

Implementation of safety checklists in medicine

Not as simple as it sounds

Øyvind Thomassen



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All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed.

Third, it is accepted as being self-evident

Schopenhauer A

Scientific environment

The studies presented in this thesis were performed in the Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen. The checklist development and implementation were performed in the operating theatres for neuro-, plastic-, burn-, and ENT surgery. The high reliability organisations interviewed were located in Norway and Sweden.

I have been a PhD fellow at the Department of Surgical Science at the Faculty of Medicine and Dentistry, University of Bergen.

I have received financial support from the Norwegian Air Ambulance Foundation (SNLA) and the Emergency Medical Services, Department of Anaesthesia and Intensive Care, Haukeland University Hospital.



Preface and acknowledgements

One day the anaesthetic nurse and I were providing anaesthesia to a healthy young man. Everything was uncomplicated and the tasks were routine work. After the patient was intubated, I discovered that the screen on the monitor was black. We had forgotten to monitor the blood pressure, heart rate and oxygen saturation as we always do. I had never experienced this before, and the nurse and I were terrified how this could happen.

The idea of checklist in health care came when working as a Helicopter Emergency Medical Service (HEMS) doctor. The pilot and the rescue man always, without exceptions, performed the “before take off” checklist. Dropping the checklist would have been a serious and unaccepted safety violation even, if the operation was time-critical. There are many similarities between health care and aviation. The operations are often complex, involves team work and requires high technology equipment. Sitting in the cabin I wondered if a pilot checklist would be useful, feasible, and effective tool to increase patient safety in health care. I shared the experience regarding the forgotten monitor with colleagues in my department, and the idea to this thesis was born.

In medical school I was taught that students with the highest level of knowledge would become the best doctor and give the safest treatment. Today, I know that patient safety is a highly complex issue, and that individual skills and knowledge only represent some parts of it.

Many have contributed to this thesis. First, I would like to thank the informants from Haukeland University Hospital and the high reliability organizations. I greatly appreciate your efforts conducting the checklist and voluntarily participating in the interviews.

Jon Kenneth Heltne has been the main supervisor. You have been supportive and your experience with former PhD work has been valuable, and thank you for the will to give supervision from Australia the last year. Hans Morten Lossius have been assistant

supervisor. You have provided stimulating discussions and kept me on track when the aims expanded. You have also been supervising the research group in Norwegian Air Ambulance Foundation. In this group I have met, discussed, and learned a lot from more than twenty other PhD students. Thank you fellows for your structural feedback and the insight you offered me in your own studies. Financial support has been obtained from the members in Norwegian Air Ambulance Service Foundation. I hope your contribution has taken patient safety a little step forward.

Assistant supervisor and my boss Guttorm Brattebø; you are a never ending fountain of energy and inspiration. Without you this thesis would not have been possible.

Torben Wisborg, Hammerfest hospital, introduced me to research and patient safety. You have a thorough insight in research and a gift to inspire others. Thank you for the honest mail you sent me after reviewing one of the first research protocols: *“You are totally lost. Call me! Torben”*. Eirik Søfteland embraced the idea of a pre-induction checklist. Through your leadership you opened up your section to the introduction of the checklist, encouraging our work and the personnel all along. You also participated actively throughout our work yourself. Ansgar Espeland introduced me to the world of qualitative method. Thank you for the dozens of meetings and litres of coffee in your office. You have an outstanding ability to see who I am, where I am, and where I am going.

At last, a well deserved thanks to my colleagues in the department of emergency medicine for your patience during these four years of 50% absence from common duties.

No accomplishments would have any meaning if it were not being shared with my wife Liv Karin and my children Jørgen and Ingrid. Your love and support have reminded me that research is an insignificant part of life.

Abstract

Background

Adverse events are documented to affect more than one in 25 hospital patients. Medical mishaps and errors are rarely the result of incompetence, poor motivation or negligence but challenges on social and cognitive skills such as loss of situation awareness, poor communication, less than optimal teamwork, problematic stress management, and memory overload. Realising how prone we as humans are for short term memory loss, it is striking how many potentially dangerous medical procedures are based on “perfect” memory.

The aims of this thesis were to develop and measure the effect of a pre-induction safety checklist in anaesthesia, explore the personnel’s acceptance and experience with this list, and further examine experiences with checklists in some non-medical high reliability organisations (HROs). This is organisations achieving high levels of safety despite facing considerable hazard and operational complexity

Methods

Statistical process control (SPC) was chosen as a quantitative approach to measure the effect of the pre-induction checklist implementation. Qualitative approaches using focus groups, key informant interviews, Delphi technique, and consensus process were utilized to develop the checklist and examine checklist experiences.

Results

During a study period of 13 weeks the 26 items checklist was used in 502 (61%) of 829 anaesthesia inductions. One or more missing items were identified in 17% (range 4-46%) of these procedures. It took a median of 88.5 seconds (range 52-118) to perform the checklist.

Some participants were concerned that patients might have become anxious about possible unpreparedness since there was a “need” for a final check. The participants had, on their own initiative, adopted strategies to reduce this potential burden to the patients. The introduction of the checklist interrupted workflow by disturbing some of

the personnel's own streamlined working habits or by causing redundant checks done by both nurses and physicians. Some participants had experienced negative or ironic comments from colleagues. They emphasised the importance of a supporting and motivating unit leader. Several of the participants had experienced increased confidence in performing challenging cases in unfamiliar places and situations. The participants discovered that the seven various operating theatres in which the checklist was used, were not designed and equipped in the same way. This highlighted the need for standardisation if the same checklist should be used in every operating theatre.

The interviews with personnel from six HROs generated 84 crucial assertions in checklist development and implementation. Several of the informants underlined the importance of an early assessment if a checklist is the right tool to solve a specific problem. Proximity (defined as ownership and nearness in relation) for all stakeholders, directly or indirectly involved, was claimed to be a key-issue during checklist development. All informants also agreed that the design and length of checklists are vital. Major issues regarding checklist utilisation were: a predefined and agreed upon phraseology, understanding of the background of each point on the list, and to be aware of automaticity. Periodic revisions were described as important for two reasons; firstly to maintain an up-to-date checklist and secondly to build a culture in which the end-user feels that their feedback is valuable for the organisation.

Conclusions

The introduction of safety checklists in health care is more difficult than it seems at first, and the best approach for achieving success and staff compliance is dependent on several factors. Our findings have provided some new insight in the challenges of developing and implementing checklists.

List of publications

The papers are refereed by their Roman numerals (I – III) in the text.

I

Thomassen O, Brattebo G, Softeland E, Lossius HM, Heltne JK.

The effect of a simple checklist on frequent pre-induction deficiencies.

Acta Anaesthesiologica Scandinavica. 2010;54:1179-84.

II

Thomassen O, Brattebo G, Heltne JK, Softeland E, Espeland A.

Checklists in the operating room: Help or hurdle? A qualitative study on health workers' experiences.

BMC Health Service Reserach 2010;10:342.

III

Thomassen O, Espeland A, Softeland E, Lossius HM, Heltne JK, Brattebo G.

Implementation of checklists in health care; learning from high-reliability organisations.

Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. In press.

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Abbreviations

AE: Adverse event

HEMS: Helicopter Emergency Medical System

HRO: High reliability organisation

ICU: Intensive Care Unit

IOM: Institute of Medicine

NTS: Non technical skills

QI: Quality Improvement

SA: Situation awareness

SPC: Statistical process control.

SURPASS: Surgical Patient Safety System

WHO: World Health Organization

Contents

SCIENTIFIC ENVIRONMENT	4
PREFACE AND ACKNOWLEDGEMENTS	5
ABSTRACT	7
LIST OF PUBLICATIONS	9
ABBREVIATIONS	10
1. BACKGROUND.....	13
1.1 The start in aviation	16
1.2 Safety checklists	17
1.3 Checklists in medicine	18
1.4 The challenge.....	23
2. AIMS OF THE STUDY	25
3. METHODS	26
4. SYNOPSIS OF RESULTS	33
5. DISCUSSION	40
5.1 Checklist scepticism	40
5.2 Challenges in checklist development	42
5.3 Guidelines for checklist development	44

5.4 Automaticity and checklist fatigue	46
5.5 Time spent and cost of checklist use	47
5.6 Non-technical skills and checklists	48
5.7 High Reliability Organisations (HRO)	50
5.8 Methodological considerations and ethics	51
6. CONCLUSION	58
7. FUTURE RESEARCH	59
REFERENCES	60
APPENDIX	69
PAPERS I – III	71

1. Background

“Medicine used to be simple, ineffective, and relatively safe.

Now it is complex, effective, and potentially dangerous.”

Chantler C [1]

What were once considered medical miracles have now become routine treatment, but the increased complexity has led to a higher risk of harming the patient. Patient safety can be defined as *freedom from accidental injury* [2]. Harm or damage from medical therapy, in contrast to complications of a disease, has been termed *adverse events* (AE) [3]. All healthcare providers have a common goal to provide safe and high-quality care. But everyone will experience that AEs are, and will always be part of, the practise of medicine. The consequences of AEs can be devastating for the patient, their families, and also the healthcare providers involved (the latter are also called “the second victim”) [4]. AEs are documented to affect more than one in 25 hospital patients [5]. AE are rarely the result of incompetence, poor motivation or negligence [6]. There are numerous causes of AEs, often with several occurring at the same time, in a complex manner. Table 1 lists some examples of contributing factors that are reported to be associated with AEs.

-
- Inadequate adverse event reporting systems
 - Not following agreed upon guidelines
 - Not seeking help when needed
 - Inadequate or not available supervision
 - Wrong treatment given, or treatment given to wrong patient
 - Inadequate handover and loss of crucial information
 - Low quality communication
 - Failure to detect missing or not functioning equipment
 - Low compliance to carry out checks agreed upon
-

Table 1. Some examples of care management challenges that may be associated with AEs (modified from [7-9]).

