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DOCTORAL DISSERTATION

Patient safety in hospitals: implementation of the surgical safety checklist

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Contents

Chapter 1
Introduction

“It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm”

— Florence Nightingale —

In recent years the interest in patient safety — not least due to several high-profile examples of how things can go wrong in hospitals — has picked up momentum among scholars as well as amongst practitioners and governments. Within this larger field, major emphasis has been placed on the incidence of adverse events. Landmark studies, alongside formal reports on the devastating consequences and costs of patient harm related to healthcare, have illustrated the relevance of patient safety in todays healthcare context. A major wakeup call emerged in 1999, after the publication of the report "*To err is human… building a safer healthcare system*".[1] This report exposed the magnitude of the number of preventable deaths in the United States of America. Following this report, a numerous amount of studies has been conducted in order to measure the quantity and quality of healthcare related harm.

Although the patient safety movement became apparent only in recent decades, the concept and interest towards patient safety are not new. As early as 1863, Florence Nightingale stated that the first requirement in a hospital is to do the sick no harm.[2] This may seem a strange principle, as hospitals are generally perceived to be safe places. Additional harm or suffering related to the care we receive is the last thing we expect when being admitted to hospital. We enter them to find hospitality, care, and healing — or at least relief and comfort — when dealing with health problems. Throughout this chapter will become clear that the patient safety problem is not only a major cause of suffering for patients, it has negative repercussions for healthcare providers as well. While the associated healthcare costs have a profound impact on the hospital and society.[3]

This patient safety movement has gradually reached policy makers and hospital boards which created a context of awareness and willingness to address the problem. Within Belgium's Flemish region this commitment is spurred by the Flemish coalition agreement. The Flemish Government has decided to revise the supervision of hospitals — and healthcare in general — by endorsing formal accreditation (e.g., Joint Commission International or NIAZ Qmentum International), its own Flemish Indicators Project (VIP^2), and by imposing a set of accreditation standards that are developed in consultation with the stakeholders involved. This context stimulates innovations to improve patient safety and creates the foundations for a necessary culture change.

Before we can solve something, we must be able to define the problem and measure the extent of its consequents. A major obstacle in the search for effective and workable remedies to the patient safety problem is the multiplicity of interpretations and definitions of the concept patient safety. Doctor Charles Vincent (Imperial College London) defines patient safety as: "*The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process or healthcare*".[4,5] The first element in this definition — *avoidance, prevention* — does not just mean avoiding serious injury. To ensure safe care, we

must strive for a reduction of any kind of preventable errors and simultaneously strive for high reliability of the care provided. This means that patient safety is to be seen as the ability to anticipate, and effectively respond to, (potential) difficulties and hazards. In order to realise this ability, we need organizations and professionals who have the necessary resilience allowing them to effectively deal with the ever-changing healthcare environment. This also means that patient safety is more than studying and preventing errors, as not all harm is caused by mistakes of professionals (e.g., long waiting times in the emergency department). The second element in the aforementioned definition — *amelioration* — refers to the need for rapid (medical) intervention to deal with the immediate crisis if there occurs any unwanted incident, but also to the need to care for the affected patient, and to the support of the professionals involved (i.e., second victim). This definition also has implications for the quantification of patient safety. The concept of *safety* is complex and contains many facets, summarizing this in one measure or indicator remains an unrealistic fantasy. If we want to measure patient safety, we need a measure of the damage related to the care (harm), a measure of the reliability and consistency of care (reliability) and a measure of ability to anticipate and effectively respond to threats and difficulties (resilience).

Improving patient safety

Defining and measuring safety is only one facet of the research in patient safety field. It is important to have a clear view on the baseline condition. But the ultimate goal is to improve safety by minimising the risks and reduce the number of adverse events. To achieve meaningful improvement we have to fulfil four conditions: [6]

1. We need to know what the risks are;
2. Effective interventions should be developed to reduce these risks;
3. These interventions must be implemented in practice;
4. We need useful indicators that can show any improvements.

First, we need to find out what factors contribute to, or create, unsafe conditions. Second, we need proven, evidence-based, interventions to prevent harm to occur by addressing the factors contributing to its ethology. Third, we need to implement these interventions in such matter that they will be used as intended to maximise the effect. Last, we need meaningful indicators to measure the effect of these interventions. Where do we stand in this matter?

The patient safety problem

Various studies and overarching meta-analyses give a clear picture of where the risks in the area of patient safety are located. Summarised, these studies show that medication errors and complications in the surgical context represent the largest clusters of adverse events. The causes are mainly found in human factors, communication, and teamwork.

The Harvard Medical Practice Study [7,8]

This study reviewed the patient records of 30,121 randomly chosen patients in 51 acute care, non-psychiatric hospitals in New York State in 1984. The goals of this study were twofold: first, to establish the level of patient injury, and second to provide data for efforts to reform medical malpractice procedures. As a consequence of the second goal only those injuries that could potentially lead to litigation — and thus represented injury due to substandard care — were measured. No attempt to detect 'near misses' (i.e., errors that did not actually harm patients) was made nor were events that caused only minor physical discomfort counted. Terminally ill patients were excluded. Thus, adverse events in patients who were certain to have died were excluded from the study. In this study adverse events occurred in 3.7 per cent of the included patients. Further, 0.5 per cent of patients died following a 'clinical error'. This equates to 1 in 200 patients dying as a consequence of an adverse event. Of all adverse events, 47.7 per cent were related to surgical care and 17 per cent of all adverse events were deemed to have been due to negligent practice, (i.e., it was judged that the management had been substandard). The most common non-operative adverse events were adverse drug events, followed by diagnostic mishaps, therapeutic mishaps, procedure-related events, and others. Overall, 37.2 per cent of the non-operative events were deemed to have been due to negligent practice. As one might expect, the most common sites for adverse events were operating theatres followed by the patients' rooms, accident and emergency departments, labour and delivery rooms, and intensive care units. Extrapolations from these data suggested that approximately 98,000 Americans would die each year following preventable adverse events. This would be eight times the number who die on America's roads.

The Quality in Australian Healthcare Study [9,10]

The Quality in Australian Healthcare Study (QAHS) investigators based their study upon the Harvard methodology. However, as their goal was to gather data to improve 'quality' efforts, they were more interested in the 'preventability' of adverse events rather than 'negligence' in a medico-legal context. They reviewed 14,179 randomly sampled records from patients in 28 hospitals in South Australia and New South Wales in 1992. As they focused on preventable events and included 'near misses', the study uncovered a much

larger number of adverse events than the Harvard study. Using their definition of an adverse event, QAHS researchers found that 16.6 per cent of the patients in the study experienced an adverse event. When adjusted to count adverse events according to the Harvard Study definition the rate was 13 per cent. Of all adverse events, 51 per cent were judged to have been preventable if there had been better communication between clinicians and better standards of checking. The higher rates of adverse events detected in the Australian study, over four times greater than that found by the Harvard study, is partly accounted for by the wider range of adverse events included (for instance, adverse events occurring outside hospital were included), the focus on quality of care rather than negligent care, and the inclusion of many more minor events in the definition of adverse events. As with the Harvard Study, most adverse events were related to surgical procedures (50.3%) followed by diagnostic errors (13.6%), therapeutic errors (12.0%), and adverse drug events (10.8%). Permanent disability resulted from 13.7 per cent of adverse events and death from 4.9 per cent. 1 in 123 patients died following a 'clinical error'. The Australian study also found that 34.6 per cent of errors were related to technical performance, 15.8 per cent to a failure to synthesize and/or act upon information, 11.8 per cent from a failure to request or arrange an investigation, procedure, or consultation, and 10.9 per cent due to lack of care and attention or failure to attend the patient communication problems between clinicians were the single most frequently occurring factors contributing to adverse incidents that harmed patients and these errors were nearly twice as common as those due to inadequate medical skill or knowledge.

The University College London Study [11]

This paper announced the results of a retrospective review of the medical and nursing records of 1,014 patients in two acute hospitals in the Greater London area. The study showed that 10.8 per cent of patients experienced an adverse event, with an overall rate of adverse events of 11.7 per cent because several patients suffered more than one event. About half of these events were judged to be preventable with ordinary standards of care. A third of adverse events led to moderate or greater disability or death. Nine patients died. This translated into 1 in 113 patients dying following an adverse event.

The University Hasselt Study [12]

During a 6-month period, records of all patients with an unplanned need for a higher level of care — defined as an unplanned transfer to the intensive care unit or an in-hospital medical emergency team intervention — were assessed by a trained clinical team. The team included a research nurse, a physician, and a clinical pharmacist. Adverse events were found in 465 of the 830 reviewed patient records (56%). Of these, 215 (46%) were judged to be highly

preventable. The overall incidence rate of patients being transferred to a higher level of care involving an adverse event was 117.6 (95% CI = 106.9 to 128.3) per 100,000 patient days at risk, of which 54.4 (95% CI = 47.15 to 61.65) per 100,000 patient days at risk involving a highly preventable adverse event. This means that 25.9 per cent of all unplanned transfers to a higher level of care were associated with a highly preventable adverse event. The adverse events were mainly associated with drug therapy (25.6%), surgery (23.7%), diagnosis (12.4%), and system issues (12.4%). The level of harm varied from temporary harm (55.7%) to long-term or permanent impairment (19.1%) and death (25.2%). Although the direct causality is often hard to prove, the authors found it reasonable to consider these adverse events as a contributing factor.

The incidence and nature of in-hospital adverse events: a systematic review [13]

In an effort to summarise the incidence of in-hospital adverse events de Vries *et al.* compared eight studies that used a similar definition of adverse events and included a minimum of 1,000 patient records. Their analysis included a total of 74,485 adult patient records. The median overall incidence of in-hospital adverse events was 9.2 per cent, with a median percentage of preventability of 43.5 per cent. More than half (56.3%) of patients experienced no or minor disability, whereas 7.4 per cent of events were lethal. Operation- (39.6%) and medication-related (15.1%) events constituted the majority. The authors concluded that adverse events during hospital admission affect nearly one out of 10 patients. A substantial part of these events are preventable. Since a large proportion of the in-hospital events are operation- or drug-related, interventions aimed at preventing these events have the potential to make a substantial difference.

