and the nurse anaesthetist.

The overall research question of this thesis was: How to design and implement a time out procedure and debriefing to improve communication and teamwork in the operating theatre?

<u>Chapter 2</u> shows the results of a systematic review of team interventions, which confirmed the relevance of studying the time out procedure. The results of this review show that although many articles were found that described interventions to improve team performance, most of these articles presented very poor scientific evidence. The interventions described included tools, training activities and organizational interven-

Summary

tions. Although most studies presented an association between the intervention and non-technical skills, the evidence was weak. However, for teams in acute care there is growing evidence that communication and coordination skills in complex medical departments can be improved by simulation training and training activities based on the concept of Crew Research Management. Yet, the specific circumstances of a team should be diagnosed before and adapt the intervention to the local context.

<u>Chapter 3</u> presents the results of a questionnaire measuring the perception of OT team members regarding communication and teamwork, before introduction of TOP*plus* in OT. A pre-study in several hospitals confirmed the need for introducing TOP*plus* in OT. Differences in perceptions were measured between surgeons, OT-nurses (scrub nurses and circulating nurses), nurse anaesthetists and anaesthesiologists. The largest differences were found in communication, especially for surgeons compared to all other team members. All team members differed in perception of teamwork, whereas for situation awareness again the surgeons were far more positive compared to all other team members. Differences were also found for OT nurses compared to nurse anaesthetists and anaesthesiologists. Moreover, most team members rated briefings and debriefings as inadequate. OT teams are ad hoc, often changing in composition and very rarely meet as a team before surgery. Adequate briefings and debriefings provide team members with actual and necessary information to anticipate possible complications.

Chapter 4 describes the design of this prototype and the underlying rationale. To be able to successfully introduce TOPplus in OT, the first step that needed to be taken was the development of a prototype. Improvement of communication, situation awareness and teamwork helps individual team members to make the transition from autonomous professional to team player and achieve safe care. To reduce the incidence of errors and to minimize the consequences of those that do occur, teams should use all available data to understand the causes of errors and take appropriate actions. As actions might also include changing policies and procedures, a system approach is required to make linkages between other departments seamless, timely, efficient and reliable. TOPplus is dialogue-based to reduce hierarchical barriers and engage OT team members in doubleloop learning to critically reflect on and improve organizational practices. TOPplus was piloted at three hospital locations. A poster was developed to support the dialogue between OT team members and tested on usability. OT team members were invited to provide feedback on the layout and structure of the poster and on the content and structure of TOPplus. Most professionals perceived TOPplus and the strategy used for implementation as very positive. They especially valued the ability to adapt the poster to their local context, by adding, rephrasing or deleting guestions, or changing team members asking or answering questions. The precise moment to perform the time out and the consequences for the number of questions asked, are still open to discussion.

<u>Chapter 5</u> describes the design and implementation of TOPplus in five hospitals. The final step, in introducing the TOPplus in OT, was the development and testing of an

implementation strategy to improve adaptation to the local context and adoption by all involved. Participatory Design (PD), a theory developed in Industrial Design Engineering, was used as a strategy to engage professionals from different disciplines in the design and implementation process. Developing TOP*plus* with a multidisciplinary design-expertteam and a multidisciplinary local hospital-expert-team, providing frequent feedback and adapting it to the local context, proved to be valuable and was much appreciated by professionals. Although TOP*plus* reduced resistance and improved adaptation, it was insufficient to fully implement TOP*plus* in all hospitals. The study in five hospitals showed that for full implementation teams needed more time to reflect on errors, discuss possible actions and experiment and learn. In some hospitals, contextual differences between but also within surgical disciplines were far greater than expected and adequate adaptations to improve adoption required more time.