Eliminating AEs is impossible because they are inherent parts of the complexity of modern medicine and large organisations, and hence AEs will always be around [10]. The major challenges are therefore how we harness the risks by identifying them or discover signs of failure, responding to them before patients injury has occurred, and to learn from them and hopefully be able to change our systems accordingly [11].

In 2005 the World Health Organization (WHO), released a guideline for AE reporting and learning systems [3]. The subtitle of this guideline was “*From information to action*”. It is a demanding and complex task to implement effective *actions* in order to reduce the number of AEs. The contributing factors of AEs are rarely short-comings in factual knowledge and skills, the majority of AEs are attributed to “human vs. human” and “man vs. machine” interfaces [12]. These interactions have been called *non technical skills* (NTS) and relate to social and cognitive competencies, such as situation awareness, communication, teamwork, stress management and memory [13, 14].

In a highly complex organisation, such as health care, reliance on memory is a core issue. Memory can be divided into short term memory, long term memory, working memory and prospective memory [15] (Table 2). *Short term memory* is information stored for seconds to minutes such as looking at the speedometer when driving a car or remembering the last blood pressures values when monitoring a patient. It has been stated that seven is the “magical” number of items that limits our capacity for short term memory [16]. Information that is possible to recall after a longer period is *long term memory*. This information has been stored by cramming (e.g. learning by rote) or by doing repeated tasks. *Working memory* is an interaction between short- and long term memory needed to do complex tasks such as reasoning, reflection and learning. Working memory is about using different kinds of memory, perception and experience in order to solve a specific operation [17, 18]. Performing a check before anaesthesia requires new information about the specific patient combined with memorized general information. *Prospective memory* is the ability to remember or continue a task as planned after a delay or disruption [19]. Interruptions are frequent in a hectic clinical environment and most health care workers will recognize these as normal. Delays and

other unforeseen events are common challenges in most professions and in our daily life. The consequences of forgetting an important step may be fatal in a nuclear power plant or anaesthesia, but acceptable in the grocery store. Failure in prospective memory has accordingly been claimed a threat to patient safety [20].

Type of memory	Definition	Example
Short term memory	New information stored for seconds or minutes	Monitoring the speedometer when driving.
Long term memory	Stored information that is possible to recall	Cramming a foreign language or repeatedly operations
Working memory	Memory needed to perform complex tasks such as reasoning, reflection and learning	Performing a pre-induction check.
Prospective memory	The ability to remember or continue a task as planned after a delay or interruption	A surgeon being interrupted during a demanding period of the surgery or a father with his crying child in the supermarket

Table 2. Classification of different types of memory (modified from [15]).

In 2000 the Institute of Medicine published the report *“To Err Is Human: Building a Safer health System”* [2]. This report was regarded a milestone in patient safety worldwide. The report gives five principles for designing safety systems in health care organisations. One of these principles is to respect human limitations and avoiding reliance on memory. Realising how prone we as humans are for short term memory loss, it is striking how many potentially dangerous medical procedures that are based on “perfect” memory [19].

1.1 The start in aviation

When the term “checklist” is used, most people will associate the word with aviation, pilots, cockpits, and aircrafts. The systematic use of safety checklists also started in aviation [21]. In October 1935, the U.S. Army held a flight demonstration with the new Boeing 299 in Dayton, Ohio. This four engine aircraft could fly longer, faster and carry more bomb loads than any other previous military aircraft. After take-off, in front of generals and manufacturing executives, the aircraft stalled and crashed in a blazing explosion [22]. This event was sentinel because of it’s consequences for further training of U.S. army pilots. Investigation showed that the crash had been due to “pilot error”. It was stated after the accident that due to the complexity, this aircraft was “too much airplane for one man to fly”. Instead of harder and longer training for the crews they came up with a simple approach; a pilot’s checklist [21]. With the checklist in hand, pilots went on to fly the Boeing 299 (which is nicknamed the B-17) for a more than 1.8 million miles without one serious incidence. Since 1935 the pilots’ checklists have been the cornerstone in flight safety. It has been stated that medicine now is about to enter its “B-17 phase” [23], indicating that the complexity has exceeded the capability for “one man”, without help or cognitive tools, to perform safe quality care.



Illustration 1. The end of B-17, Wright Field, Ohio, October 30, 1935.

Aviation belongs to a type of organisations called *high reliability organisations* (HRO). HROs are organisations achieving very high levels of safety, resulting in fewer

than expected accidents, despite facing considerable hazards and operational complexity [24]. Nuclear power production, aerospace industry, fire fighting, military operations, and engineering also represent examples of such organisations. Some characteristics of HROs are their preoccupation with the possibility of failure, resistance to oversimplification, commitment to resilience and self-preservation, deference to shifting locations of expertise, and prevention of small mishaps to escalate [25]. Checklists are commonly used in HROs, and these organisations have decades of experience with checklist development and their implementation.

1.2 Safety checklists

There is no uniform definition of “checklists” in health care. However, the most common understanding is that a checklist is a cognitive tool that can help us to remember and perform tasks or operations. These can vary from as simple as not forgetting to buy milk at the grocery, to commanding an aircraft carrier [26]. Some checklists are performed as background checks when planning an activity, others checks are performed immediately before a procedure is about to start, e.g. the pilot’s before-take-off checklist [19]. The latter checks allow errors occurring at an earlier stage in the “causation chain” to be detected. Such checklists are commonly called safety checks.

In medicine, there are many other tools that help us to perform various tasks safely. Terms as clinical and practice guidelines, treatment protocols, a variety of algorithms, and diagnostic criteria are often used interchangeably with checklists, but differ substantially from a safety checklist. A clinical guideline or a treatment protocol gives a kind of “recipe” to support and guide decision making and planned interventions. They are also introduced to improve workflow and reduce variation [26]. The Institute of Medicine defines clinical guidelines as “*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*” [2]. A safety checklist is an overriding aid to ensure that planned activities or operations are performed in a certain manner and order [27]. In

our department we have a difficult airway algorithm and a safety checklist. The algorithm guides the clinical decisions and the pre-induction checklist ensures that the equipment is available and functioning, and hence improves preparedness.

Generally, a checklist is intended to be a memory aid, but have several other functions. One objective is enhancing the team's preparedness by keeping the team members "in the loop", promoting a higher level of situation awareness, and improving communication [28]. Checklists can also serve as a quality control tool. In aviation checklists are viewed as a tool to structure the man-machine interfaces [29].

There are mainly two methods of conducting a safety checklist. The *do* list where the checklist is used to lead the operation step by step, and the *challenge-response* list where the operation is prepared according to normal standard procedures, where the checklist is used to verify or check each item as they are performed or checked. The challenge-response method is used in cockpits and is also the most frequently used method in medicine. In this thesis the term "checklist" is used synonymous with a "safety checklist".

1.3 Checklists in medicine

Checklists, in various forms, have probably been used as memory aid from the dawn of health care. The ABC (Airway, Breathing and Circulation) principle in first aid is a well-known type of checklist. The letters are easy to remember, reminds us of the most important interventions in a chronological and medically correct order. Interestingly, it is also used by both laypersons and professionals. The ABC checklist is short, and designed for emergency situations. On the other hand, the WHO checklist for influenza pandemic preparedness planning, contains 39 pages and 168 items [30]. To prepare for a pandemic requires a completely different tool than what is needed when treating a critically ill or injured patient. However, both checklists are useful in their context.

A literature search on the PubMed database revealed an increasing number of published scientific papers regarding safety checklists since the IOM report in 2000, with a dramatic increase the last few years (search words: [checklist AND safety] (Figure 1).

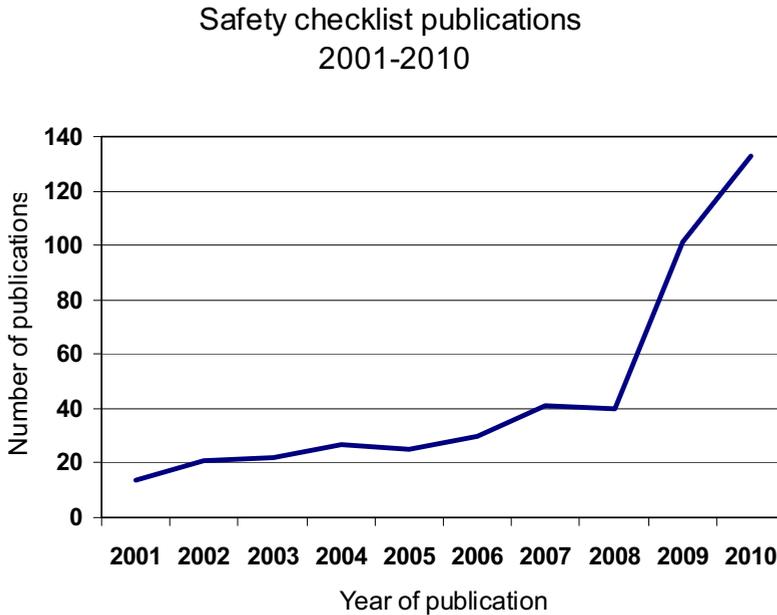


Figure 1. The number of scientific publications on safety checklists listed on PubMed from 2001-2010.

As an example from medicine, important steps in preparation for surgical procedures are frequently missed [31, 32]. Preoperative checklists have shown to reduce problems with surgical equipment during the procedures [33] and anaesthetic set-up [34]. Poor inter-professional communication is also known to often play a part in the development of adverse events [2, 35]. Two clinical intervention studies among

surgeons, nurses, and anaesthesiologists have shown to reduce the number of communication failures and also to improve team cohesion [36, 37].

Checklists are shown to be effective tools ensuring that specific care processes were performed according to plan and established protocols. One study reported an increased number of patients receiving treatment according to the local protocols after the implementation of a “clinical pathway checklist” [38]. Another clinical pathway checklist has demonstrated to reduce the length of post operative stay [39]. In a similar study a 16 items checklist identified that several specific aspects of care were not delivered when appropriate [40]. Further, a mandatory verbal review of a checklist was an effective method to improve both considerations and implementation of best clinical practise in a surgical/burn/trauma ICU [41]. The three latter studies have in common that none of the actual clinical guidelines were new or modified, they just weren’t always followed. The single and simple intervention was the introduction of a checklist!