Surgical adverse events [14]

As previous papers mention, surgery related incidents, represent a significant proportion of in-hospital adverse events. Anderson *et al.* conducted a systematic review to quantify potentially preventable patient harm from the frequency, severity, and preventability of the consequences and causes of surgical adverse events. The authors included fourteen record review studies incorporating a total of 16,424 surgical patients. Adverse events occurred in 14.4 per cent of patients (interquartile range [IQR], 12.5% to 20.1%), and potentially preventable adverse events occurred in 5.2 per cent (IQR, 4.2% to 7.0%). The consequences of 3.6 per cent of adverse events (IQR, 3.1% to 4.4%) were fatal, those of 10.4 per cent (IQR, 8.5% to 12.3%) were severe, those of 34.2 per cent (IQR, 29.2% to 39.2%) were moderate, and those of 52.5 per cent (IQR, 49.8% to 55.3%) were minor. Errors in non-operative

management caused more frequent adverse events than errors in surgical technique.

The patient safety problem summarised

In addition to the aforementioned studies, others research has been conducted in Denmark, New Zealand, Canada, France, and Ireland. In aggregate, these studies have an average adverse event rate of almost exactly 10 per cent, which is very similar to most published work. If we consider the available knowledge in its totality, we can conclude that despite the expertise, knowledge, and skills of doctors and nurses as many as 10 per cent of hospitalised patients will be confronted with an adverse event of which half is assumed to be avoidable.[13] In addition, some studies suggest an increase in the number of incidents.[15] This increase is mainly attributed to the increased attention towards patient safety and better reporting of incidents.[6] Although it remains difficult to measure the correct amount of healthcare related harm, there is a consensus in the literature that patient safety is a persistent problem.[15,16] When focusing on the underlying causes, it becomes apparent that the lack of adherence to proven standards and communication and teamwork between all layers of involved individuals constitute the most important cause of adverse events. It has to be noted that safety is a team effort; it cannot be reached by the success of one individual. Safety needs to be a continues condition, independent of who is in charge or who is providing the service. To achieve this, we need measures and interventions that create a secure environment regardless of the circumstances. Alongside, we need a cultural change allowing these conditions to arise and grow until it has become the standard way of practice.

Interventions to improve patient safety

In addition to the interest and recognition of the patient safety problem, the search for appropriate solutions has also been ongoing for more than 100 years. Already in 1912, dr. Richard Cabot advocated the use of a systems approach without blaming individuals — *"The methods of diagnosis, not the men who used them, are flawed. Reform, not blame, is the message".* Nowadays it has become evident to address all system aspects in order to design a safe healthcare context. The search for solutions remains a continuous challenge. Safety is a moving target, requiring constant adjustments in function of changing circumstances and new innovations in healthcare — which inevitably create new risks. This has translated into a variety of strategies to improve patient safety. For an overview of current available evidence, we refer to a recent report — Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices

— by the Agency for Healthcare Research and Quality (AHRQ).[17] In this report 41 interventions, based on the existing literature, were analysed by an international panel of experts in the field of patient safety. The experts agree that there is sufficient evidence for 10 to improve patient safety (effectiveness and implementation) so that they are "strongly encouraged" to implement in practice (See Box 1: Ten interventions strongly encouraged to improve patient safety). In addition, 12 other interventions are "encouraged" for implementation.

Box 1: Ten interventions strongly encouraged to improve patient safety

- Preoperative checklists and anaesthesia checklists to prevent operative and post-operative events
- Bundles that include checklists to prevent central line-associated bloodstream infections
- Interventions to reduce urinary catheter use, including catheter reminders, stop orders, or nurse-initiated removal protocols
- Bundles that include head-of-bed elevation, sedation vacations, oral care with chlorhexidine, and subglottic- suctioning endotracheal tubes to prevent ventilator-associated pneumonia
- Hand hygiene
- "Do Not Use" list for hazardous abbreviations
- Multicomponent interventions to reduce pressure ulcers
- Barrier precautions to prevent healthcare-associated infections
- Use of real-time ultrasound for central line placement
- Interventions to improve prophylaxis for venous thromboembolisms

The implementation problem

Innovation — *an idea, practice, or object that is perceived as new by an individual or other unit of adoption. It matters little, so far as human behaviour is concerned, whether or not an idea is "objectively" new as measured by the lapse of time since its first use or discovery."* [18] — is indispensable if we want to provide an adequate answer to the ever-changing demands and challenges in healthcare. The changing context and evolving needs in healthcare, complicated by concomitant complexity, require the development of new technologies, materials, and devices; but also call for new organisational models and processes including new modes of healthcare delivery. The decision to adopt innovations into practice should be based on evidence, derived from rigorous scientific research. The latter to ensure

that application of the innovation will lead to improved clinical and health economical outcomes (i.e., without causing additional harm and/or costs lower than the existing standard of practice). From that perspective healthcare innovation and quality of healthcare are tightly connected.

Although many innovations — aimed at improving patient safety — demonstrate promising results within the study context, healthcare providers and the public become increasingly aware that these results are not easily transferable into daily healthcare practice. Often, initiatives trying to implement innovations into healthcare settings result in limited changes for the better or no meaningful changes at all, and the few that are successful are often hard to sustain or replicate in other contexts.[19] Implementation of innovations has shown to be difficult in various healthcare settings.[20-23] In fact, estimations indicate that about 70% of organizations' efforts to implement change fail.[24] The availability of innovations by itself does not guarantee improved outcomes; the innovation must become part of daily practice.[19,25] To attain the true added value, it is imperative that innovations are used as intended. This highlights the importance of the implementation process.[26,27]

The use of surgical safety checklists, by example, is supported by a solid body of research, demonstrating that the correct usage of this tool can significantly reduce the risk for postoperative complications, including mortality.[28-32] However, studies using "real life" administrative health data have failed to show improvement.[33-35]

Why do innovations fail in real life?

The cause of innovations failing in real life settings can be attributed to the innovation itself (i.e., the innovation does not work), or to the implementation process (i.e., the innovation is proven to be effective, but is not implemented or used as intended).

The first cause can be perceived as controversial, as many healthcare innovations — certain those used in direct patient care — require scientific evidence on their effectiveness prior to adoption in practice. However, some have argued that most scientific evidence doesn't prove efficiency in other contexts. Hence, it is possible that in some cases the first cause of failing (i.e., ineffectiveness of the innovation itself) is blurred by — or buried under — the results of scientific studies. Several examples exist of pharmaceutical innovations found to be ineffective only after years of prescription and usage. It would be, at least, negligent to assume that this phenomenon is limited to pharmaceutical innovations. The results of other innovations aimed to improve health outcomes can also suffer from inappropriate methodology or statistics. The second cause (i.e., failing implementation) results from inadequate implementation of the innovation. In order to make a distinction in the cause

of failure — ineffective innovation vs. failing implementation — we must first ensure ourselves that the innovation is used as intended.[36,37] Systematic evaluation of implementation fidelity (i.e., the degree to which innovations are implemented and used as intended by the innovation developers) is often difficult, particularly for complex interventions.[36] Therefore, indicators are often used instead. Which measure adherence to certain aspects of the innovation, or at best its administrative reflections. Furthermore, the lack of theoretical and practical guidance is regarded as a strong barrier to evaluating implementation fidelity.[36]

The example of surgical safety checklists illustrate the above-mentioned methodological difficulties clearly. Checklists usage compels more than checking off boxes; it is essentially a complex social intervention with an expectation of interaction and cooperation between surgeons, anaesthesiologists, and nurses. It is however difficult to measure and quantify teamwork. To capture the true extent, clandestine observation (by video or observer) is recommended. However, practical, ethical, and medico legal considerations often hinder reliable observation. Hence, measuring implementation fidelity is often limited to checking whether or not checklist items are ticked off. It has, however, been demonstrated that a discrepancy exists between ticking off a box and performance of the action it calls for.[38-42]

Notwithstanding these difficulties measuring implementation fidelity is important. It does not only reveals if the failure can be attributed to the innovation or the implementation process; if done in detail, it provides insight into the parts or elements of the innovation that we struggle with to implement.[36]

Why do implementation efforts fail?

Many theories and frameworks have been published to promote effective implementation of innovations in healthcare. Some have focused on implementing interventions (including those termed interventions, programs, innovations, complex interventions/innovations, shared-decision making, technologies, evidence-based practices, and tele health), guidelines (including clinical-practice, best-practice, and evidence-based guidelines), knowledge, evidence-based practice model, and packaged implementation programs for innovations.[43]

Despite the existence of many different frameworks similarity exist. They overlap considerably in the constructs included, and a comparison of theories reveals that each is missing important constructs included in other theories.[43] In addition, terminology and definitions are not consistent across theories.[44] Attempts have been made to define a standard glossary [45], to consolidate

existing frameworks [43-46], and even to propose a general theory of implementation.[46] Despite this meaningful work, to date consensus is lacking.

Factors affecting the implementation process

Based on the existing frameworks the variables that may affect the implementation process — also termed facilitators and barriers or determinants of practice — have been grouped into five domains:[43,44,47]

1. **Innovation domain**: A grouping of related influencing factors regarding the characteristics of the innovation to be implemented.
2. **The context domain**: Grouping of related influencing factors regarding the circumstances that surround the innovation to be implemented.
3. **Individuals**: Characteristics and agency of the people involved with the innovation and/or implementation process.
4. **Organization**: Conditions and characteristics of the setting(s) in which the innovation is to operate.
5. **Local environment**: Circumstances immediately surrounding the organization(s) including the community, patients and network.
6. **External system**: Broad economic, political and professional environment.

The number of studies focus specifically on the implementation issues around the surgical safety checklist are limited. Existing research suggest that the implementation process is impeded or advanced by aspects within four major domains: organizational factors, systems factors, team factors, and tool-specific factors.[48] Organizational barriers include the implementation approach and lack of culture for change. Facilitating organizational factors include education/training, feedback on local data, accountability for non-compliance, and support from hospital management. System factors like time wasting and repetition, failing to add anything to the system are considered as barriers. While integration with existing paperwork/processes to streamline and remove repetition are considered as facilitating factors. Resistance and noncompliance form certain individuals within the team make it very difficult to complete the checklist without confrontation, or certain individuals are not engaged in the checks. On the contrary, senior clinicians (surgeons and anaesthesiologists) buy-in, strong individual leadership skills and passionate leaders stimulate participation from the rest of the team. Likewise, involving all team members in the implementation and modification of the checklist improves uptake. Tool-specific, design problems — the content and/or structure of the checklist is inappropriate, irrelevant and/or illogical — the fact that the checklist is not suitable for use in certain specialties and/or certain types of procedure (i.e., emergencies, day-case) — unsuitable timing of checks, unintended negative

effects, concerns regarding patient perceptions, and scepticism regarding the evidence base hamper the implementation process. Where, ownership and effective use of the checklist are improved by customization of the layout and/or content to the specific surgical context facilitate the implementation process. However, the complex reality in which the surgical safety checklists must be implemented requires an approach that includes more than getting rid of the barriers and supporting facilitating factors. The complex interplay between the barriers, facilitators and involved individuals is of equal importance.