<u>Chapter 6</u> describes how participatory design and experiential learning were combined in a new model called Adaptive Design. It also presents a detailed description of the use of Adaptive Design in implementation processes where the local context requires tailor-made solutions. To put more emphasis on the team learning process and to create more time to experiment and learn as a team, PD was complemented with Experiential Learning (EL), which resulted in a new model called Adaptive Design (AD). The aim of the study was to find out if Adaptive Design would support a team learning process to structure and monitor the design and implementation process of TOP*plus*. The results show that teams in each hospital were able to adapt TOP*plus* to their own needs and context. The iterative process of redesigning, experimenting and learning stimulated engagement of professionals, improved adaptation and facilitated adoption. Adaptive Design creates the possibility to add extra iterative cycles, depending on the complexity of the local context, without losing the fundamental objective of TOP*plus*.

<u>Chapter 7</u> presents the results of this pre-post study to measure the effect of design and implementation of TOP*plus* on improved perception of communication and teamwork between OT team members. The results of the introduction of TOP*plus* were measured by performing a pre-post study in all participating hospitals. T_0 resulted in an overall response rate of 44%(n=725) and T_1 in 36% (n=554). At T_1 all disciplines showed significant higher ratings in non-technical skills, especially in Communication and Decision-making. Exchanging critical information about the patient and the surgical procedure pre-operatively improves situation awareness and encourages speaking-up intra-operatively. Most significant improvements were found for OT nurses, the least for nurse anaesthetists. To gather evidence on sustainable effects, it is recommended to repeat measurements over a longer period of time and to include a combination of process outcome measures, or patient reported outcomes. Furthermore, a combined approach of safety procedures and team interventions might reinforce the effect on team performance.

Summary

Chapter 8 describes the results of a multi-site study to explore the effect of TOPplus. The aim of introducing TOPplus was not only to improve teamwork in OT, but also to improve processes elsewhere in the surgical pathway to prevent errors from occurring in the future. It was expected that TOPplus would not only lead to process improvement in OT, but would also improve team learning across disciplinary and departmental boundaries. To identify improvements in processes or supporting organisational structures, the Clinical Micro Systems (CMS) framework was used. The CMS-framework looks at health care from a systems perspective and is defined as: the combination of a small group of people who work together on a regular basis, or come together as needed around the patient. to provide care to a small well-defined group of patients. A CMS includes administrative and management support, information and information technology and is embedded in the processes and structures of a larger organizational system. For this study, it provided a framework for the interviews and to analyse results at process and structure level. In six hospitals, 55 semi-structured interviews were carried out involving professionals from different disciplines. TOPplus was adopted as a daily routine procedure, adapted to the local context, but not always with the whole team present. In all six hospitals, the effects of TOPplus were visible organization-wide, at process and structure level. The team discussions helped to gain insight in the interrelatedness and interdependency not only between team members, but also with other disciplines and departments. This study showed the importance of a process-oriented and a system approach and how individual learning can be changed to team learning and from single-loop learning cycles to double-loop learning cycles.

In <u>Chapter 9</u> all research findings are recapitulated and discussed. The advantages of using Adaptive Design as a design and implementation strategy in combination with Participatory Action Research as research method are discussed. The necessity of learning on the job as a team is emphasized, preferably as an integrated part of daily work processes. Future perspectives for clinical practice and further research are discussed and recommendations given. For studies addressing patient safety practices, it is strongly recommended to use a multifactor approach, to combine research methods from different scientific domains and to include professionals from different scientific and healthcare disciplines.

Samenvatting

Sinds de publicatie van de Harvard Medical Practice studie van het Institute of Medicine (IOM) "To Err is Human", twee jaar later gevolgd door "Crossing the Quality Chasm", staat patiëntveiligheid bij patiënten, zorgprofessionals en ook zorgorganisaties, volop in de belangstelling. De laatste 10 jaar zijn al veel initiatieven ontplooid om de zorg aantoonbaar te verbeteren, maar onderzoek laat zien dat er nog veel medische fouten gemaakt worden en veel vermijdbare fouten voorkomen kunnen worden. De oorzaken voor medische fouten zijn divers en variëren van technische fouten en fouten die met de organisatie van zorg te maken hebben, tot patiënt gebonden en vooral menselijke fouten. In veel studies is aangetoond dat communicatie en teamwerk, of juist een gebrek daaraan, de oorzaak zijn van vermijdbare fouten. Een groot deel van de vermijdbare fouten vindt men in ziekenhuizen en vooral in de operatiekamers. Fouten als verkeerde patiënt, verkeerde procedure en verkeerde kant komen nog steeds voor en resulteren veelal in ernstige complicaties voor patiënten. Het verbeteren van communicatie en teamwerk en het reduceren van fouten zijn een grote uitdaging voor teams in de operatiekamer. Uit onderzoek blijkt dat er vier factoren zijn die de implementatie van initiatieven om de patiëntveiligheid te verbeteren bemoeilijken:

- 1) het complexe en dynamische karakter van operatieve interventies
- 2) de monodisciplinaire professionele silo's en medische afdelingen, die teamcohesie en het uitwisselen van informatie bemoeilijken
- de organisatiecultuur, die moet veranderen van een "blaming-and-shaming" cultuur, naar een veilige cultuur, zonder hiërarchische barrières, waar fouten worden gezien als een kans om van te leren en
- 4) het onvermogen om gezamenlijk als team te leren.

Dit proefschrift richt zich op het ontwerpen en implementeren van een time out procedure en debriefing in de operatiekamer om daarmee de communicatie en samenwerking van multidisciplinaire teams in de operatiekamer te verbeteren en daardoor ook de patiëntveiligheid. Een time out procedure is een "double-check" van kritische factoren, die te maken hebben met de patiënt of met de operatieve ingreep om fouten te voorkomen, voorafgaand aan de operatieve ingreep. In de debriefing bespreekt men incidenten of complicaties die zich tijdens de operatie hebben voorgedaan om fouten in het postoperatieve traject te voorkomen. Een basisteam voor een operatieve ingreep bestaat uit een operateur, twee OK-assistenten, een die assisteert tijdens de operatieve ingreep en een omloop, een anesthesioloog en een anesthesiemedewerker.

De centrale vraag van dit proefschrift luidt als volgt: Op welke manier kunnen we een time out procedure en debriefing ontwerpen en implementeren en daarmee de communicatie en samenwerking tussen teamleden en tussen teams in de operatiekamer verbeteren?

<u>Hoofdstuk 2</u> presenteert de resultaten van een systematic review van teaminterventies, waarmee de relevantie om een time out procedure en debriefing als onderzoeksobject te nemen bevestigd werd. Ofschoon veel artikelen zijn gevonden met een beschrijving van

Samenvatting

interventies om het functioneren van teams te verbeteren, lieten de meeste artikelen zeer weinig wetenschappelijk bewijs zien. Interventies waren o.a. instrumenten, trainingen en interventies gericht op de organisatie. Weliswaar is in een aantal artikelen een relatie gevonden tussen de interventie en de niet-technische vaardigheden, maar was er weinig bewijskracht. Ten aanzien van teams in de acute zorg is er echter in toenemende mate bewijs te vinden dat communicatie en samenwerking verbeterd kunnen worden door deelname aan simulaties of trainingsactiviteiten die gebaseerd zijn op het concept van Crew Resource Management (CRM). Het advies is wel om voorafgaand aan de interventie de actuele situatie in kaart te brengen.

Hoofdstuk 3 presenteert de resultaten van een vragenlijst waarmee bij teamleden van operatiekamers de perceptie gemeten is van communicatie en teamwerk op de operatiekamer. Dit alles voorafgaand aan de introductie van een Time Out Procedure (TOP) in combinatie met een debriefing (plus). Een voorstudie in enkele ziekenhuizen bevestigde de noodzaak en het nut om procedures als TOPplus te introduceren. Verschillen in perceptie zijn gemeten bij operateurs, ok-assistenten, anesthesiemedewerkers en anesthesiologen. De grootste verschillen zijn gevonden in relatie tot communicatie. De perceptie van de operateurs was meer positief dan die van de andere teamleden. In relatie tot teamwerk verschilden alle groepen van elkaar, maar in relatie tot situation awareness scoorden de operateurs opnieuw veel hoger dan de andere teamleden. Er zijn ook verschillen gevonden in scores tussen de ok-assistenten vergeleken met die van de anesthesiemedewerkers en de anesthesiologen. Bovendien zijn briefings en debriefings door de meeste teamleden als onvoldoende beoordeeld. In de operatiekamers werken teams veelal niet in vaste samenstelling en hebben zij slechts incidenteel gezamenlijk overleg voorafgaand aan de ingreep. Door een goede briefing en debriefing zijn medewerkers in staat om de juiste maatregelen te nemen en in te spelen op mogelijke complicaties tijdens het per- of postoperatieve proces.