In 2004, Peter Pronovost and colleagues at Johns Hopkins University Hospital, achieved a significant decrease in catheter related infections after introduction of a simple checklist ensuring that established guidelines were followed [42]. They calculated that during a period of five years, the checklist had prevented forty-three infections and eight deaths and thereby saved about two million US dollars per year. In a follow up study including 106 ICUs, these findings were confirmed [43]. Pronovost was among the first to recognize and document, the checklist’s power to improve care processes and thereby save lives.

Surgical Safety Checklist		
 World Health Organization		Patient Safety <small>A World Alliance for Safer Health Care</small>
Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
(with at least nurse and anaesthetist)	(with nurse, anaesthetist and surgeon)	(with nurse, anaesthetist and surgeon)
<p>Has the patient confirmed his/her identity, site, procedure, and consent?</p> <input type="checkbox"/> Yes	<p><input type="checkbox"/> Confirm all team members have introduced themselves by name and role.</p> <p><input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.</p> <p>Has antibiotic prophylaxis been given within the last 60 minutes?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>Nurse Verbally Confirms:</p> <input type="checkbox"/> The name of the procedure <input type="checkbox"/> Completion of instrument, sponge and needle counts <input type="checkbox"/> Specimen labelling (read specimen labels aloud, including patient name) <input type="checkbox"/> Whether there are any equipment problems to be addressed
<p>Is the site marked?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>Anticipated Critical Events</p> <p>To Surgeon:</p> <input type="checkbox"/> What are the critical or non-routine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss?	<p>To Surgeon, Anaesthetist and Nurse:</p> <input type="checkbox"/> What are the key concerns for recovery and management of this patient?
<p>Is the anaesthesia machine and medication check complete?</p> <input type="checkbox"/> Yes	<p>To Anaesthetist:</p> <input type="checkbox"/> Are there any patient-specific concerns?	
<p>Is the pulse oximeter on the patient and functioning?</p> <input type="checkbox"/> Yes	<p>To Nursing Team:</p> <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns?	
<p>Does the patient have a:</p> <p>Known allergy?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes	<p>Is essential imaging displayed?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	
<p>Difficult airway or aspiration risk?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available		
<p>Risk of >500ml blood loss (7ml/kg in children)?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and two IVs/central access and fluids planned		

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

Figure 2. The WHO Surgical Safety Checklist.

A milestone for safety checklists in medicine was the Second Global Patient Safety Challenge: “Safe Surgery Saves Lives” initiative, launched by the WHO in 2008 [44]. One of the final products of this program was the Surgical Safety Checklist (Figure 2 and appendix 1) [45]. This checklist is conducted in the operating theatre and consists of three parts; Sign in, Time out, and Sign out. This checklist was piloted in 8 hospitals worldwide during 2007-2008 to study whether it actually improved safety. Complication rates dropped significantly and the in-hospital mortality decreased from 1.5% to 0.8% after the introduction of the checklist [46]. Today, this checklist apparently has been implemented in over 3000 hospitals worldwide [47].

Parallel to the development of the WHO Surgical Safety Checklist the Surgical Patient Safety System (SURPASS) checklist was developed and implemented in the Netherlands [48]. This checklist follows the surgical pathway from admission to discharge. The number of complications decreased significantly and the in-hospital mortality decreased from 1.5% to 0.8% [49].

The WHO Surgical Safety Checklist is perhaps the most widely cited and debated safety checklist in medicine. This may have contributed to the increased interest for safety checklist since 2008. Table 3 shows some selected publications from studies on the effects of checklists, and also the diversity of the study aims.

Author and year of publication	Aims
Wolff AM et al. 2004 [38]	Whether the quality of hospital inpatient care was improved
Romagnuolo J et al.2005 [39]	To measure the length of post-operative hospital stay
Hart EM et al. 2005 [34]	Whether a checklist helped in preparation for general anaesthesia
Hewson KM et al. 2006 [40]	Whether certain care processes were performed systematically in the ICU
Pronovost P et al. 2006 [43]	Incidence of ICU catheter-related bloodstream infections
Verdaasdonk EGG et al. 2008 [33]	Whether a checklist reduced the number of incidents with laparoscopic equipment
Lingard L et al. 2008 [37]	Whether structured team briefings improve operating room communication
Byrnes MC et al. 2009 [41]	Whether clinical considerations were improved and practice patterns changed
Haynes AB et al. 2009 [46]	Complications and morbidity associated with surgery
De Vries EN et al. 2010 [49]	To compare complications and mortality in surgery

Table 3: Some examples of safety checklist effect studies and their aims.

So there are numerous publications indicating that checklists are useful and effective in improving quality of care. On the other hand, we have not identified studies claiming that checklists have *decreased* patient safety. Despite this, there seems to be challenges adopting this seemingly very effective tool.

1.4 The challenge

Since 2007, numerous reports on challenges with checklist acceptance and inadequate suggestions for checklist development and use have been published [50-53]. Similarly, reports about weaknesses in guidelines for clinical protocol development also have been reported [54-56]. Checklists can improve quality of care, however there are at least two major challenges. Firstly, attitudes towards checklists vary and secondly, although checklist implementation might seem deceptively simple, their development and use is a rather complex issue.

Quality improvement and resistance to change

Any kind of quality improvement means some type of change, but any change doesn't necessarily guarantee that the quality improvement has occurred. Changing behaviour is never easy and therefore some resistance always accompanies a change or improvement process [57]. This is especially the case in medicine, which tend to be a rather slow-changing part of society. Even well documented improvements can take many years before being adopted by all. Examples of this are the low implementation rate of therapeutic hypothermia after cardiac arrest [58], and beta-blocker use after myocardial infarction [59].

There are numerous reasons why some people resist change, but this can be on the personal level like loss of freedom or more work. Further, misunderstanding the aims and consequences of the proposed change, or a belief that the change does not make sense. It can also be a result from lack or limited trust in leadership [60]. Individuals neither "buy in" nor adapt innovations at the same time. A few people are "innovators" who greet new ideas and changes always welcome. The majority are "early adaptors" or "late adaptors", while a few are "laggards" who have an inherent scepticism to all types of change [57]. Understanding how resistance to change can be handled is crucial to success. Introduction of aviation style challenge-response checklists in medicine may be perceived as a major change in "our own way of doing things" and consequently lead to a diversity of adapting behaviours.

Checklist development and implementation

Prior to the first article in 2007, only one medical publication concerning checklist development was identified [61]. A more extensive search identified several non-medical organisations with experience in checklist development and implementation. In aviation, where an established checklist culture exists, we identified three reports [28, 29, 62]. These reports have limited content on checklist scepticism or key issues regarding first time development. On the other hand they present a thorough guidance on design, correct use, checklist objectives, types of checklists, certification, and standardisation.

Unlike health care, HROs have succeeded to create checklist acceptance and experience in development and use. The extensive experience gained in aviation and other HROs can be a valuable and unutilized source of learning. The challenges with acceptance and development may have a common feature. This thesis focuses on the understanding of safety checklist development, implementation, and acceptance in health care.

My vision is that the science of how to do checklists is in its infancy

Pronovost P. [53]

2. Aims of the study

To better understand some of the effects of a checklist, and the challenges its development and implementation represent we conducted three studies.

Study I: The possible causes of several adverse events in our department were identified as lack of, or malfunctioning equipment or improper use, or missing medications. The aim of this study was to develop and implement a pre-induction checklist to identify and ideally solve these problems before the induction of anaesthesia. The outcome measures were: Staff compliance, number of identified missing items, and time spent on using the checklist.

Study II: Despite the successful effect on reducing number of missing required items in Study I, challenges with compliance and scepticism towards the checklist were evident. Informal discussions among the nurses and physicians were also observed, sharing valuable insight into issues and experiences regarding checklist use. Based on these observations, the aim of the second study was to further explore nurses' and physicians' acceptance of and experience with the new safety checklist.

Study III: The study setting in Study I and II were limited to one anaesthetic department. The aim of the third study was to explore ideas and lessons learned from checklist development and implementation in a group of non-medical HROs.

3. Methods

To pursue the aims of the three studies a combination of both quantitative and qualitative approaches were employed. Statistical process control (SPC) was chosen as the most suitable quantitative approach to measure the effect of the novel pre-induction checklist implementation in Study I. Qualitative approaches using focus groups, key informant interviews, Delphi technique, and consensus process were utilised to answer the questions posed in Study II and III.

A brief outline of the methods is described in this section, and further methodological considerations are presented in the Discussion section.

Study I

In this study the development and implementation of a pre-induction checklist in an anaesthesia and intensive care department of a tertiary teaching hospital is presented. We used a modified Delphi technique to design the checklist and SPC to measure number of identified missing items and personnel compliance.

Delphi technique

The term “Delphi” goes back to the oracle of Delphi in ancient Greek mythology [63]. This method is defined as series of questionnaires (“rounds”) interspersed by controlled feedback from the participants and the moderator [64]. The main goal is to gather the most reliable consensus of opinions from a group of experts [65, 66]. Since its introduction in the late 1940s, the method has been used in more than 1000 scientific publications [67]. The Delphi technique is suitable in situations where the participants have a strong personality. Anonymity enables the participants to learn and get ideas from each other, without being provoked, influenced, or lead by any of the other participants [66].

The development of the checklist itself was a three-step process. First, adverse event reports, literature search and expert opinion were used to develop the first version of the checklist. Secondly, a modified Delphi approach was employed to construct the second version. This use of the method was considered “modified” as the experts were consultant anaesthesiologists in our department and the “rounds” were both verbally and in writing. The consultants were asked to add or remove checklist items through an anonym two-step revision process. Thirdly, the final version was made after pilot testing (Figure 3).