Complex adaptive systems

Many of the difficulties of securing improvement lie in the enormous complexity of healthcare delivery systems, including their challenging technical, social, institutional, and political contexts.[44,49] Healthcare organizations have diverse agents that learn including providers, patients, and other stakeholders. Diversity is often a source of creativity and problem-solving ability but can also be a source of communication difficulties. Learning is not one-dimensional, focusing on uncertainty reduction, but it also incorporates learning aimed at uncertainty absorption. Relationships among agents are usually nonlinear. Outputs may be disproportional to inputs — small inputs can produce large outcomes and large inputs can produce small outcomes.

Healthcare, as many other systems, can be characterized as a complex adaptive system. Within this framework, organizations are considered as living entities or organisms existing within a complex ecosystem. In any ecosystem, individual agents are independent and have their own identity, yet coexist and are dependent on each other for the maintenance of the whole system and therefore their survival. The living entities interact with the environment and are affected by it, creating a balance of interdependent elements. The complex set of relationships existing between these various elements of an ecosystem is often described as a web. These living systems are not fixed but rather change, grow, repair, adapt, reproduce and slowly evolve. Although no real consensus exists on the set of characteristics that define a complex adaptive system, the following set of five key characteristics captures the major concepts from the literature: (a) diverse agents that learn, (b) nonlinear interdependencies, (c) self-organization, (d) emergence, and (e) coevolution. We are not attempting in this chapter to give a deep review of complexity science or complex adaptive systems theory.

When people seek to implement an innovation, they express their agency (i.e., their ability to make things happen through their own actions). This is expressed in interaction with other agents, other processes, and contexts.

Professional groups can facilitate as their focus and orientation are guiding for professional behaviour and therefore also for change. Agents seek to make these processes and contexts plastic: for to do one thing may involve changing many others. Implementation therefore needs to be understood from the outset as a process — that is, as a continuous and interactive accomplishment — rather than as a final outcome.[46] Moreover, 'implementation' never refers to a single 'thing' that is to be implemented. Whenever some new way of thinking, acting, or organizing is introduced into a social system of any kind, it is formed as a complex bundle — or better, an 'ensemble' — of material and cognitive practices. Even what appear as very simple implementation processes involves many moving parts.

The implementation problem summarised

Implementing innovations in healthcare settings is complex. Despite the availability of various frameworks current insights do not allow specifying one single solution. The use of theory in implementation research offers — at least — three important potential advantages:

1. Theories offer a generalizable framework that can apply across differing settings and individuals;
2. they offer the opportunity for the incremental accumulation of knowledge;
3. and they offer an explicit framework for analysis.

Appropriate consideration of theory is an important element of implementation research. As well as a more thoughtful use of theory, there is a need to work through the various stages of using theory and resolving such apparently simple issues as what it means for an intervention to be theory-based or what is the theoretical basis of behaviour change. Frameworks are potentially useful tools for considering the issues that a research agenda needs to address. Inevitably there is no one ideal, universally accepted framework that will fit all purposes; different frameworks will often reflect different purposes, disciplinary, or philosophical standpoints, and so will appeal to different groups or individuals. Complex adaptive systems theory suggests that an implementation process involves many, unpredictable, interactions within a hierarchical social system. It is important to consider the multiple levels at which healthcare is delivered and the interplay between them in their cultural context. Last, implementation research centrally involves the study of changing behaviour and maintaining change – in organizations, and the groups and individual healthcare professionals within them.

The objective of this research

Based upon the aforementioned literature concerning the patient safety problem, we conclude that surgical complications constitute a significant proportion of in-hospital adverse events. Focusing on this group of patients is therefore a legitimate choice in improving patient safety in hospitals. If we look at the available interventions, we know that the use of perioperative safety checklists is recommended as a solution to prevent the occurrence of surgery related adverse events. Nevertheless, from the summary of the implementation problem we learn that the implementation of innovations to improve patient safety is not an easy task.

In **PART I** of this dissertation the effectiveness of the WHO surgical safety checklists to improve patient safety is examined. At the start of my PhD several studies demonstrating the effectiveness of checklist to improve patient safety had already been published. Still, a systematic review and meta-analysis was lacking. This type of research is often emphasized as the highest possible evidence when selecting interventions and ensuring evidence-based care. Therefore, using a systematic review methodology, the existing evidence was thoroughly and rigorously reviewed, analysed, and summarized. The purpose of the first part was to provide an overview of the current evidence on the use of surgical safety checklists. This part aims at answering the following research question:

RQ1: To what extent are surgical safety checklists effective tools to improve patient safety outcomes?

Chapter 2 describes the results of a systematic review and meta-analysis on the effectiveness of the WHO surgical safety checklist. The first objective of this study was to assess the effect of the WHO surgical safety checklist on postoperative complications and mortality following implementation; the second aim was to assess the relationship between clinical outcome and adherence with the WHO surgical safety checklist. The aim of **chapter 3**, is to provide an up-to-date, and critical overview of the growing evidence regarding surgical safety checklists, by addressing effectiveness combined with the insights regarding the implementation of surgical safety checklists.

PART II of this dissertation deals with the dissemination, adoption, and implementation of surgical safety checklists. As mentioned earlier, the mere availability of evidence-based interventions is no guarantee for improvement. To be effective, the checklist should be used as intended. The literature shows considerable variation in the adoption and implementation of surgical safety checklists. Therefore, the objective of this part was to describe the dissemination, adoption, and implementation of surgical safety checklists in Flemish hospitals. This part aims at answering the following research question:

RQ2: To what extent is the WHO surgical safety checklist disseminated, adopted, and implemented in Flemish hospitals?

For various reasons, which are further described in the closing discussion section, the content of this part is limited to a single chapter. The aim of **chapter 4** was to describe the adoption rate of surgical safety checklists amongst Flemish hospitals and to assess the modifications that were made to these checklists. For this purpose we used an observational study design combined with a content-driven evaluation by a panel of experts.

In **PART III** of this dissertation, the factors and underlying mechanisms influencing the implementation of surgical safety checklists are examined. The use of checklists makes eminent sense from a safety point of view, however research has shown that the perceptions of doctors and nurses working with the checklist show otherwise. This part aims at answering the following research question:

RQ3: What factors and underlying mechanisms influence the implementation process of a surgical safety checklist in the operating theatre?

In **chapter 5**, we analysed the user-related barriers to, and facilitators of, the implementation of surgical safety checklists based on a systematic review of the published qualitative literature. Thematic synthesis was used to integrate the emergent descriptive themes into overall analytical themes. Thematic synthesis is a tried and tested method that preserves an explicit and transparent link between the conclusions and text of the primary studies; as such it preserves principles that have traditionally been important to systematic reviewing. The overall objective of **chapter 6** was to understand and compare clinicians perception and attitude towards the surgical safety checklist and patient safety. In particular, using survey methodology, we questioned nurses, surgeons, and anaesthetists from four hospitals of different types that had been exposed to the surgical safety checklist for various lengths of time. This may reveal approaches for optimizing surgical safety checklist implementation, which could be tested in future research and, if widely adopted, lead to more consistent surgical safety checklist use, and improved outcomes among surgical patients. In **chapter 7** we sought to understand and compare the processes and factors influencing fidelity to the surgical safety checklist in multiple hospitals. In seeking to understand stakeholders' experiences, it was appropriate to take a qualitative, inductive approach. Specifically, we interviewed nurses, surgeons, and anaesthetists from four hospitals using a grounded theory approach. Grounded theory methodology was chosen as it is suitable for studying social processes in areas where little explanatory theory or knowledge currently exists. Grounded theory is a qualitative, systematic approach used to explore processes in the context of situated interaction, with an embedded focus on human action and interactions,

and involves the concurrent collection and analysis of data to formulate theories that are grounded in the world of the participants. The intent of this research method is to move beyond description, and to generate or discover a theory that explains the situated actions and interactions as they experience, engage with, and manage the phenomenon of study. This is done by focusing on the main concern or problem that the individuals' behaviour is designed to resolve. The goal of grounded theory is thus to discover this main concern, and hence the social processes that explain how people continually resolve it. The main concern or problem must be discovered from the data. The aim was to develop a theory about the complex mechanism influencing checklist implementation. Finally, in **chapter 8** we reply to one of the specific concerns expressed by clinicians; the concerns around patients' experiences and perceptions. This concern often leads to the omission of checklist items that are perceived to cause stress in patients (e.g., expected blood loss) or performing of the checks without verifying out loud. This chapter explores the attitude and perception Flemish patients have towards surgical safety in hospitals, with an emphasis on the usage of surgical safety checklists. As a secondary aim, we also explored if previous experience of error in hospital or other respondent characteristics influence these views.