<u>Hoofdstuk 4</u> geeft een beschrijving van het ontwerpen van het prototype van TOP*plus* en de basisbegrippen die daaraan ten grondslag liggen. Dit was de eerste stap in het proces om TOP*plus* op een goede manier in de operatiekamer te introduceren. Goede communicatie en teamwerk en goed op de hoogte zijn van alle bijzonderheden maken dat teamleden in staat zijn de transitie te maken van autonome professional naar teamspeler en gezamenlijk de patiëntveiligheid te verbeteren. Om fouten te voorkomen en zo goed mogelijk om te gaan met de consequenties van fouten die *toch* gebeuren, moeten teams zo veel mogelijk informatie verzamelen om zicht te krijgen op de (mogelijke) oorzaken en dan adequaat te reageren. Omdat dit ook kan betekenen dat richtlijnen en procedures moeten veranderen, is een systeembenadering noodzakelijk om de verbinding/samenwerking met andere afdelingen naadloos, tijdig, efficiënt en betrouwbaar te kunnen organiseren. TOP*plus* is gericht op het versterken van de dialoog tussen teamleden om zo hiërarchische barrières te verminderen, teamleden te betrekken bij "double-loop" leren en samen te reflecteren op bestaande organisatorische processen en procedures en deze te verbeteren. In drie ziekenhuizen is met TOP*plus* een pilot uitgevoerd om de bruikbaarheid te testen. Om de dialoog tussen de teamleden te ondersteunen is een poster ontwikkeld. Teamleden zijn uitgenodigd om feedback te geven op de inhoud, de structuur en de lay-out van zowel de procedure als de poster. TOP*plus* en de implementatiestrategie die gebruikt is, zijn door de meeste teamleden als zeer positief ervaren. Vooral de mogelijkheid om de poster aan te passen aan de eigen context door vragen te herformuleren, toe te voegen of te verwijderen, omdat deze vragen niets toevoegen, is door veel teamleden gewaardeerd. De discussie over het moment van de time out procedure en de gevolgen van het toevoegen van extra vragen (tijd) is nog niet afgerond.

Hoofdstuk 5 geeft een beschrijving van het ontwerp- en implementatieproces in vijf verschillende ziekenhuizen. Een van de laatste stappen in het onderzoek rond de introductie van TOPplus in de operatiekamer was het ontwerpen en toetsen van een implementatiestrategie om alle professionals te betrekken bij het aanpassen van de procedure en toepassen daarvan in de eigen situatie. Om dit te bereiken is gebruik gemaakt van Participatory Design dat binnen Industrieel Ontwerpen gebruikt wordt als methode om eindgebruikers te betrekken bij een ontwerp- en implementatieproces. Het werken met een multidisciplinair ontwerpteam en een multidisciplinair lokaal team van zorgprofessionals was nuttig en werd erg op prijs gesteld. Alhoewel met de introductie van TOPplus de weerstand onder professionals verminderde, was de tijd voor experimenteren en leren nog onvoldoende voor acceptatie van TOPplus door alle professionals in alle ziekenhuizen. Met deze studie is aangetoond dat voor volledige acceptatie en gebruik van TOPplus, teams meer tijd nodig hebben om gezamenlijk te reflecteren, te experimenteren en te leren. In sommige ziekenhuizen was het verschil tussen disciplines te groot en te divers, waardoor een adequate aanpassing om TOPplus op een goede manier te gebruiken, meer tijd kostte.