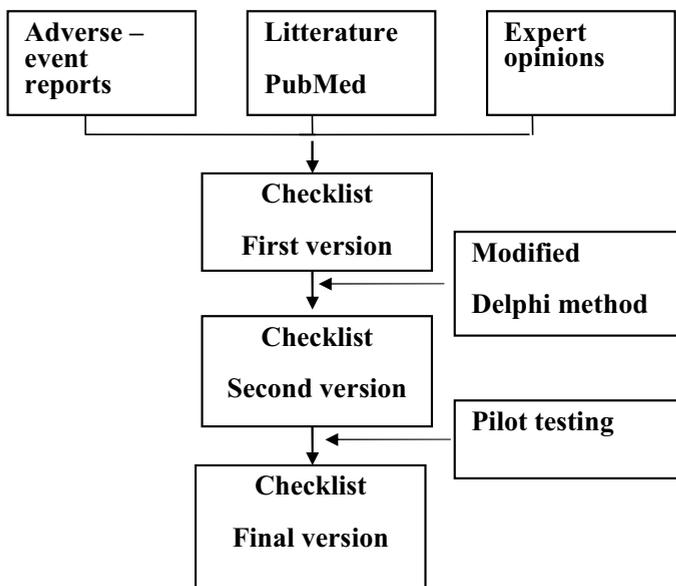


Figure 3. Development process of the pre-induction checklist.

Statistical Process Control (SPC)

SPC was developed in the 1920s by the physicist Walter Shewart to improve industrial manufacturing [68]. SPC is a statistical method to monitor a process during its run, and has three goals: 1) understanding the process itself, 2) understanding the causes of process variation and, 3) elimination or limitation of these causes [69]. Unlike other

quantitative statistical methods, SPC monitors the process on an ongoing basis, checking whether the process is deviating from the expected pattern. SPC combines the rigour of classical statistical methods and the effect of time (time sensitivity) as data is plotted consecutively. SPC has shown to be a feasible and very useful method to measure quality improvement in medicine [70-72]. We used SPC with so-called control charts to describe and quantify process variability. There were two main outcome measures; number of missing items identified by the checklist and the personnel's checklist compliance.

Study II

Focus groups

In Study II the nurses' and physicians' acceptance and experiences with the novel pre-induction checklist used in Study I was explored. Both quantitative and qualitative methods have previously been used to explore opinions and experiences [36, 48, 61]. We selected a qualitative approach to explore experiences in greater depth than what would be possible in a quantitative study (e.g. a questionnaire survey on pre-selected topics). A focus group is a semi-structured group interview moderated by a researcher [73]. A group discussion will also allow the participants to reflect upon what the other participants say, unlike individual interviews where the single informant do not get any other input, alternative views, or experiences [74].

Study setting

The informants were all involved in the development, implementation, and use of the pre-induction checklist introduced in Study I. The interviews were carried out one, and five months after Study I was completed. During this period the original list was become part of the department's standard routines. Most informants were not relieved from their duties for the sessions, and regularly experienced disturbances from telephones and pagers during the interviews. Some informants chose to come voluntarily on their day off, and were not disturbed.

Participants

We used a purposeful sample of the involved personnel. This type of sampling is in contrast to random sampling, a method to recruit informants who are believed to be more suitable to answer the actual research questions [75]. The total number of potential informants in our study was 34. From this group, we recruited both the most and the least experienced nurse on duty during the actual interview day. Gender was not considered to be a relevant factor. Some informants were interviewed before or after their “on-call” the actual day. The expected contribution from each informant and practicalities are considered important factors in decisions about group size. Six to ten informants are believed to be optimal [73]. We decided that a group size of five to eight informants would be suitable and also possible to organize within a hectic clinical environment. A total of fourteen informants (nine nurses, four residents and one consultant) with 1 - 23 years of experience were included in the two focus groups.

Interviews

Each interview lasted 60 minutes with OT as the moderator. The interview guide consisted of broad, open-ended questions (e.g., “Tell me about your experiences with the checklist use” and “How do you think the checklist use affected daily routines”). The main findings from the first interview were used to modify the questions used in the second interview. The interviews were tape recorded and transcribed verbatim.

Analysis

The analysis was performed in collaboration between OT and AE. Unlike OT, AE had minimal personal or professional insight in our department. On the other hand, he has a thorough experience in qualitative research and sharp-end use of checklists in radiology.

A systematic text condensation inspired from Giorgi and modified by Malterud was used [76, 77]. The analysis comprised the following steps: 1) Reading the transcripts to get an overall impression, 2) Identifying text units relevant to the aim and code

these, 3) Interpreting similar codes for a common meaning, and 4) Summarising the content within the coded groups into descriptions reflecting the most important issues.

Validation was made by comparing each description to the interview context and the transcripts, searching for disproving data. In addition the informants were asked to read and confirm that they recognised their described opinions (member check).

Study III

In this study ideas and lessons learned from checklist development and implementation in a group of six non-medical HROs were explored. Key informant interviews and field notes were used to generate assertions and recommendations. A total of 84 assertions for checklist development and implementation were identified during the process. Seventeen of the assertions were excluded from the analysis because they were not easily transferable to health care. Examples were: “*Checklists can not be written, they must be learned by memory*”, to prevent the enemy identifying captured soldiers. Further, “*A checklist must be as long as it takes to get the job done in a safe manner*”, said from the nuclear power production who do not have time critical events during normal operations, unlike normal workflow in an anaesthesia or intensive care unit where time is often a limit.

These assertions were further analysed using a Delphi process (Figure 4).

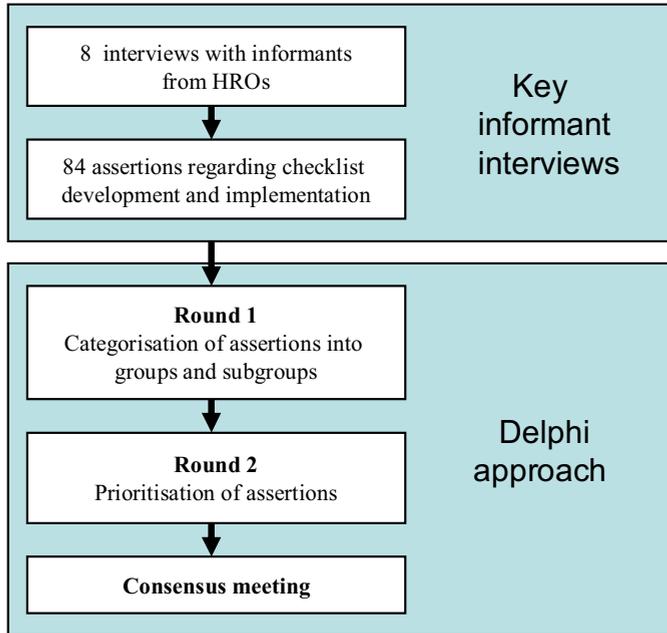


Figure 4: Flow of the analysis of the key informant interviews and application of the Delphi process.

Key informant interviews

Traditionally, key informant interviews are used in ethnographic research studying culture and community, but the technique is also used in health care research. The key informants differ from other informants by the nature of their position within a culture or context studied. They have a particular in-depth knowledge about the research aim and hence, possess the ability to articulate this to the researcher [75]. Unlike focus groups, in depth interviews make it possible to discuss sensitive topics and receive candid information.

Participants and interviews

Six HROs (nuclear power production, off-shore oil production, civil aviation, submarine operations, military special operations, and military aviation) were

contacted by telephone and introduced to the study aims. The organisations were kindly asked to identify one or two informants, who then underwent a pilot telephone interview to ensure that they had comprehensive experience in checklist development. Further inclusion criteria were “sharp-end” experience with checklists, in addition to a comprehensive cultural understanding of their own organisation. One informant was excluded because he had not been using checklists for the last ten years. The eight informants, all males, had 10 - 30 years of experience with checklists. As the informants had some restrictions on sharing standing operating procedures with the public, they had to have an organisational standing giving them permission to disclose and discuss potentially sensitive information.

Six of the experts underwent a semi-structured interview at their work place, and two were interviewed by telephone. Field notes were taken during parts of interviews when audio recording was inconvenient or not permitted (e.g. during a tour of the nuclear plant or inside the parachute packing area). The interviews (lasting 45 to 90 minutes) were audiotape recorded and transcribed by OT.

Analysis

All transcripts and field notes were reviewed by two of the authors (OT & GB) who identified and agreed on 8–12 citations from each informant. These citations were assertions regarding important issues and elements in checklist development and implementation. The assertions were then returned to the informants for validation (member check), resulting in only minor revisions.

The authors (except AE) who all have previous experience with quality improvements projects analysed the assertions from the interviews in a three-step Delphi approach. We thought health care workers were more likely than the HRO informants, to assess whether assertions were relevant to the medical field. Initially, each of the researchers proposed groups and subgroups of the assertions, and then they pinpointed the most important assertions. Thereafter, a consensus meeting was arranged in which the identified groups and subgroups were further discussed. OT & GB performed the final analysis and then all members agreed on the result.

4. Synopsis of results

In the following the results from each study are presented individually. In the discussion section the results from each study will be linked together and put into a broader perspective.

Study I

Thomassen O, Brattebo G, Softeland E, Lossius HM, Heltne JK.

The effect of a simple checklist on frequent pre-induction deficiencies.

Acta Anaesthesiologica Scandinavica. 2010;54:1179-84.

In Study I a new pre-induction checklist in an anaesthesia and intensive care department was developed and implemented. The checklist (Figure 5) contained 26 items. The graphical layout was made by a professional designer and foliated in pocketsize. The lists were made available in every operating room and attached to every anaesthesia machine.

The checklist was used in 502 patients. One or more missing items were identified in 17% (85 checklists), with a range from 4-46% on a weekly basis (Figure 4 in Paper I).

The checklist was performed in 61% of all anaesthesias during the study period. During these 13 weeks there were three weeks with a special cause of variation (defined as results lower or higher than ± 3 SD from the mean) (Figure 3 in Paper I).