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Part I

Evidence supporting the use of surgical safety checklists in hospitals

"The volume and complexity of what we know has exceeded our individual ability to deliver its benefits correctly, safely, or reliably"

— Atul Gawande —

Chapter 2

Systematic review and meta-analysis of the effect of the world health organization surgical safety checklist on postoperative complications

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Hospitals are not as safe as generally believed.[1] Overall, the incidence of in-hospital adverse events is about 10 per cent, of which three-quarters are related to surgery. At least half of these adverse events are considered preventable within the current standards of care.[2–4] The rate of patients experiencing an adverse event is even expected to increase over time.[5] The incidence of surgery-related adverse events combined with the increasing volume of surgery results in an important healthcare problem.[6]

With the aim of improving patient safety following surgery, a checklist was developed by the World Health Organization (WHO) patient safety programme, similar to those used in aviation, aeronautics and product manufacturing. The WHO surgical safety checklist consists of 19 items and is used at three critical perioperative moments: induction, incision and before the patient leaves the operating theatre. The items contain an oral confirmation by the surgical team of the completion of some key steps for ensuring safe delivery of anaesthesia, antibiotic prophylaxis, effective teamwork and other essential practices in surgery.[7] Previous studies suggested that implementation compliance was low, despite checklist awareness by the theatre team.[8,9] The knowledge that checklists are executed incompletely makes the evaluation of a team's compliance with the checklist as important as evaluating clinical outcomes.[9,10] However, to date, only one single-centre study has examined the extent to which the WHO surgical safety checklist effectiveness is related to checklist adherence.[11]

The aim of this review was to assess the effectiveness of the WHO surgical safety checklist. The first objective was to assess the effect of the checklist on postoperative complications and mortality following implementation; the second was to assess the relationship between clinical outcome and adherence with the WHO surgical safety checklist.

Methods

Data sources

The Cochrane Library, MEDLINE, Embase and Cumuative Index to Nursing and Allied Health Literature (CINAHL) databases were searched systematically for all publications until February 2013. The following medical subject heading (MeSH) search terms and keywords were used, either individually or in combination: 'Postoperative complications'[MeSH], 'Checklist'[MeSH], 'Post- operative complications, prevention and control'[MeSH]. The MEDLINE search strategy (Appendix S1, supporting information) was adjusted to the dictionary of the other databases as appropriate. This was accompanied by a checklist-specific query using the following keywords: 'Safety Management'[MeSH], 'Risk Management'[MeSH], 'Checklist'[MeSH]. In addition, bibliographies of included

articles were hand searched for other relevant articles. During the preparation of the manuscript, the MEDLINE strategy was consulted weekly in order to identify potentially new relevant publications. Grey literature was not considered.

Study selection

Only English language studies were included. Potentially included study designs were: randomized clinical trials, non-randomized controlled trials, controlled before–after studies, interrupted time series (ITS) and repeated-measures studies. Only studies with a quantitative evaluation regarding the impact of the WHO surgical safety checklist on postoperative complications, including postoperative mortality, were included. Studies were excluded if they addressed only a particular issue or complication, such as those solely focusing on the effectiveness of surgical-site marking.

Data extraction

After removal of duplicates, a first selection of references was made based on title and abstract. Papers selected for full-text review were screened according to the inclusion and exclusion criteria. Two independent reviewers carried out data extraction and critical assessment of included studies, with disagreements settled by a third reviewer. Study setting, design, selection and measurement bias, baseline outcome measurements and characteristics, risk of contamination, data analysis, selective outcome reporting, other risks of bias, and issues relating to generalizability and sustainability were extracted and recorded. Assessment for risk of bias and critical appraisal was conducted using the Cochrane Collaboration's Effective Practice and Organisation of Care Group guidelines.[12]

Data synthesis and analysis

Data were analysed using R (a language and environment for statistical computing).[13] All reported *P*-values are two-sided; $P < 0.05$ was considered to indicate statistical significance.

Postoperative complications discussed in at least two studies were included in the narrative synthesis. Meta-analysis was performed for three main patient outcome measures: occurrence of any postoperative complication, surgical-site infection (SSI) and mortality. If a study provided data for more than one site, than data from the individual sites were used in order to overcome the effect of aggregated data reporting as well as to limit in-study heterogeneity. Risk ratios (RR) with 95 per cent confidence intervals (95% c.i.) were calculated as summary estimates of the effects using a random-effects model, as proposed by DerSimonian and Laird.[14] Heterogeneity of the study results was assessed using the Cochran Q test and the Higgins I^2 test. $P < 0.100$ in Cochran's Q test and an I^2 value exceeding 50 per cent were considered to show significant heterogeneity.

Yule's Q contingency coefficient was used as a measure of association between effectiveness and checklist adherence. Yule's Q is a transformation of the odds ratio (OR) designed to vary, not from 0 to infinity with 1 indicating no effect, but from −1 to +1 with 0 indicating no effect, as the Pearson correlation. Conceptually, this is the number of pairs in agreement (ad) minus the number in disagreement (bc) divided by the total number of paired observations.[15] Effectiveness of the WHO surgical safety checklist was represented using a binary variable indicating the occurrence of a significant risk ratio for any complication.

All authors reviewed the measures of adherence individually and determined whether adequate adherence to the checklist could be expected. Adequate adherence was defined as adherence to the provided measures for at least 90 per cent of all patients. Following these individual assessments, a consensus meeting was held, at which consensus was sought in cases of disagreement. Throughout this procedure the authors were blinded to outcome data and study references. Agreement between the authors regarding their interpretation of checklist adherence was assessed using Fleiss' κ. The resulting decision was expressed as a binary variable representing presence or absence of adequate adherence to the checklist.

Results

In total, 723 potentially relevant articles were retained. After critical assessment of title and abstract, nine papers were selected for full-text evaluation of which two [16,17] were excluded because they did not meet the inclusion criteria. Finally, seven papers were considered for further analysis.[11,18–23] One study was excluded from meta-analysis as it was a reanalysis of a sub cohort of patients undergoing non-elective surgery already reported in another study.[19] The PRISMA diagram showing the selection of articles is presented in figure 1.

Included studies

Haynes *et al.* assessed the effectiveness of the WHO surgical safety checklist at eight hospitals worldwide.[18] This study, with an ITS design, included patients aged 16 years or older undergoing non-cardiac surgery. After a first exploratory baseline measurement, each institution received feedback about areas of deficiencies identified and was subsequently asked to implement the checklist. The checklist was introduced to the operating theatres over a 1-week to 1-month interval. To facilitate implementation, the checklist was translated to the local language and adjusted to fit into the care process at each institution. A local dedicated study team guided the introduction of the checklist to the staff. Effectiveness was measured as the reduction in any major complication, including

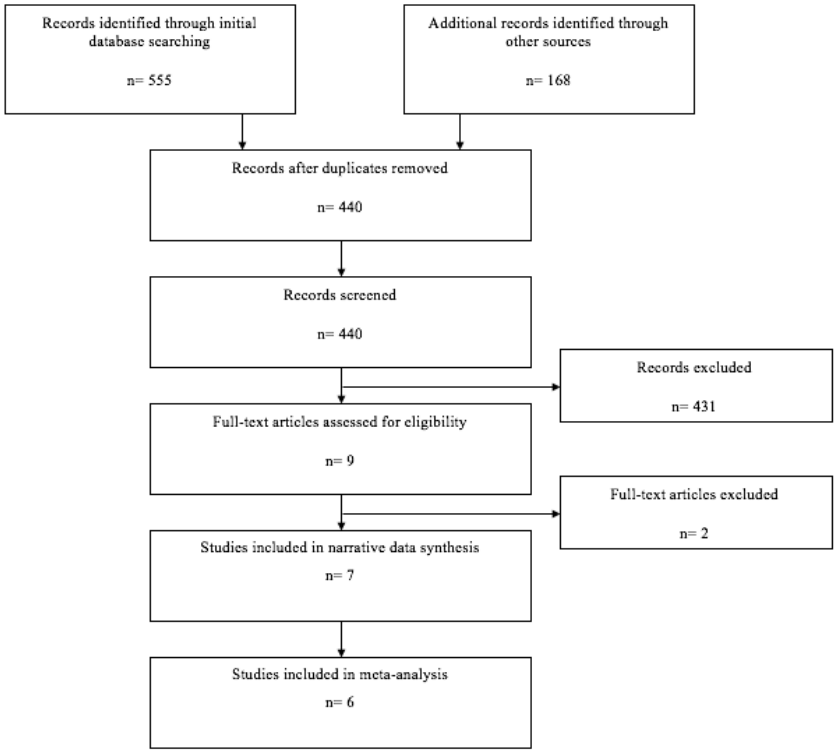

Figure 1 PRISMA diagram showing selection of articles for review

death, during the postoperative hospital stay (up to 30 days) or until hospital discharge. Weiser *et al.* conducted a reanalysis of a subsample of adult patients undergoing urgent, non-cardiac surgery.[19] The subsample was drawn from the data used by Haynes and colleagues.[18]

Sewell *et al.* evaluated the use of the WHO surgical safety checklist before and after implementation of an educational programme in one hospital in the UK.[20] This study, with an ITS design, considered trauma and orthopaedic surgery. The programme, which was designed to improve checklist use, consisted of the following measures: checklist forms were placed in the operating theatre so staff members could become more familiar with their use; a compulsory training video was produced, detailing the correct way to fulfil the checklist; and educational sessions were delivered, discussing the main causes of adverse events associated with surgery, and explaining how to use the checklist appropriately. Effectiveness was measured as the reduction in any major complication, including death, during the postoperative hospital stay, up to 30 days or until hospital discharge.

Askarian *et al.* evaluated the effect of the WHO surgical safety checklist on postoperative morbidity and mortality rates in a tertiary-care hospital in Iran.[21] This study, with an ITS design, included patients aged at least 16 years

undergoing elective general surgery. End-stage and immunocompromised patients were excluded. Baseline assessment was carried out during the first 3 months of the study; postoperative complications were recorded in four hospital wards until hospital discharge. The checklist was introduced during meetings, and an educational package, containing the checklist and accompanying guidelines, was provided to operating theatre personnel. Effectiveness was measured as the reduction in postoperative complications.

van Klei *et al.* evaluated the effect of an adapted version of the WHO surgical safety checklist on in-hospital mortality, together with the impact of checklist compliance on outcome, in a tertiary hospital in the Netherlands.[11] This retrospective cohort study included all adult patients who underwent a surgical procedure. Modifications of the WHO checklist were made to enhance local applicability, resulting in a 22-item checklist. The entire surgical and anaesthesia team briefly reviewed each surgical patient, replacing the sign-in part of the WHO surgical safety checklist. To ensure that checklist items were also available to caregivers before a patient entered and left the operating theatre, structured handovers were implemented from the ward to the theatre holding area as well as from the theatre to the recovery room. Implementation information was provided both at regular meetings and during extra meetings with the entire staff (surgeons, anaesthetists and nurses), where the importance of the checklist was emphasized. In addition, the checklist was made available in poster format in every operating theatre and electronically in the scheduling system. Effectiveness was measured as any reduction in in-hospital mortality within 30 days of surgery.