<u>Hoofdstuk 6</u> bevat een beschrijving van een nieuw model: "Adaptive Design", waarin participatory design is samen gevoegd met experiential learning. Het hoofdstuk geeft ook een gedetailleerde beschrijving van de toepassing van "Adaptive Design" in implementatieprocessen waar de lokale context om op maat gesneden oplossingen vraagt. Om meer nadruk te leggen op het gezamenlijke leerproces van teamleden en meer tijd te creëren om samen na te denken en te experimenteren, is participatory design aangevuld met experiential learning. Het doel van de studie was om te toetsen of "Adaptive Design" als implementatiestrategie geschikt was om het leerproces rond TOP*plus* te structureren en te monitoren. Uit de resultaten is te concluderen dat de teams op deze manier in staat waren om TOP*plus* aan te passen aan de eigen lokale context. Het iteratieve proces van herontwerp, experimenteren en leren stimuleerde de participatie van professionals, bevorderde aanpassen van de procedure en faciliteerde adoptie. "Adaptive Design" creëerde de mogelijkheid om extra cycli toe te voegen, indien dat in verband met de complexiteit van de eigen context nodig was, zonder de basisdoelstelling van TOP*plus* te ondergraven.

Samenvatting

<u>Hoofdstuk 7</u> presenteert de resultaten van een voor- en nastudie waarin het effect is gemeten van het ontwerpen en implementeren van TOP*plus* op de perceptie van communicatie en samenwerking van teamleden. De voor- en nastudie zijn uitgevoerd bij alle ziekenhuizen (n=15) die aan de TOP*plus*-studie hebben meegedaan. De T_o gaf een respons van 40% (n=725) en in T₁ een respons van 36% (n=554). In T₁ is bij alle disciplines een verbetering te zien bij de niet-technische vaardigheden, vooral bij Communicatie en Besluitvorming. Het uitwisselen van kritische informatie over de patiënt of de operatieve ingreep bevordert dat teamleden tijdens de operatie opmerkingen durven te maken. De meest significante verbeteringen zijn gevonden bij de operatieassistenten, weinig verbetering is te zien bij de anesthesiemedewerkers. Om het effect op de langere termijn vast te kunnen stellen, is het aan te bevelen de metingen regelmatig te herhalen en aan te vullen met resultaten gekoppeld aan het zorgproces of aan patiënt-gerelateerde uitkomsten. Daarnaast zou een gecombineerde aanpak van een veiligheidsprocedure met een teaminterventie het effect op teamprestaties kunnen versterken.

Hoofdstuk 8 geeft een beschrijving van een multi-site studie, die is uitgevoerd om het effect te meten van TOPplus op het hele zorgproces. TOPplus was niet alleen bedoeld om de communicatie te verbeteren, maar ook om fouten in de toekomst te voorkomen door het aanpassen van processen in eerdere stadia van het zorgproces. De verwachting was dat TOPplus niet alleen de processen in de operatiekamer zou verbeteren, maar ook invloed zou uitoefenen op het leren van teams over de grenzen van afdelingen en die van medische disciplines heen. Om verbeteringen elders in het zorgproces van de operatieve patiënt te identificeren is het Clinical Micro-Systems (CMS) model gebruikt. Het CMS biedt een kader om vanuit de systeembenadering naar zorgprocessen te kijken en kan gedefinieerd worden als de combinatie van een kleine groep mensen, die op reguliere basis samenwerkt of, afhankelijk van de situatie van de patiënt, bij elkaar komt om voor een kleine, helder omschreven patiëntengroep de gewenste zorg te verlenen. Een CMS omvat ook de administratieve en technische functies, die zijn ingebed in de processen en structuren van de organisatie en nodig zijn om de dagelijkse zorgverlening te ondersteunen. Voor deze studie vormde het CMS een mooi kader om gegevens te verzamelen en de resultaten op proces- en structuurniveau te analyseren. In zes ziekenhuizen, die aan de TOPplus-studie hebben meegedaan zijn 55 semigestructureerde interviews uitgevoerd, waarbij professionals van verschillende disciplines en ondersteunende stafdiensten betrokken waren. TOPplus is, aangepast aan de lokale context van de verschillende disciplines, geïmplementeerd als een dagelijkse procedure, maar niet altijd in aanwezigheid van het hele team. In de zes ziekenhuizen zijn naar aanleiding van TOPplus door de hele organisatie heen veranderingen gevonden zowel op proces- als op structuurniveau. De discussies tussen teamleden hielpen om inzicht te krijgen in de onderlinge relatie en afhankelijkheid tussen teamleden, maar ook met en tussen andere afdelingen. Deze studie benadrukt het belang van een proces- en systeemgerichte benadering en laat zien hoe individueel leren kan veranderen in teamleren en in cycli van "single-loop" leren naar cycli van "double-loop" leren.