CHECKLIST - BEFORE INTUBATION

Hode Hals seksjonen, KSK, HUS, 2008

	Missing
VENTILATOR	
Controlled	<input type="checkbox"/>
Vaporizer filled	<input type="checkbox"/>
Simple leakage test	<input type="checkbox"/>
Extra ventilation bag (Laerdal)	<input type="checkbox"/>
Remote-control for operation table	<input type="checkbox"/>
INTUBATION	
Laryngoscope blade length	<input type="checkbox"/>
Additional laryngoscope	<input type="checkbox"/>
Magill's forceps	<input type="checkbox"/>
Suction working	<input type="checkbox"/>
Suction catheter connected	<input type="checkbox"/>
Tube sizes	<input type="checkbox"/>
Cuff leakage	<input type="checkbox"/>
Tube introducer preformed	<input type="checkbox"/>
Bougie available	<input type="checkbox"/>
Xylocain gel (nasal intubation)	<input type="checkbox"/>
Guedel air ways	<input type="checkbox"/>
PATIENT	
IV running	<input type="checkbox"/>
BP, HR, SpO2 recorded	<input type="checkbox"/>
MEDICATION	
Type, volume and dose agreed	<input type="checkbox"/>
Double checked and labeled	<input type="checkbox"/>
TIVA: correct syringe in pump	<input type="checkbox"/>
Suxamethonium available	<input type="checkbox"/>
Anti anaphylactic drug available	<input type="checkbox"/>
IF UNEXPECTED DIFFICULT INTUBATION	
Algorithm agreed upon	<input type="checkbox"/>
Necessary equipment available	<input type="checkbox"/>
Available senior if airway problems	<input type="checkbox"/>
Comments on the back side	

Figure 5. Final English version of the pre-induction checklist (original Norwegian version in Appendix 2).

It took a median of 88.5 seconds to perform the checklist (range 52-118). The mean time spent in the operating theatre, defined as time from the patient came through the door to start of induction, was not significantly different after the introduction of the checklist (25.1 minutes, n = 502 vs. 24.3 minutes, n = 502, t-test 1.15, P = 0,25).

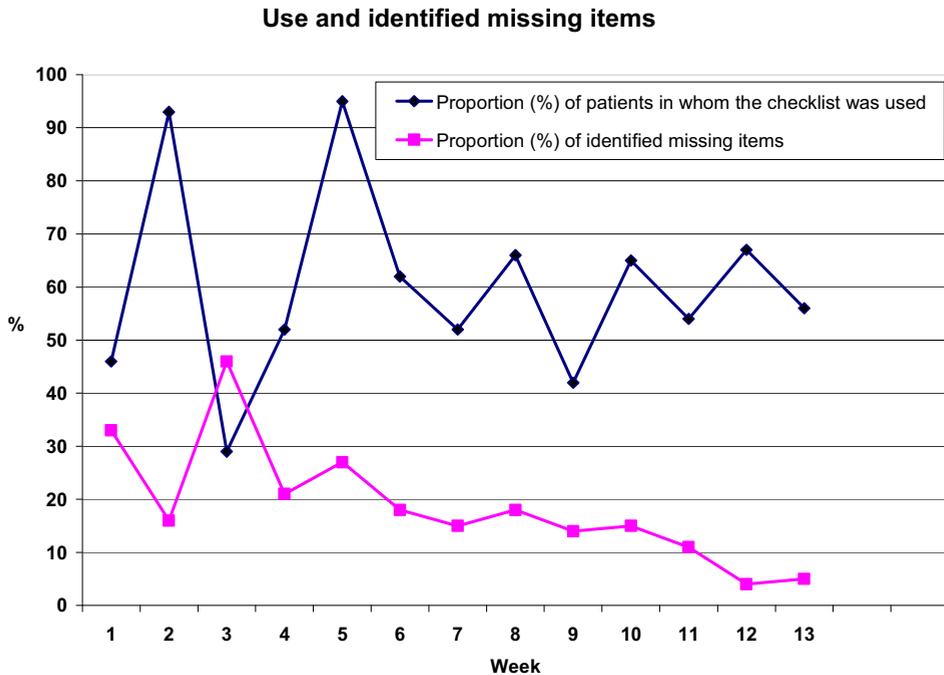


Figure 6. Proportion of patients in whom the checklist was used, and identified missing items.

Study II

Thomassen O, Brattebo G, Heltne JK, Softeland E, Espeland A.

Checklists in the operating room: Help or hurdle?

A qualitative study on health workers' experiences.

BMC Health Services Research 2010;10:342.

In the second paper nurses' and physicians' acceptance and experience with the safety checklist was explored. The participants' views and experiences were summarised in five categories; the patient, the workflow, the attitude from colleagues, and last, spin-off effects and need for standardisation.

The checklist could divert attention away from the patient

The participants thought most patients did not notice that a new tool was introduced in the pre-induction stage. But a few participants were concerned that some patients might have become anxious about possible unpreparedness since there was a "need" for a final check. However, the participants had, on their own initiative, made strategies to reduce this potential burden on the patients. Avoiding turning the back to the patient during checklist conduction, completing as much as possible of the checklist before the patient arrived if extra patient attention seemed needed, and providing clear and calm information, were such strategies used to overcome these problems.

The checklist influenced workflow and doctor-nurse cooperation

The introduction of the checklist interrupted workflow by disturbing personal and streamlined working habits or causing redundant checks by the nurses and physicians.

Senior consultants were both sceptical and supportive

Some participants had experienced negative or ironic comments from colleagues. They emphasised the importance of a supporting and motivating leader.

The checklist improved confidence in unfamiliar contexts

Several of the participants had used the checklist when performing anaesthetic work outside of the department where the study was performed, experiencing increased confidence in doing challenging work in unfamiliar places and situations.

The checklist revealed insufficient equipment standardisation

During the study period the participants discovered that the seven different operating theatres, in which the checklist was used, were not identically designed and equipped. This observation highlighted the need for standardisation if the same checklist should be used in all operating theatres.

Study III

Thomassen O, Espeland A, Softeland E, Lossius HM, Heltne JK, Brattebo G.

Implementation of checklists in health care; learning from high-reliability organisations.

Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine. In press.

Study III explored ideas and lessons learned from checklist development and implementation in a group of six non-medical HROs. The interviews generated 84 assertions for checklist development and implementation. These were categorized into five main groups with further subgroups.

Assumptions for checklist acceptance

Several of the informants underlined two critical assumptions before introducing a checklist; firstly, the importance of an early assessment whether a checklist is the right tool to help solve a specific problem. Secondly, that the end-user must not feel that he or she is denied opportunity to applying common sense in a given situation.

Stakeholders in checklist development

Proximity to the actual process for which introduction of a checklist is planned (defined as ownership and nearness in relation) for all stakeholders, directly or indirectly involved, was claimed to be a key-issue during checklist development.

Characteristics of the checklist itself

All informants agreed that the design of checklists is important. Table 4 lists some relevant points regarding checklist length, graphical lay-out, and content.

<ul style="list-style-type: none"> • Length 	<ul style="list-style-type: none"> • Limiting the length is crucial for feasibility and usefulness • Careful about gradually extending a well-adapted list
<ul style="list-style-type: none"> • Lay-out 	<ul style="list-style-type: none"> • Adapting to the surroundings in which the list is to be used • Using a professional graphic designer
<ul style="list-style-type: none"> • Content 	<ul style="list-style-type: none"> • Identifying and prioritising items by scrutinising actual adverse events • Content must directly reflect the specific operation
<ul style="list-style-type: none"> • Communication 	<ul style="list-style-type: none"> • Using well-known professional and scientific terminology

Table 4. Important issues regarding checklist length, lay-out, and content.

Human factors during checklist utilisation

Important issues regarding checklist use were: a predefined and agreed upon phraseology, the understanding of the text must be clearly defined, to be aware of automaticity and a good understanding of the background of each item on the list.

Revisions and validation

All the informants described a thorough system for maintaining a checklist. Periodic revisions were described as important for two reasons; firstly to maintain an up-to-date checklist, and secondly, to build a culture where the sharp-end users feel that their feedback is received as a valuable input for the organisation.

5. Discussion

Quality is a never ending cycle of continuous improvement.

Edwards Deming [69]

In Study I it was found that a pre-induction checklist was a suitable and effective tool to detect and also help correcting missing or malfunctioning equipment. Despite the success in detecting and solving problems with missing items, the low personnel compliance raised new questions and fuelled the need for further exploration of the participants' experiences in Study II. Based on these findings, but also similar experiences from other studies, like the implementation of the WHO Surgical Safety Checklist worldwide, we realized that development and implementation of checklists are a complex and resource-demanding exercise. Study III explored the extensive experiences gained in aviation and other non-medical HROs.

Study I – III describe the journey from identification of a local problem with adverse events, through the development of a new checklist, the need for a thorough study involving our local experiences regarding implementation, and finally to explore ideas and lessons learned in some non-medical HROs with decades of checklist experience.

In the following the results from the studies will be discussed with respect to the relevance of human memory, and situation awareness. Methodological considerations and ethical issues are also examined.

5.1 Checklist scepticism

Initially we thought that developing a safety checklist would be a fairly simple process. However, soon we experienced that some personnel made jokes and did not believe in the project. At a time the negative feedback almost terminated further progress.

It has been stated that *the checklist concept could easily be implemented into each physician's own operating room protocol* [78]. One might assume that adoption and implementation of an effective and low-cost intervention could easily be done, but implementing checklists or procedures can interfere with the established organisational culture and some resistance to change will certainly develop [53, 79, 80]. According to previous statement, checklist implementation should be an easy task, but that was not the case. Pronovost and colleagues also experienced this after the successful study demonstrating a significant decrease in central line infection by simply employing a short checklist [43]. Despite the promising results adopters were slow to follow. He travelled around the US showing his results in dozens of hospitals, but still few adopted the idea [21]. Pronovost is not the only one who has had to deal with resistance in checklist implementation. Few, if any, innovations in quality and safety have easily achieved successful implementation without “fighting” scepticism [81]. The implementation of the WHO surgical safety checklist was also met with similar resistance and debate. In the British Medical Journal, some surgeons raised concerns about negative staff and embarrassments due to obvious items. They meant that that an inappropriate checklist, rigidly enforced is counterproductive [82, 83].