Bliss *et al.* evaluated the effects of the Association of Perioperative Registered Nurses Comprehensive Surgical Checklist at a 600-bed tertiary-care facility and major teaching hospital in the USA.[22] This checklist incorporates mandated clinical practice required by the WHO, the Joint Commission, and the Centers for Medicare and Medicaid Services. This study used an ITS design with historical controls, and included all patients aged 18 years or older undergoing high-risk surgical procedures. Implementation of the checklist involved a three-session team-based training programme. Surgical services staff were oriented to the use of the checklist, and barriers to checklist use were discussed at the training session. Effectiveness was evaluated as any reduction in 30-day mortality and/or postoperative complications.

Kwok *et al.* evaluated the effectiveness of the WHO surgical safety checklist at a public, university-affiliated general and trauma hospital in Chisinau, Moldova, using an ITS design.[23] The intervention comprised a hospital-wide implementation of the checklist. A local implementation team was created consisting of hospital administrators and representatives from the surgical, anaesthesia and nursing departments. The implementation team was trained during four weekly 30 to 60 minutes video conferences, using checklist and oximetry training materials

developed by the WHO, Harvard School of Public Health, the World Federation of Societies of Anaesthesiologists, and the Association of Anaesthetists of Great Britain and Ireland. These materials included presentations, manuals, clinical scenarios and videos. Thirty-day complication data were collected as defined by the American College of Surgeons National Surgical Quality Improvement Program.

Risk of bias of included studies

All studies were prone to confounding and bias owing to methodological decisions. All papers reported the results of non-randomized studies, resulting in potential bias. As methodological information was difficult to find, many questions concerning bias and confounding were unanswered. The following potential sources of bias and confounding could be generalized. A first source concerns compliance with checklist use. Six studies reported a measure of a subgroup of safety indicators that reflect compliance with the checklist, with a range between 0 and 97.3 per cent.[18–23] All studies demonstrated variability in compliance between checklist items. This incomplete implementation makes it difficult to attribute the measured effect to the WHO surgical safety checklist alone. A second source of bias is the implementation strategy used in the studies. Various, often unclear, implementation approaches were used, possibly resulting in different levels of compliance with the checklist. Third, in some studies direct observation was used to evaluate compliance, potentially leading to a Hawthorne effect.

Effects of checklist use on postoperative complications

Any complication

Six studies reported data on any complication within 30 days following surgery or until hospital discharge (Table 1).[18–23] Five studies found decreasing complication rates: 11.0 versus 7.0 per cent ($P < 0.001$)[18] , 18.4 versus 11.7 per cent ($P = 0.001$)[19] , 22.9 versus 10.0 per cent ($P = 0.03$)[21] , 23.6 versus 8 per cent ($P < 0.001$)[22] and 21.5 versus 8.8 per cent ($P < 0.001$)[23]. One study did not demonstrate a significant difference between evaluation intervals (8.5% versus 7.6%; RR = 0.89, 95% c.i. 0.58 to 1.37)[20]. Meta-analysis for any complication across five studies yielded a risk ratio of 0.59 (95% c.i. 0.47 to 0.74; $P < 0.001$). There was significant heterogeneity (Cochran's Q = 44.07, 11 d.f., $P < 0.001$; I^2 = 75%, 95% c.i. 56 to 86) (see figure 2).

Mortality rates

Thirty-day mortality was reported in five studies (Table 2).[11,18–20,23] A significant effect on mortality following checklist implementation was found in two studies: 1.5 versus 0.8 per cent ($P = 0.003$)[18] and 3.7 versus 1.4 per cent ($P = 0.007$)[19]. van Klei and colleagues reported a decrease in crude mortality rates from 3.1 to

2.9 per cent, but this was not statistically significant (P = 0.19).[11] After adjustment for baseline differences, mortality decreased significantly after checklist implementation (OR = 0.85, 95% c.i. = 0.73 to 0.98). This effect was strongly related to checklist compliance; the odds ratio was 0.44 (0.28 to 0.70) if the checklist was completed fully, compared with 1.09 (0.78 to 1.52) and 1.16 (0.86 to 1.56) for partial and non-compliance respectively.[11] Two studies [20,23] did not demonstrate a significant reduction in mortality. Meta-analysis for crude mortality revealed that across four studies the risk ratio for mortality with the use of the WHO surgical safety checklist was 0.77 (0.60 to 0.98; P = 0.035), without significant heterogeneity (Cochran's Q = 13.15, 10 d.f., P = 0.216; I^2 = 24%, 95% c.i. 0 to 62) (see figure 3).

Surgical-site infections

Surgical site infection rates were reported in six studies (Table 3).[18–23] Three reported a significant decrease in surgical site infections rates following checklist implementation: from 6.2 to 3.4 per cent (P < 0.001)[18], 11.2 to 6.6 per cent (P < 0.001)[19] and 14.9 to 4.7 per cent (P < 0.001)[23]. The other studies did not demonstrate a significant change in surgical site infections rate following checklist implementation: 4.4 versus 3.5 per cent [20], 10.4 versus 5.3 per cent (P = 0.1)[21] and 6.2 versus 5 per cent (P = 0.845)[22]. Meta-analysis revealed that across five studies the risk ratio for surgical site infections with the use of the WHO surgical safety checklist was 0.57 (95% c.i. 0.41 to 0.79; P < 0.001). There was significant heterogeneity (Cochran's Q = 41.74, d.f., P < 0.001; I^2 = 74%, 95% c.i. 53 to 85) (see figure 4).

Blood loss

Two studies reported on blood loss.[19,22] In the article by Weiser and colleagues, the proportion of patients with estimated blood loss greater than 500ml declined from 20.3 to 13.3 per cent (P < 0.001).[19] Bliss *et al.*, however, did not demonstrate a significant difference in the percentage that required transfusion for bleeding (6.1 to 5.5 per cent; P = 0.392).[22]

Unplanned return to operating theatre

Three studies reported details on unplanned return to the operating theatre.[18,20,23] In the Haynes study the unplanned return rate dropped from 2.4 to 1.8 per cent (P = 0.047).[18] Sewell and colleagues reported unplanned return to the operating theatre after 1 per cent of procedures in both audits.[20] Kwok and co-workers reported that the unplanned return rate decreased from 1.9 to 1.5 per cent (P = 0.151).[23]

Pneumonia

Pneumonia or lower respiratory tract infections were reported in five studies.[18,20–23] One study reported a significant decrease in pneumonia rates, from 4.7 to 2.6

per cent ($P < 0.001$).[23] The others all reported a non-significant difference: 1.1 versus 1.3 per cent ($P = 0.46$)[18] , 2.1 versus 2.5 per cent (no P-value reported)[20], 7.6 versus 3.3 per cent ($P = 0.10$)[21] and 2.4 versus 0 per cent ($P = 0.362$)[22].

Relation between checklist compliance and effectiveness

Six studies measured adherence with the WHO surgical safety checklist. Five reported adherence to a subgroup of six safety measures as an indicator of checklist adherence.[18–22] One study used a subset of five safety measures as an indicator of checklist adherence.[23]

A significant risk ratio — favouring use of the WHO checklist — was found in six of the 12 sites (Figure 2). Within this group, four reported adequate adherence with the safety measures. Of the five sites with adequate adherence, four demonstrated a significant reduction in postoperative complications. In contrast, two of seven sites reporting inadequate adherence demonstrated a significant reduction in postoperative complications. These results suggest a correlation between a significant decrease in postoperative complications and adequate adherence to the reported safety measures ($Q = 0.82$, $P = 0.042$).

Discussion

The results of this meta-analysis suggest that the WHO surgical safety checklist reduces postoperative complications, including mortality. Meta-analysis demonstrated a significant effect of the checklist on any complication (RR 0.59, 95% c.i. 0.47 to 0.74), mortality (RR 0.77, 0.60 to 0.98) and surgical site infections (RR 0.57, 0.41 to 0.79). The present study also suggested that sites with adequate compliance with aspects of care embedded in the checklist were more likely to demonstrate a significant reduction in postoperative complications.

Pooled analysis showed significant improvements in postoperative complications following implementation of the WHO surgical safety checklist. Yet, there was variability in effect sizes among the studies. The variation becomes even more evident when the Haynes study [18] is analysed at site level (Table1). Even when a uniform implementation method is used (as assumed in the Haynes study), variation in adherence and outcome is observed. It is likely that the implementation method has an impact, but it is not the only determinant. Haynes and colleagues showed that improvements in postoperative outcomes were associated with improved perception of teamwork and safety climate among respondents, suggesting that changes in these aspects may be partially responsible for the effect of the checklist.[17]

This study highlights that evaluation of a team’s compliance with the checklist, which is measured by adherence, is as important as evaluating outcomes.[9,10]

Hospital administrators, implementation leaders and researchers need to measure and report compliance with the checklist in association with clinical outcomes. There is a need for a reproducible method of measuring compliance that allows a better understanding of its potential effect as a confounding variable affecting checklist efficiency.[10,24] In addition, there is a need to identify the key barriers to improve adherence to the surgical safety checklist.[8]

One other review has dealt with the effectiveness of a checklist during surgery.[25] This general review by Borchard *et al.* did not consider the WHO surgical safety checklist exclusively. The present review excluded the SURgical PAtient Safety System (SURPASS) checklist, which is conceptually different from the WHO surgical safety checklist.[26] The SURPASS is a comprehensive multidisciplinary checklist divided into parts that correspond to the different phases of the entire surgical pathway (preoperative, operative, recovery or intensive care, and postoperative hospital stay); the WHO surgical safety checklist covers only the perioperative phase. Inclusion of the SURPASS would therefore be methodologically incorrect here as the two instruments are different. Furthermore, this study used the impact of adherence with individual items singled out for measurement to explain the variation in effectiveness between sites. Only one other study demonstrated the relationship between adherence with the WHO surgical safety checklist and reduction in postoperative complications.[11] In their study, van Klei and colleagues also showed a decrease in mortality related to the degree of checklist completeness.[11]

The present findings should be interpreted in the context of the included studies and their limitations. Several potential biasing and confounding elements must be considered. First, considerable methodological, clinical and statistical heterogeneity among studies might have hampered the meta-analysis. As a result of various methodological issues and the lack of detailed information regarding implementation and adherence, meta-regression could not be performed in order to explain statistical heterogeneity. Second, as mortality rates were relatively low, some studies were underpowered and as such not able to detect a potential difference in mortality.[20–23] Third, the size of the benefit found in these low-quality studies, expressed as a risk ratio, is not close to the size postulated in general methodological discussions as being sufficient to rule out the need for a randomized trial.[27] Fourth, considering the different cohorts studied, paediatric patients were not investigated. Finally, the interpretation of compliance with the checklist was based on the adherence to a subgroup of safety measures. This is an important distinction as these reported measures represent adherence to specific aspects of care embedded in the WHO checklist. The full checklist probably functions in a different way to the individual items singled out for measurement. Studies emphasize the importance of team function and communication in checklist use, a factor not included in the measures of adherence in the included

studies. Compliance with the subgroup of safety measures does not necessarily imply appropriate use of the checklist.