In *hoofdstuk 9* zijn de onderzoeksresultaten kort samengevat en besproken. De voordelen van het gebruik van "Adaptive Design" als ontwerp- en implementatiestrategie in combinatie met Participatief Actie-onderzoek als onderzoeksmethode zijn toegelicht. Nadruk is gelegd op het belang van het leren als team op de werkplek, bij voorkeur als een routineprocedure die in de dagelijkse werkprocessen is ingebed. Mogelijke toekomstige ontwikkelingen zijn aangegeven, gevolgd door aanbevelingen voor de klinische praktijk en voor vervolgonderzoek. Het is zeer aan te bevelen om bij studies, die gericht zijn op patiëntveiligheid een multi-factor benadering te hanteren, onderzoeksmethoden uit verschillende theoretische domeinen te gebruiken en professionals vanuit verschillende wetenschappelijke en medische disciplines bij het onderzoek te betrekken.

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Biography

Connie Dekker-van Doorn was born in Haarlem, The Netherlands, on July 25 1946. Early 1969 she successfully completed the in-service program "Verpleegkundige A met aantekening Kraamverpleegkundige" (R.N. with Obstetrics certificate) at the St. Joannes de Deo Hospital in Haarlem. In August that year she accompanied her husband to Eugene (Oregon, USA) where she worked as a R.N. at the River Road Medical Clinic until December 1972. Upon her husband finishing his MBA, Connie and he returned to The Netherlands and then moved to Brussels (Belgium) in 1974.

Having started a part-time study (Family Sciences) there in 1984, Connie returned to The Netherlands and enrolled in the Human Resource Development program in the Department of Education of Utrecht University, where in May 1992 she graduated with a Master Degree in Education, while holding a part-time job at IBM Nederland as Consultant Management Development. When she and her family moved to Paris (France) for a year, she worked as an independent consultant on a number of management development projects for international clients in the computer industry.

In 1994 Connie returned to her first love, the Health Care sector where during 7 years she held various positions such as Head of Training, Head of Ambulatory Surgical Care Facilities with special responsibilities for the integration of ambulatory and clinical care and was member of various task forces on Quality & Safety. In 2001 she joined Erasmus Medical Center in Rotterdam where she started out as Consultant Quality & Innovation Patient Care and chaired the Nurse Practitioner task force and the Protocol Committee, while in 2003 being appointed Manager Patient Care.

At the beginning of 2008 Connie was named Erasmus Medical Center's Project Manager TOPplus (Time Out Procedure and Debriefing in the Operating Theatre) and started at the same time her PhD research on Patient Safety and Team Learning at the Institute for Health Policy & Management (iBMG) of Erasmus University.

As of January 2014 Connie is Professor of Evidence-Based Care in Nursing at Rotterdam University (University of Applied Sciences), where she is responsible for setting up and developing a program on Evidence-Based Care that integrates research, education and practice.

Connie is married, has three children and two grandchildren.

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Dekker-van Doorn CM., Wauben LSGL. (2014). "One size fits all?" Lecture at Conference "Beyond the Checklist" 9 September. Oosterwijk, The Netherlands

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