In Study III the informants were asked about their opinions regarding checklist acceptance. Several of the informants stressed the importance that all stakeholders, particularly the end-users, must be involved from the start. The critical time is not when the checklist development commences, but when the discussion whether a checklist is the right tool to solve the problem or not, begins. Perhaps the experiences regarding scepticism towards the new checklist in Study I could have been alleviated if a more transparent discussion about methods and needs had been done during the planning stage. The results from Study II expressed that backing and encouragement from the leaders was important to reduce scepticism. In Study I the staff compliance with the checklist ranged from 29% - 95% (Figure 6). Before the two weeks with more than 90% use, the lead consultant had sent an e-mail to all involved personnel with encouragements to use the checklist. Similar results have been confirmed during the introduction of the WHO surgical checklist [51] and team training [84].

Creating checklist enthusiasm should be initiated a long time before the actual implementation starts. Table 5 is based on the findings from Study II and III, and lists some assertions on how to increase checklist acceptance.

- There must be a predefined and agreed problem
 - A checklist is decided the right tool for possibly solving that problem
 - The department head and other leaders are enthusiastic
 - Local champions are identified and used
 - Local opponents are encouraged to speak up
-

Table 5. Assertions on how to prevent scepticism and checklist resistance.

It has been stated that sceptical personnel can be inspired to support change, but this is a rather long and demanding process [85]. When introducing checklists into practise, recognising compliance issues is an important first step. According to the findings in Study II and III, including all stakeholders from the start and ensuring support from leaders are key requirements for success.

5.2 Challenges in checklist development

Implementation of checklists is not a simple matter of handing them out and requesting personnel to follow them. *"Checklists are not Harry Potter's wand"* [53]. After Study II was performed in 2008, several publications reported challenges in checklist development and inertia to integrating them into clinical practise.

Barriers to successful implementation are diverse and involve different issues including communication, logistics and interpersonal relations. Table 6 lists some of these barriers.

-
- Feeling of unfamiliarity with the list
 - Embarrassment of having to articulate the obvious
 - Strong hierarchy which limit communication
 - Negative impact on workflow and delays
 - Feeling of checklist as irrelevant or unnecessary
 - Poor performance when conducting the checklist
 - Lack of local adaptations
-

Table 6: Reported challenges with checklist development and use [50-52, 86].

Some of the findings in Study II and III are similar to the ones listed in Table 6, but some of the other findings do not seem to have been discussed in previous research. In Study II the informants had concerns that some patients might become anxious when observing the checklist procedure being conducted. Such concerns may reinforce the feeling of unfamiliarity among personnel. Potential negative effects to the patients must be taken into account when new checklists are introduced.

Performing the checklist in Study I revealed insufficient equipment standardisation in the operating theatres, and this could have caused some of the non-adherence and scepticism. Such findings underline the importance of locally adapted checklists. In our department the various operating theatres are designed for specific surgical procedures and the needs for adapting the checklists are present.

In study III the informants from the HROs all agreed on the importance of proximity for all stakeholders. The surgical safety checklist has been implemented with minimal collaboration with the end-users in some other units in our hospital (personal communication). Regardless of the impressive results presented in New England Journal of Medicine [46], a too simple implementation in these departments may have increased checklist resistance and complicated a successful implementation process.

5.3 Guidelines for checklist development

When Study I was started, most publications on checklist development were from non-medical organisations. However, one publication was identified, and the aim of this was to develop a checklist to promote interprofessional communication in the OR [61]. A four step approach was used in the development; collecting of information, editing the first checklist draft, piloting, and final brief informal interviews. Feasibility and maintaining workflow were key elements in the developing process.

The development of the WHO surgical checklist was inspired from the aviation industry and focused on five important issues: content and format, follow the natural flow of work (workflow patterns), trial and feedback, evaluation, and local adaptation. The experiences from Study I and II indicate that a successful checklist implementation requires some additional steps: awareness of the patients' understanding of the situation, and the importance of involving the negative, and non-adhering personnel. Study III adds the importance of proximity to the developing process for all stakeholders. In addition there must be agreement on the problem the checklist is intended to solve.

The team who developed the SURPASS checklist performed a more thorough and extensive method compared to the WHO surgical checklist [48]. They used a three step approach; 1) Developing a prototype using literature and adverse events, 2) A three step validation study using observational study and expert panel, and 3) Evaluation of usability by interviewing the sharp-end personnel.

Merely two other publications aiming to describe checklist development have been identified [87, 88]. Both studies are literature searches combined with authors' personal experience or "talk to the experts". The results from these studies are mainly derived from aviation or a description of the development process for "specific" checklists in medicine. They also mainly focus on giving a step-by step strategy, and

to a lesser extend the underlying assumptions for organisational success in checklist development.

In Table 7 the most important findings from Study II and III regarding checklist development are presented.

-
- Maintain attention on the patient during the checklist routine
 - If possible, perform part of the checklist before the patient arrives
 - Consider informing the patient properly in advance
 - It takes some time to become accustomed to a checklist
 - Do not draw premature conclusions about usefulness and feasibility
 - Expect and prepare for scepticism
 - Be aware that the checklist may be used in situations (and locations), for which it initially was not intended
 - Consider to standardise equipment and workflow before implementing safety checklist.
 - Limit the length of the list to enhance feasibility and usefulness
 - Be careful with gradually extending well-adapted and accepted lists
 - Pay attention to the lay-out and graphical details of the list
 - Identify and prioritise items from adverse events
 - Content must directly reflect the specific operation
 - Use common professional and scientific terminology
-

Table 7. Important issues regarding checklist development and use (From Study II and III).

In Study I the pre-induction checklist was developed in a stepwise manner.

Unfortunately, we did not include all stakeholders in this process. All personnel participated during the piloting, but only consultants developed the list. As a result of the findings in Study II and III regarding assumptions for successful development and implantation, it was realised that the stepwise method used had major weaknesses.

5.4 Automaticity and checklist-fatigue

Automaticity describes the ability to perform tasks or actions with only a minimum of active thinking [19]. People often refer to automaticity as “on auto pilot” or “as in my sleep”. Automaticity develops as results of numerous repetitions, and helps us to perform routine activities like drive a car, ride a bicycle or walk without being mentally exhausted. However, in the context of checklists there appears to be a risk associated with bypassing perception and reflection. If performing a checklist becomes only a ritualised automatic ceremony, the probability of missing an item increases. Then the checklist may become counter-effective or even represent a threat to patient safety. Automaticity has been associated with accidents in aviation [89] and medication errors in medicine [90].

During the field study at the nuclear power plant in Study III, a meltdown situation was simulated. The reactor operators were aware of automaticity and had developed a preventive three step communication approach; 1) reading the item on the checklist (verbally), 2) pointing out the action or measurements on the monitors (physically), and, 3) ensure eye contact with the co-worker (awareness).

Checklist-fatigue is another threat and can be described as a situation where personnel have too many mandatory checks to perform. At best, this may cause interruption in workflow and thereby delays. But likely, and worse, it may undermine the safety culture and allow development of individually adapted random checks or shortcuts. Sceptic colleagues made us aware of someone’s “quality improvement fatigue” during the development of the pre-induction checklist in Study I. Their opinion affected the timing of the project. The implementation was scheduled to a period where no other patient safety projects were performed in the department.

An outdated or not longer required checklist can also overburden staff, cause irritation, enhance scepticism, and generate fatigue [27, 88].

5.5 Time spent and cost of checklist use

There were critical comments on the time having to be spent on performing the checklist before the start of Study I. It took a median of 88.5 seconds (range 52 – 118) to perform the checklist when no items were missing. If an item was found missing the check was paused and continued when corrected. We did not measure the time spent to prepare or get ready to start the check. One could imagine that the checklist itself was quickly performed, but that time spent in the operating theatre before induction would increase. Therefore, we retrospectively measured from the patient charts, the mean time span from the patient arrived in the theatre to induction was started. Then the time used on the 502 study patients was compared with 502 patients prior to the study. There was a tendency, but not significant, of a reduction in “door – induction” time. One possible explanation is that the checklist streamlined the preparation and prevented delays due to missing or malfunctioning equipment. Perhaps the negative comments from some consultants prior to implementation of the checklist rather were expressions of a general frustration concerning the ever increasing load of documentation and administrative paperwork in general, than genuine checklist resistance.

All the informants in Study III agreed that limiting the length of a checklist is essential. Reasons for this may be two-fold: Firstly, time itself has implications for both economy and safety. Secondly, is the feeling of feasibility and usefulness. Often, there are comprehensive guidelines supplying a checklist, to assist a more stepwise approach. Such guidelines will contain relevant background information explaining why certain activities are more important than others. In aviation each item on the checklist is described in comprehensive manuals.

It has been stated that checklists may be cost-ineffective [91]. On the other hand, it has been claimed that the checklist is a cost saving strategy [92]. We have not been able to identify publications describing time spent performing neither the safe surgery checklist, nor other checklists. Further research on resistance towards checklists in general should also take time issues into consideration.

5.6 Non-technical skills and checklists

Shortcomings in non-technical skills are reported to be contributing factors in adverse events in surgery [35, 93], anaesthesia [32, 94], and underuse of AE reporting systems [7]. In the next sections the terms “memory” and “situational awareness” are discussed. Memory will first be viewed from a psychological perspective. Thereafter the implications memory has on the need for checklist will be described.

Memory

Before the introduction of the pre-induction checklist in our department in 2008 (Study I), there were no system or written guidelines on what to check immediately before induction of anaesthesia. The system relied upon a perfect working- and prospective memory of the staff involved.

Memory and complexity are two fundamental terms in quality and safety in medicine. Different types of memory have been discussed earlier (Table 2). In medicine long on-call hours, work overload, stress, and fatigue are well known. Despite research showing impaired performance after long on-calls, the working hours especially for physicians remain unacceptable long. The evident impaired cognitive performance, especially memory, must to a higher degree be identified as a threat to patient safety. Hence, tools, such as checklists, should be considered and eventually implemented.