Conclusion

The available evidence is supportive of a reduction in postoperative complications and mortality following implementation of the WHO surgical safety checklist, but cannot be regarded as definitive in the absence of higher-quality studies. Reduction in postoperative complications correlates with adherence to aspects of care embedded in the WHO surgical safety checklist.

Table 1 Summary of published results: any complication before and after checklist implementation

	Before	After	*P-value*
Haynes *et al.*[18]	11%	7.0%	<0.001
Site 1	11.6%	7.0%	<0.05
Site 2	7.8%	6.3	>0.05
Site 3	13.5%	9.7%	>0.05
Site 4	7.5%	5.5%	>0.05
Site 5	21.4%	5.5%	<0.05
Site 6	10.1%	9.7%	>0.05
Site 7	12.4%	8.0%	<0.05
Site 8	6.1%	3.6%	>0.05
Weiser *et al.*[19]	18.4%	11.7%	=0.001
Sewell *et al.*[20]	8.5%	7.6%	RR=0.89 95%CI 0.58-1.37
Askarian *et al.*[21]	22.9%	10%	=0.03
van Klei *et al.*[11]	N.A.	N.A.	N.A.
Bliss *et al.*[22]	23.6%	8.2%	=0.001
Kwok *et al.*[23]	21.5%	8.8%	<0.001

Legend: N.A. = Not available; OR = odds ratio; RR = Risk Ratio; 95% CI = 95% confidence interval

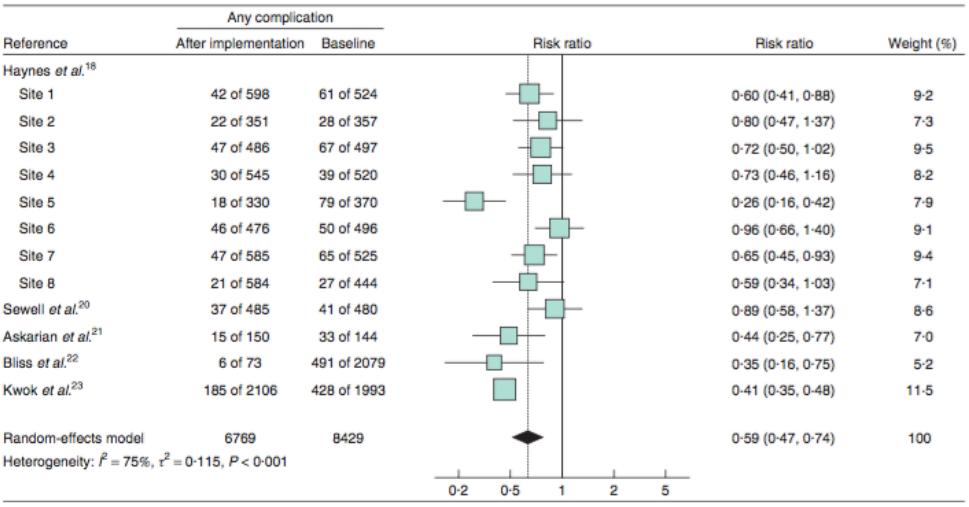

Figure 2 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing any complication. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

Table 2 Summary of published results: mortality before and after checklist implementation

	Before	After	*P-value*
Haynes *et al.*[18]	1.5%	0.8%	=0.003
Site 1	1.0%	0.0%	<0.05
Site 2	1.1%	0.3%	>0.05
Site 3	0.8%	1.4%	>0.05
Site 4	1.0%	0.6%	>0.05
Site 5	1.4%	0.0%	<0.05
Site 6	3.6%	1.7%	>0.05
Site 7	2.1%	1.7%	>0.05
Site 8	1.4%	0.3%	>0.05
Weiser *et al.*[19]	3.7%	1.4%	=0.007
Sewell *et al.*[20]	1.9%	1.6%	RR=0.88 95%CI 0.34-2.26
Askarian *et al.*[21]	N.A.	N.A.	N.A.
van Klei *et al.*[11]	3.13%	2.85%	OR=0.91 95%CI 0.78-1.05
Bliss *et al.*[22]	N.A.	N.A.	N.A.
Kwok *et al.*[23]	4.0%	3.1%	0.151

Legend: N.A. = Not available; OR = odds ratio; RR = Risk Ratio; 95% CI = 95% confidence interval

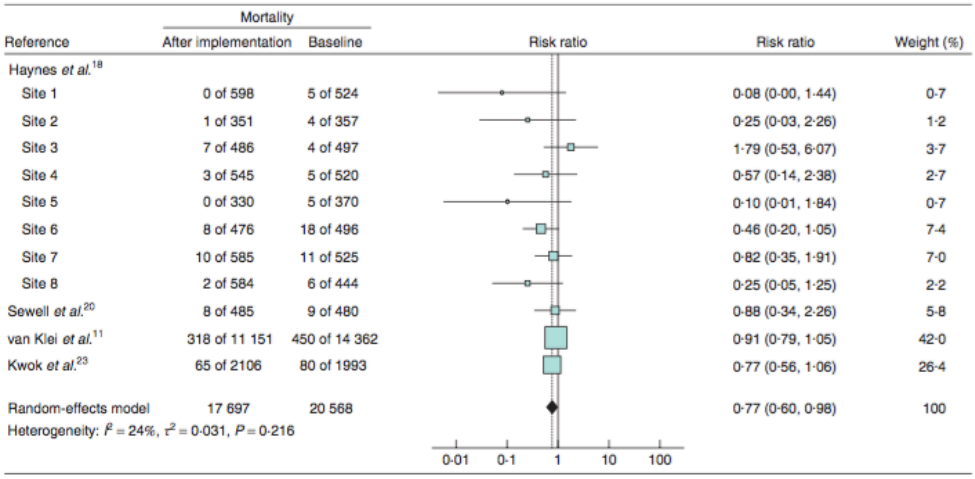

Figure 3 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing mortality. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

Table 3 Summary of published results: surgical site infections before and after checklist implementation

	Before	After	*P-value*
Haynes *et al.*[18]	6.2%	3.4%	<0.001
Site 1	4.0%	2.0%	<0.05
Site 2	2.0%	1.7%	>0.05
Site 3	5.8%	4.3%	>0.05
Site 4	3.1%	2.6%	>0.05
Site 5	20.5%	3.6%	<0.05
Site 6	4.0%	4.0%	>0.05
Site 7	9.5%	5.8%	>0.05
Site 8	4.1%	2.4%	>0.05
Weiser *et al.*[19]	11.2%	6.6%	=0.001
Sewell *et al.*[20]	4.4%	3.5%	N.A.
Askarian *et al.*[21]	10.4%	5.3%	=0.1
van Klei *et al.*[11]	N.A.	N.A.	N.A.
Bliss *et al.*[22]	6.2%	5.5%	=0.845
Kwok *et al.*[23]	14.9%	4.7%	<0.001

Legend: N.A. = Not available; OR = odds ratio; RR = Risk Ratio; 95% CI = 95% confidence interval

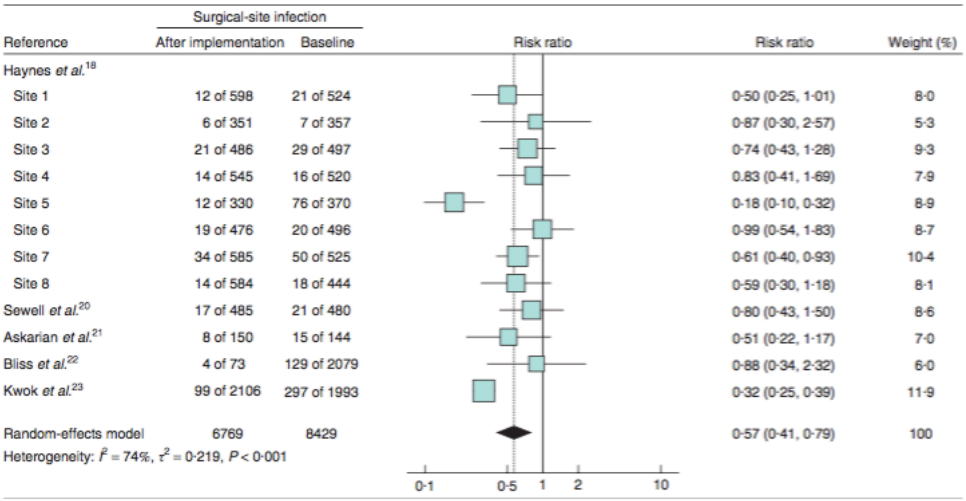

Figure 4 Forest plot showing the effectiveness of the World Health Organization surgical safety checklist in reducing surgical-site infection. A random-effects model was used for meta-analysis. Risk ratios are shown with 95 per cent confidence intervals

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Chapter 3

Surgical Safety Checklists: an update

An abridged vision of this chapter was published as:

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Surgery is an important part of modern healthcare. The annual volume of major surgical procedures is estimated around 234.2 million worldwide.[1] It is well known that surgical patients are prone to healthcare related harm. The rate of adverse events for surgical patients has been estimated to range from 12.5 per cent to 20.1 per cent, the rate of potentially preventable adverse events ranges from 4.2 per cent to 7.0 per cent.[2] In Europe, mortality rates following surgery have been described as 'higher than anticipated', with significant variations between countries (1.2% to 21.5%).[3] These numbers demonstrate that patient safety within the surgical context is a major challenge. With these findings in mind, it has been suggested that there is an increased need for national and international strategies to improve the quality and safety of care for surgical patients.[3]

The most important adverse events within the surgical context include: wrong site/procedure/patient surgery, unanticipated blood loss, surgical items left inside the patient, anaesthesia equipment problems, lack of availability of necessary equipment and the use of non-sterile equipment. Most errors leading to adverse events are caused by factors unrelated to surgical techniques, but rather to non-operative management.[2] These reasons include, inter alia, inadequate teamwork, poor relationships with patients, poor understanding of human factors and inadequate knowledge of the potential impact of the complexity of healthcare.[2,4,5] The latter has been recognised by leading agencies involved in patient safety. The complex mechanisms underlying the formation of undesirable events are not only being recognised within the healthcare context; other high-risk industries — aviation for example — have a long tradition in searching solutions to improve safety. The use of checklists is one of the suggested solutions to improve safety in complex environments. Safety checklists which have been demonstrated to be effective tools in ensuring safe operations.[6]

With regard to medicine, there is currently no uniform definition about what a safety checklist should be or look like.[7] Checklists can have several objectives, including memory recall, standardization and regulation of processes or methodologies.[4] The main objective of their implementation is common error reduction and improvement of best practice adherence. A safety checklist consists of a limited list of action items or criteria that are crucial for safety. These items or criteria are arranged in a systematic manner, which allows the users to record their respective presence/absence in order to ensure they are considered or completed. A sound checklist highlights the essential criteria in a particular area.