All elective patients planned for general-, regional-, and local anaesthesia were included in Study I. Since the checklist potentially could delay induction, patients who required emergency surgery were excluded. Stress is associated with impaired prospective memory and situation awareness [15]. In an emergency or high stress situation, a checklist can create structure and overview and keep the team in the loop. After Study I was completed the checklist also was used for emergency cases.

Situation awareness

Situation awareness (SA) is the perception and understanding of environmental elements and surroundings [95]. SA is an active process involving awareness of what

is happening in the surroundings in order to understand how inputs, information, and events may have impact on the planned activity. Given a sufficient level of SA, one will know what is most important for handling the situation. Short term memory and perception are basic elements in SA. SA was first described in single-pilot air-to-air combat but has also been introduced to several other fields like driving a car, air traffic control, fire fighting, and medicine. These activities have common characteristics such as complexity and fatal outcome if significant adverse events occur. In medicine anaesthesiology, intensive care, and emergency medicine are some examples of specialities where the requirements for optimal SA are important.

Impaired SA has been described as root causes in fatal aviation incidents [96], and is also described as fundamental for efficacious and correct decision-making in medicine [97]. If the checklist procedure interferes with workflow, leads to irritations, or disturb attention it may reduce the SA and thereby threaten patient safety. During Study I some the staff members were negative. Some informants had their full attention towards “defending” the study protocol while conducting the list (personal communication). In Study III one of the main findings was the HROs’ culture for team- and simulator training to incorporate checklists into daily workflow and work habits. It is likely to believe that targeted team training, before the start of Study I, could have reduced this perceived stress and impaired SA.

A momentary loss of SA may lead to an incorrect understanding of a given situation and thereby impairing decision making. For anaesthetists serving several operating theatres at the same time, it is impossible to be continuously present. Jumping into an emergency situation “mid-stream”, trying to make sound decisions based on fragmented verbal or written information is difficult. In such situations, a checklist can help by creating more structure. A checklist can be a tool which forces the team to be gathered when performing team tasks. When disturbances occur, the checklist may also unify the team, increase awareness, keep everyone in the loop, and reduce the risk that individuals lose focus.

The Easter holiday occurred during the third week of the project. Despite preparation of the staff not on vacation, and informing new or unfamiliar personnel properly on the study aims, checklist use declined to 30%. At the same time, detection of errors increased to 46%. Operating team members change quite frequently in large organisations as ours, and even more frequently during holidays. Unfamiliar team composition combined with new equipment and high workload may increase the probability of AEs [98]. When workflow or personnel are deviating from normal, checklists may be even more important.

5.7 High reliability organisations (HRO)

Prevention and resilience

In HROs, two main approaches are used to achieve reliable results; prevention and resilience [99]. Prevention is to identify possible harmful events or conditions, stop the chain of events before injury or loss occurs, and design systems to avoid them. To identify potential threats there must be a high level of anticipation. Prevention alone has its limitations when unforeseen situations emerge. Resilience is the ability to operate reliably under stress or unexpected situations. Resilience can be described with three characteristics; 1) maintaining functioning in spite of uncertainties, 2) ability to adapt, absorb, and “stretch” rather than collapse, and 3) ability to learn from and implement necessary changes based on experiences [24]. Despite their operational diversity, researchers have found many similarities in the way the HROs are organised and their safety culture [24, 100, 101].

The environments and challenges are similar in health care and HROs, but health care is most often not defined as an HRO. Reasons for this can be the variation in reliability and resilience within organisations, hospitals, and teams [102]. It is widely accepted that experiences and lessons learned in HROs are transferable to health care [78, 103-106]. It may be pertinent to cite Winston Churchill who asked the following: “*Why*

didn't I know? Why didn't my advisors know? Why wasn't I told? Why didn't I ask?" [24].

5.8 Methodological considerations and ethics

Validity

The issues of validity and reliability in qualitative research differ from quantitative science by the lack of numerical proofs and statistical generalisability [107]. Internal validity can be defined *whether the study investigates what it is meant to*, whereas external validity ask *in what contexts the findings can be applied* [108]. Qualitative researchers have to make different approaches to make assertions of validity. Reflexivity and transferability are terms closely related to aspects of validity [75, 108].

Reflexivity can be defined as *the degree of influence that the researcher exerts, either intentionally or unintentionally, on the findings* [107]. Reflexivity is also about preconception, meaning the researchers expectations of what questions should be asked and what the answers will be [76]. All researchers, both in quantitative and qualitative studies, have their personal "backpack" of previous personal or professional experiences. The danger lies in not being aware of one's own prejudices and assumptions. It is not a matter of "if" the researcher is objective or not, but of being transparent.

Study II was based on focus group interviews in which nine nurses and five physicians participated, all from the same department. All the informants had experiences with the pre-induction checklist (Study I). They were also all familiar with each other and had from 1 to 23 years of experience.

The main researcher (OT) has previously been working in the department, and was to some extent familiar with the participants, the department's social setting, and its ordinary work flow. All the informants were also aware of OT's interests in checklists. A researcher's proximity to the informants and their culture is both strength and a

challenge. On one hand, it enables a deeper understanding and allows for “reading between the lines”, particularly when the informants share experiences that contain a longer history or generally known conflicts, or require a cultural understanding for interpreting the meaning of comments. On the other hand, it is important to separate own experience and knowledge from those of the participants [76]. The interviewer’s interest in checklists could have made the informants more willing to report positive experiences rather than difficulties with the checklist. The participants were encouraged to speak freely, and a range of both benefits and difficulties were actually reported. The chief consultant was, intentionally, not invited as an informant in order to prevent potentially pressure as to express positive experiences.

In Study III the informants were met for the first time at the day of the interview, but they had all been through a short telephone interview verifying that they met the inclusion criteria for being key informants. They were all prior to the interviews informed about the background and the aims of the study, and former research on quality and safety issues. Some of the HROs had restrictions and limitations to visitors and interviews. In order to gain access to perform interviews it was a necessity to show that we had an understanding and experience with checklists. Unlike Study II, our presence in Study III probably did not affect the informants to any great degree. My experience from helicopter emergency services and both sharp- and blunt-end experience from checklist use and development enabled and constructed a cohesion that would not be apparent to an outsider without such a background.

Transferability, or external validity, is about how our results can be transferred to other persons and other settings [109]. A common concern as to qualitative methods is the small sample size which precludes transferability [74]. These concerns have traditionally been claimed by quantitative researchers, and are part of the “quantitative research paradigm” where knowledge is defined as facts which can be empirically proved [110]. Medicine and clinical knowledge also involve human factors such as experiences, communication and opinions. Qualitative research on the other hand, has limitations in transferability, but a thorough, transparent, and systematic methodology

will help the reader to use the results, not as facts but as a guide for reflexion on clinical decisions.

Study I was performed in an anaesthesia and intensive care department of a tertiary teaching hospital. The background of the study was reported adverse events where some contributing factors had been identified as lack of appropriate airway management equipment and wrong use of or missing medications. Most anaesthesiologist will recognise such events in their clinical practice [111, 112]. In 2007, we were not able to identify a validated methodology to develop and design specific medical safety checklists from previously published studies. This obliged us to develop a self-designed stepwise method (Figure 3). The method included adverse event reports, literature search, expert opinions, a Delphi approach, and pilot testing. We believe this rather thorough process was essential in order to generate a useful and feasible checklist, and this experience can be useful for others regardless of speciality and local differences.

The low compliance was affected by local factors, but implementation of the checklist will probably generate critical voices elsewhere. The literature also confirms this [53, 86].

The findings in Study I reflect the informants' personal experiences and opinions. These results can be used in further evaluation and development in our department. However, their validity in other contexts, in other countries or cultures is not certain. The main statements identified in Study II, combined with similar findings in the literature and research reports, increases the transferability indicating that the findings may be useful to others.

The main question regarding transferability in Study III is whether experiences with checklists in non-medical HROs are relevant in medicine. These organisations have decades of sharp- and blunt-end experience with checklists, and are often referred to in the medical literature [24, 25, 113]. Some have questioned whether medicine has gone too far in translating checklist experiences from HROs in general [114]. Interviewing and visiting the HROs in Study III revealed that these organisations have remarkably

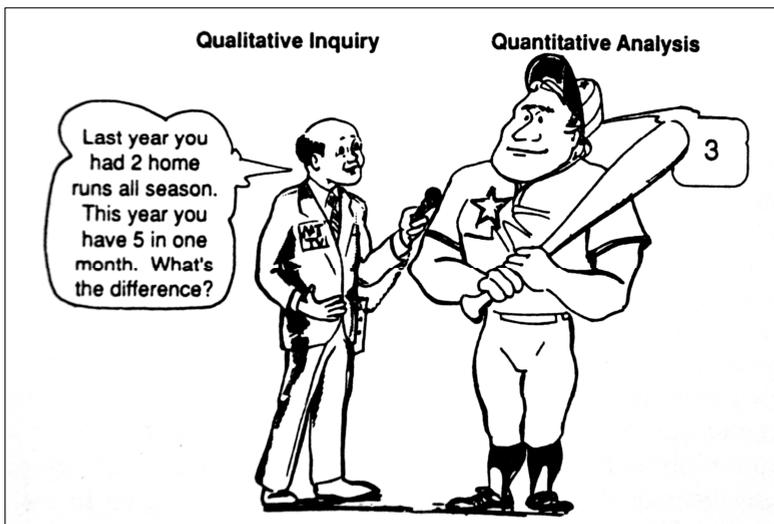
similar challenges with safety as health care. Their long tradition with safety checklists and the thorough system for revisions and validation makes their experiences and observations relevant to medicine.