The aim of this literature review is to provide an up-to-date and critical overview of the growing evidence regarding surgical safety checklists, by addressing checklists effectiveness and discussing the insights regarding the implementation of surgical safety checklists.

Surgical safety checklists

One of the first formal safety checklists related to surgery was the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™.[8] It became available July 2004 for all accredited hospitals, ambulatory care and office-based surgery facilities. The Universal Protocol was created to tackle the persistent occurrence of wrong site, wrong procedure and wrong person surgery in Joint Commission accredited organizations. The three principal components of the Universal Protocol include a pre-procedure verification, site marking, and a time out.

In 2008, the World Health Organization (WHO) published the WHO Surgical Safety Checklist and implementation manual.[9] This 19-item checklist intended to be widely applicable in order to reduce the number of major surgical complications. The WHO checklist is designed around three main phases of an operation, each corresponding to a specific phase of the regular work flow, respectively before the induction of anaesthesia (sign in), before the incision of the skin (time out) and before the patient leaves the operating theatre (sign out). In 2009 the checklist was updated, following the input of its users, resulting in 22 items.

In 2009, a research group from the Netherlands introduced the Surgical Patient Safety System (SURPASS) checklist.[10] This checklist standardizes the operative process of all procedures and appoints responsibilities and specific checks. It includes almost every process from the preadmission phase to the post-discharge phase, aimed to reduce surgical process-related complications and in-hospital mortality.

To meet accreditation requirements, many hospitals expressed the need for a single checklist that includes both the safety checks outlined in the WHO Surgical Safety Checklist and the safety checks of The Joint Commission's Universal Protocol. In response, the Association of periOperative Registered Nurses (AORN) developed the AORN Comprehensive Surgical Checklist in 2010.[11]

How surgical safety checklists work

Surgical safety checklists are intended to work as a barrier system against well-known safety threats. By prompting the attention of the surgical team towards critical steps it aims to improve compliance with proven interventions (e.g., prophylactic antibiotic administration and monitoring prior to induction of anaesthesia). Besides its direct function as a barrier, surgical safety checklists also intend to improve the underlying mechanisms of safe environments. These mechanisms are most likely multi-factorial and not well understood. Key factors include communication and teamwork and the surgical teams' culture/climate.[12]

Effects of surgical safety checklists

The implementation of surgical safety checklists has been associated with increased patient safety awareness [13], improved communication [6,14-19], reduction of surgical claims [20], and a reduction of postoperative complications including mortality [20-28].

Postoperative complications and mortality

The incidence of postoperative complications and mortality are frequently used outcome indicators for patient safety within the surgical context. Five systematic reviews evaluated the available literature related to the impact of surgical safety checklists on these clinical outcomes.[6,14,29-31] One provides a general overview of safety checklists in medicine.[6] Whereas the other four reviews focus specifically on surgical safety checklists.[14,29-31] Three reviews pooled data from the original studies and estimated the effect size by means of meta-analysis. All studies concluded that surgical safety checklists are associated with decreased surgical complications rates and mortality.

The meta-analysis by Borchard *et al.* combined the results from three studies.[29] They reported on the effectiveness of the WHO surgical safety checklist and SURPASS in reducing in-hospital 30-day postoperative complications and mortality rates. The relative risk for any postoperative complication was 0.63 (95% confidence interval 0.58 to 0.67), the relative risk for mortality was 0.57 (95% c.i. 0.42 to 0.76).[29]

The meta-analysis by Lyons & Popejoy included the results from five studies.[14] They also reported on the effectiveness of the WHO surgical safety checklist and SURPASS in reducing in-hospital 30-day postoperative complications and mortality rates. The standardised mean difference of post-intervention scores for morbidity and mortality was 0.123 (P = 0.003) and 0.088 (P = 0.001), respectively.[14]

The meta-analysis by Bergs *et al.*, based on seven studies, pooled data for the effectiveness of the WHO surgical safety checklist in reducing in-hospital 30-day postoperative complications and mortality rates.[31] This study found a decreased probability for postoperative complications (from 16.7% to 7.6%; risk ratio = 0.59, 95% c.i. 0.47 to 0.74) and mortality (from 2.9% to 2.4%; risk ratio = 0.77, 95% c.i. 0.60 to 0.98). The authors concluded that the totality of evidence is highly suggestive regarding the reduction of postoperative complications and mortality following WHO checklist implementation, but cannot be interpreted as definitive in the absence of higher quality studies.[31]

Wrong site surgery

Currently, there is no literature available confirming the effectiveness of surgical safety checklists in decreasing the rate of wrong site or wrong level surgery.[30,32,33] As wrong site surgery is rare; demonstrating a statistical reduction would require an unfeasibly large study.[30] Based on clinical expertise some arguments exist regarding the ability of surgical safety checklists to prevent wrong site surgery.[30,32]

Safety climate

Besides increasing compliance with proven interventions, another objective of surgical safety checklists is to ameliorate the safety climate. Improved perception of teamwork and safety climate among team members in the operating theatre has been associated with improvements in postoperative outcomes.[34] Suggesting that these changes could be partially responsible for the effect of the checklist. There are indications that the exposure to pre-surgery briefings and the perception of safety climate are linked, with higher exposure related to improved perceptions of safety climate.[35] Where we should note that this improvement often only involves specific aspects of a safety climate (e.g., frequency of events reported).[36]

Communication and teamwork

Two specific aspect of a of a safety climate, communication and teamwork, have been extensively investigated within the surgical context. Two systematic reviews addressed the impact of surgical safety checklists on teamwork and communication in the operating theatre.[14,15]

The review by Lyons and Popejoy included ten studies.[14] The effect size was estimated by using the standardised mean difference of post-intervention scores. Given the considerable methodological differences between the included studies (e.g., surveys, observations) one might argue that pooling the results was rather inappropriate from a methodological point of view. Results obtained from surveys based on the Safety Attitude Questionnaire are difficult to compare with survey results obtained from locally self-developed questionnaires or observational data. Therefore, it is challenging to draw stringent conclusions based on this meta-analysis.

The review by Russ *et al.* included twenty studies assessing the impact of safety checklist on communication and teamwork.[15] The included original studies did not always assess team skills as the primary outcome and varied widely on the methodologies, including: surveys, observations, interviews and 360° assessments. Seven of the twenty articles focused on the effect of the WHO surgical safety checklist. The remaining 13 articles reported on perioperative briefings (e.g., Joint Commission's Universal Protocol) or locally developed checklists. Russ and colleagues reported the following findings:

- Self-perceptions of teamwork and communication improved following the implementation of safety checklists.
- Visible consequences of poor communication and near-misses associated with communication errors reduced after the checklist implementation.
- The observed mechanisms through which checklists improved teamwork centred around establishing an open dialogue at the start of the case, promoting provision of case-related information, revealing knowledge gaps, encouraging articulation of concerns, provoking a change in the care plan, supporting interdisciplinary decision making and coordination, and enhancing team "feeling."
- The effect of the checklist on teamwork differed between disciplines. Nursing personnel perceive the most positive impact, while surgeons perceive the least positive impact, anaesthesiologists fall somewhere in between.

These reported improvements were, as previously mentioned, measured by a wide variety of methods and relatively soon after the introduction of a checklist. Despite these short-term improvements, evidence regarding long-term effects are scarce and could not demonstrate long-term improvements.[37] Other studies reported only little or no change for the entrenched hierarchy and relationship dynamics of the operation theatre staff after implementing the WHO checklist.[28,38,39]

The totality of evidence regarding communication and teamwork is divided between suggestions of positive effects and the lack of beneficial effects. It has to be noted that surgical staff members rated teamwork with members of their own profession higher than teamwork with those of other professions; surgeons rated overall teamwork higher than perioperative nurses.[40] These results are not surprising as communication and teamwork takes place in a complex environment it is influenced by various factors. Assuming that simple interventions, like checklists, could mitigate complex social interventions, as communication and teamwork, seems unrealistic. Qualitative research demonstrates that the relation between communication, teamwork, climate and checklist usage is not static; it suggest that team involvement is adjusted to obtain professional and social acceptance within the team.[41] To date, the exact underlying principles and possible covariates remain unclear. It is by example plausible that communication and teamwork are, at least partially, influenced by the climate established in the operating theatre. If this climate relies heavily on hierarchical differences among team members, the implementation of a checklist will probably not lead to sustainable improvements in communication and teamwork.

In conclusion, the implementation process of surgical safety checklists has an effect on team dynamics and safety climate. The underlying paradigms and their

methodological implications complicate the pragmatic interpretation and comparison of published studies. The complex reality requires methods with sufficient depth; however, the current evidence is largely based on (not validated) questionnaires. Therefore, it is premature to assume communication would not improve as a result of implementing surgical safety checklists. Further research using more specific methods is needed to fully understand the complex relations between culture, communication and teamwork and checklist implementation. Surgical safety checklists, by themselves, do not improve safety climate. Instead, a good safety climate prior to the introduction of the checklist is likely to enhance successful implementation and could therefore positively influence the impact of the checklist usage on safety outcomes.