Study design

In Study I we designed implemented and measured the effect of a pre-induction checklist. The outcome measures were the identified number of missing items, personnel compliance and the time spent. Another outcome measure could have been morbidity, mortality, or the incidence of adverse events before and after the introduction of the checklist. Conducting a study with these outcome measures would have been a challenge for two reasons. Firstly, the number of anaesthesia related deaths are very low (0,1 – 3,3 /10.000 anaesthetics) [115]. Therefore, the number of patients needed would have been very high and had required a multi-center design or a long study period. After Study I was completed, two studies have showed a decrease in morbidity and mortality after introduction of pre- and post-operative checklists [46, 49]. The numbers of included patients in these studies were 3733 and 3820, respectively. Secondly, underreporting of adverse events makes it hard to compare the numbers before and after implementation of a checklist. We believe underreporting exists in our department, as reported elsewhere [2, 116].

Someone might claim that a weakness is that there was not a control group in Study I. We could have divided the seven operating theatres or the nurses and doctors into two groups, introduced the checklist in one group and used an observational approach on the other group. A blinding would have been practically impossible. The aim of Study I was three-fold; to develop, implement and measure the effect of a checklist. Given these aims a comparison to a control group would not have given any valuable or useable information. Absence of control groups is common in quality improvements studies [117, 118].

If we had chosen a classical statistical method in Study I the results would have been less informative. The findings of a special cause of variation during Easter holiday would not have been identified, nor had the effect on the chief consultant's admonitions regarding compliance been described. Another benefit of using SPC and control charts was the opportunity for the nurses and physicians to follow the process on a weekly basis. Each week the updated chart enabled the participants to see changes. The poster was placed on a wall outside one operating theatre. This wall became a bulletin board where comments and important messages also were posted.



SPC is a feasible method provided that the probability for a positive or negative outcome does not change during the study period (e.g. the probability for successful intubation will be affected if the potential difficult airways patients are excluded from the start, but included when the skills are improving). In Study I the setting and the included patients were the same throughout the study period.

One limitation may be that we conducted only two focus groups in Study II. The rule of thumb is to stop collecting data when more groups probably will not provide meaningful new insight [73]. The discussions in the two interviews were fairly similar;

thus we considered that a third group would probably not enrich the findings to any greater extent. Since 14 of total 34 potential informants had participated in the interviews, it also would have been a practical challenge to organise further groups. If we had suspected that important data was missing we could have used additional methods, such as individual interviews or questionnaires to expand the results (method triangulation). However, conducting a low number of interviews is not infrequent. Eleven previous publications have conducted only one focus group [119]. Although group interviews are ideal for exploring common experiences, more sensitive or personal attitudes may have been omitted.

Understanding, rather than avoiding, bias

In quantitative research a key element is to eliminate bias. In quality improvement (QI) research, the key issue is to measure the effect of an action or intervention in a real clinical setting. In clinical practice quality improvement interventions influence the participants' communication, attitudes, and workflow. Before Study I, all participants were "sensitised" through informative e-mails, personal letters, morning briefs, and training during the development of the list. In traditionally quantitative research, or in a laboratory setting, these elements could have been described as bias. In QI research this "bias" has an intrinsic value as long as they are identified and part of the analysis. To understand the effect of an intervention it is important to also consider the culture and context in which the study is undertaken. The operation theatres have limitations compared to a laboratory where the possibility to eliminate all possible confounding factors exists. We did not try to eliminate all other influencing factors. Instead, we tried to describe them in order to better understand the implementation process and report the findings.

Ethical considerations

The studies were approved by the local Institutional Research Ethics Committee (REK), the Norwegian Social Science Data Services (NSD) and the head of the Anaesthesia and Intensive Care department according to current regulations.

In agreement with REK, the patients were not informed that the checklist was performed in Study I. We considered that it would be a potential burden to the patient to get information about a QI project that had no influence on normal clinical management of the anaesthetic or surgical procedure. On the other hand, it would have been ethically difficult to drop the checklist after we saw the positive effect on preparedness.

In Study II we obtained written consent from the informants to participate in the focus groups. The questions in the interviews were not personally sensitive, but we were prepared to stop discussions on colleagues that were not present or other sensitive topics not concerning the project. None of the above occurred.

In Study III the informants represented civil and military aviation, nuclear power production, off-shore drilling, submarine and military operations. They all had restrictions in sharing standard operation procedures and experiences were, to some degree, classified. Before the interviews and field visits the informants were told that it was their own responsibility to consider what type of information they could share. The results were also returned to the informants for validation and final approval before the paper was submitted for publication, resulting in only minor revisions.

6. Conclusions

In this thesis I have described the effects of a pre-induction safety checklist, explored the personnel's acceptance and experience with this list, and further examined the experiences from non-medical high reliability organisations, and discussed the relevancy to health care. In accordance with the aims of this thesis, the following conclusions can be drawn:

A pre-induction checklist is a useful tool to detect missing or malfunctioning equipment. It is possible to develop and use such a list even in a hectic and stressful clinical environment. Performing a pre-induction checklist does not increase time spent in the operating theatre, however staff compliance is a challenge.

The nurses' and physicians' suggest several issues and actions that seem to be important during checklist development and use. These experiences are summarised in five categories; checklists can divert attention away from the patient, interrupt the workflow, supportive and sceptical attitude from colleagues, improved confidence, and highlights the need for standardisation. Informants from non-medical HROs emphasise the assumption of a recognised and predefined problem for which the checklist is developed. A close cooperation between sharp-end personnel and the management to create a feeling of ownership is also important. The checklist must be short and well designed, and simulation is a necessary part of checklist implementation and revision.

Choosing the best approach for achieving staff compliance when introducing a checklist, is not as simply as it may sound. The studies presented in this thesis provide some new insight in the challenges of developing and implementing checklists.

7. Future research

Merely providing checklists to healthcare workers will not empower them to actually use this tool or create a safety culture alone. Just having a checklist on a piece of paper will necessarily not lead to any changes. I suggest two main aims for further research:

- The checklist in this thesis differs from the WHO surgical checklist in many ways. The most important disparity is the magnitude of the projects. We did not have financial resources or time, similar to most other, to have safety managers motivating for the process. It is likely to believe that the large and highly profiled WHO safe surgery checklist project have less negative participants in the pilot phase. The challenges with resistance to change have surfaced when the checklist were implemented locally around the world. Future research should be focused on challenges of local adaption and wise methods for overcoming resistance to change.
- HROs are far ahead of medicine in checklist development and use. Their experiences are a valuable and under-utilized source for learning how to improve and use checklists wisely in health care. Future research should explore both disparities and similarities between healthcare and HROs and the transferability of their experiences with safety issues in general.

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9. Appendix

Surgical Safety Checklist


World Health Organization

Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

Before skin incision

Before patient leaves operating room

(with at least nurse and anaesthetist)

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

Yes

Is the site marked?

Yes

Not applicable

Is the anaesthesia machine and medication check complete?

Yes

Is the pulse oximeter on the patient and functioning?

Yes

Does the patient have a:

Known allergy?

No

Yes

Difficult airway or aspiration risk?

No

Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

No

Yes, and two Ws/central access and fluids planned

(with nurse, anaesthetist and surgeon)

Confirm all team members have introduced themselves by name and role.

Confirm the patient's name, procedure, and where the incision will be made.

Has antibiotic prophylaxis been given within the last 60 minutes?

Yes

Not applicable

Anticipated Critical Events

To Surgeon:

What are the critical or non-routine steps?

How long will the case take?

What is the anticipated blood loss?

To Anaesthetist:

Are there any patient-specific concerns?

To Nursing Team:

Has sterility (including indicator results) been confirmed?

Are there equipment issues or any concerns?

Is essential imaging displayed?

Yes

Not applicable

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:

The name of the procedure

Completion of instrument, sponge and needle counts

Specimen labelling (read specimen labels aloud, including patient name)

Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:

What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009 © WHO, 2009

Appendix 1. The WHO Safe Surgery Checklist

SJEKKLISTE FØR INNLEDNING ANESTESI

Hode Hals seksjonen, KSK, HUS, 2008

ANESTESIAPPARAT	Funn/mangler
Kontrollert	<input type="checkbox"/>
Gassfordamper påfylt	<input type="checkbox"/>
Apparatbag/-slange koblet og tett	<input type="checkbox"/>
Løs ventilasjonsbag og O ₂ kolbe	<input type="checkbox"/>
Operasjonsbord fjernkontroll	<input type="checkbox"/>
INTUBASJON	
Laryngoskop: Lyser	<input type="checkbox"/>
Reserve laryngoskop/blad lyser, tilgjengelig	<input type="checkbox"/>
Magills tang	<input type="checkbox"/>
Sug, virker	<input type="checkbox"/>
Sugekateter på sugeslange	<input type="checkbox"/>
Tube størrelse (ekstra: +/- en størrelse)	<input type="checkbox"/>
Cufflekkasje sjekket	<input type="checkbox"/>
Tubemandreng tilpasset	<input type="checkbox"/>
Bougie tilgjengelig	<input type="checkbox"/>
Xylocain gel ved nasal intubasjon	<input type="checkbox"/>
Svelgtube tilgjengelig	<input type="checkbox"/>
PASIENT	
IV kanyler koplet til væskeinfusjon som går	<input type="checkbox"/>
BT, hjerterefreknens og SpO ₂ registrert	<input type="checkbox"/>
MEDIKAMENTER	
Type, mengde, doser avtalt	<input type="checkbox"/>
Dobbeltkontrollert, merket	<input type="checkbox"/>
TVA: Rett medikamentsprøyte i rett pumpe	<input type="checkbox"/>
Suxamethonium tilgjengelig	<input type="checkbox"/>
Anafylaksi-medikamenter tilgjengelig	<input type="checkbox"/>
OM UVENTET VANSKELIG INTUBASJON	
Avdelingens algoritme avtalt	<input type="checkbox"/>
Nødvendig utstyr tilgjengelig	<input type="checkbox"/>
Lege som kan tilkalles/calling nummer, avtales med operasjonssykepleier.	<input type="checkbox"/>
Eventuelle kommentarer skrives på baksiden	

Appendix 2. The original pre-induction checklist