Dissemination

Since the publication of the landmark study by Haynes *et al.* in 2009, a widespread interest in the WHO surgical safety checklist occurred. Today, 1970 hospitals worldwide have indicated to use the WHO checklist in at least one operating theatre.(http://maps.cga.harvard.edu:8080/Hospital/)

The Joint Commission's Universal Protocol has been implemented in every institution certified by the Joint Commission; which is active in more than 90 countries. (http://www.jointcommissioninternational.org/About-JCI/) Apparently, the SURPASS has not been widely used outside the Netherlands. Although, locally adapted versions of this checklist probably exist. Due to its simplicity and its affiliation with the WHO's 'Safe surgery, safe lives' programme the WHO surgical safety checklist is the most widely accepted checklist overall. In accordance with the literature, the WHO checklist has become the golden standard.

Implementation

Notwithstanding the previously described positive effects associated with the implementation of surgical safety checklists, the actual impact of using surgical safety checklists on patient outcomes varied consistently with the effectiveness of the hospital's implementation process. The implementation of surgical safety checklists is complicated by several factors.[19,42-54] As these checklists rely heavy on communication between team members, it should be of no surprise that the previously mentioned issues regarding communication and safety climate are reflected in the literature regarding the implementation of surgical safety checklists.

Compliance

Full compliance with checklists is often difficult to achieve. As a result, the potential clinical benefit is hard to detect. Compliance rates differ among hospitals, surgical staff members, and for specific items and parts of the checklists.[10,29,30,55] Borchard *et al.* summarised 15 studies evaluating the compliance with surgical safety checklists.[29] The overall compliance rate ranged from 12 per cent to 100 per cent (mean: 75%) and for the time-out from 70 per cent to 100 per cent (mean = 91%). Other studies, based on administrative data, showed that even if checklists seem to be used almost routinely during surgery, compliance with the underlying actions could not be consistently observed. This implies that items could be marked, without actually performing the tasks.[43,47,50,56,57] This behaviour leads to a 'false sense of safety'.[12]

Barriers to implementation

Several studies provide insights into potential barriers when implementing surgical safety checklists.[30] These barriers generally can be distinguished into four categories — i.e., confusion regarding how to properly use the checklist, pragmatic challenges to efficient workflow, lack of access to resources, and individual beliefs and attitudes.[30] However, one single theory with relevant hypothesis is still lacking.

Facilitators for implementation

The current literature provides different methodologies for effective implementation of surgical safety checklists. Three main steps are highlighted. First, checklist items should be perceived as relevant and effective by clinical staff. Checklists are only effective if the items they contain match real safety risk events and if these items are supported by sufficient evidence without any redundant items.[29] Second, the checklist should fit the process flow in the operating theatre. Third, the checklist should be implemented according to its intentions. As checklists aim to improve communication and teamwork in the operating theatre, the implementation process should be aligned with these objectives. This requires a different approach compared to implementing a list of items to be checked.[17]

Conclusion

Surgical safety checklists are promising tools to improve surgical safety. Implementation of the WHO surgical safety checklist and the SURPASS have been associated with a reduction of postoperative complications and mortality. The clinical effectiveness of these checklists has been related with improvements in team communication and safety climate following implementation. Hence, the

precise way these underlying mechanisms affect safety outcomes remain unclear. Surgical safety checklists by themselves do not improve safety climate nor team communication. Instead, a good safety climate prior to introduction of a checklist enhances its implementation.

The actual impact of these checklists on patient outcomes varied with the effectiveness of the hospital's implementation process. It has become clear that implementation of surgical safety checklists is difficult to achieve. Even if all items are marked, it cannot be assumed that the underlying tasks have been correctly executed. If compliance to the checklists is measured by assessing the number of checked boxes, a false sense of safety is created. More precise indicators describing the actual use of these checklists by operating theatre personnel need to be considered.

As surgical safety checklists aim to improve communication between surgical team members, the implementation of surgical safety checklists is in essence a complex sociological intervention. This implies that these checklists should be implemented differently than e.g. technical applications. The correct way to do so remains unclear. The use of leading clinicians as role models, accompanied with effective leadership seems most crucial and promising among implementation facilitators. In order to maximise the full potential and clinical benefit of these surgical safety checklists, further research focusing on the implementation and the achievement of sustained compliance is necessary.

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Part II

Dissemination, adoption, and implementation of WHO surgical safety checklist in Flemish hospitals

"One essential characteristic of modern life is that we all depend on systems—on assemblages of people or technologies or both—and among our most profound difficulties is making them work"

— Atul Gawande —

Chapter 4

The world health organisation's surgical safety checklist in Flemish operating theatres: a content-driven evaluation

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The importance of patient safety, especially within the surgical context, has been expressed in various publications. Despite awareness of the patient safety problem, a clear view on the causes, and the availability of interventions to improve patient safety [1,2], the reduction of healthcare-related harm has not reached the surgical community's expectations.[3-6] Some even suggest that the high risks present in the surgical process have increased over time. Others relate this increase to improved attention and reporting regarding adverse events.[7] The estimated prevalence of surgical adverse events varies among studies ; a systematic review estimated that adverse events occurred in 14.4 per cent of surgical patients (interquartile range [IQR], 12.5% to 20.1%), and potentially preventable adverse events occurred in 5.2 per cent (IQR, 4.2% to 7.0%).[3] These numbers are probably an underestimate of the true extent as, though varying by procedure, 41.5 per cent of the postoperative complications occur after discharge.[8] This substantial amount of complications is often not included in the existing incident recording systems. Nevertheless, patient harm related to healthcare is a persistent problem that is hard to influence and results in noticeable burden with financial consequences for patients, hospitals, and society alike.[9]

Surgery is, due to its complex nature, prone to unsafe conditions. The cause of surgical adverse events, however, cannot always be attributed to the surgical technique.[10] On the contrary, healthcare related harm often results from errors in non-operative management.[3] In response to the complex nature of surgery, the World Health Organization (WHO) launched its 'surgical safety' program. The perioperative aspects of this program were pragmatically translated into a surgical safety checklist. This checklist aims to improve compliance with evidence-based practices by prompting the surgical teams' attention towards critical steps in the surgical process (e.g., prophylactic antibiotic administration and monitoring prior to induction of anaesthesia). In addition, the checklist intends to improve the underlying conditions for a safe environment (i.e., facilitating team communication and promoting teamwork). The use of the WHO checklist has been associated with a significant reduction in postoperative complications, including mortality, and with improved teamwork and communication in the operating theatre.[11-14]

To achieve its full potential, the checklist must be implemented as intended by the developers.[15,16] It has been shown that full implementation of the WHO checklist is difficult to accomplish, which in turn can jeopardise adequate adherence.[17,18] In general, successful implementation of an intervention — in this case the use of the WHO checklist — is influenced by several factors: characteristics of the intervention being implemented, the outer setting, the inner setting, characteristics of individuals involved in the intervention and/or implementation process, and the implementation process.[19] Adaptability of an intervention has been described as an important aspect in facilitating

implementation.[19] The WHO encourages modifications of its checklist to account for setting-specific variations across facilities with respect to their processes, culture, and the degree of familiarity between team members. Removing checklist items because they cannot be accomplished in the existing environment or circumstances is strongly discouraged.[20] Thoughtless modification may lead to reduced effectiveness of the WHO surgical safety checklist. This applies especially when items are removed. Given the current state of evidence, it is unclear which items and underlying principles are responsible for the benefits associated with the use of this checklist. From a policy point of view it is recommended to include all of the 22 items as purposed by the WHO.

A growing number of organisations, worldwide, are endorsing the widespread use and implementation of the WHO surgical safety checklist. The current guidelines detailing and allowing checklist modifications might lead to the development of a variety of checklists in terms of there content. Some of these modified checklists will be used under the pretend of the WHO label while bearing little or no resemblance to the original checklist. This highlights the importance of knowing what modifications are made by hospitals. As the literature does not provide any data on this, this study aimed to describe the modifications made by hospitals by conducting a content-driven evaluation of the surgical safety checklists used in Flemish hospitals.

Methods

Design and setting

This cross-sectional, web-based survey is part of a broader research project evaluating the implementation of the WHO surgical safety checklist in Flemish hospitals (Dutch speaking part of Belgium). Since January 2013 governmental legislation obliged the use of the WHO surgical safety checklist for all elective surgical procedures. In collaboration with the respective professional associations of surgeons, anaesthesiologists, and perioperative nurses, the research group patient safety & health economics of Hasselt University established a consortium to support Flemish hospitals with the implementation of the surgical safety checklist.

Sample

All Flemish hospitals with an operating theatre were identified (n = 56). The chief executive officer (CEO) and chief medical officer (CMO) of each hospital were sent an invitation letter explaining the purpose of the study and inviting the hospital to participate in a survey.

The survey

A structured online survey was set up using LimeSurvey® (http://www.limesurvey.org). The survey consisted of three parts. The first part contained general questions regarding the hospital and the operating theatre : type of hospital, size of the department, and number of nurses. The second part covered 12 questions about the use of the surgical safety checklist (see table 1). The third and last part of the survey asked to provide a copy of the checklist used by the hospital. The survey was electronically distributed by sending an e-mail to the hospitals' contact person. A reminder was sent, respectively two and four weeks after the first invitation. After this four week period the survey was closed and the online dataset was converted to an IBM® SPSS® statistics compatible dataset.

Checklist evaluation

To verify the content of the received checklists, a panel of healthcare professionals was assembled, consisting of one surgeon (representative from the national association of surgeons), one anaesthesiologist (representative from the national association of anaesthesiologists), one perioperative nurse (representative from the national association of perioperative nurses), one hospital's quality officer, one expert on hospital accreditation, and one patient safety expert. The expert panel was brought together during a consensus meeting where the retrieved checklists were discussed under the guidance of a facilitator and referee.

In preparation of the meeting, all experts were provided with a copy of the original WHO surgical safety checklist accompanied by the implementation manual two weeks in advance.[20] In preparation, two researchers (JB & DV) independently screened the checklists for the presence of the 22 WHO items. All findings were noted and the WHO items were highlighted. Discrepancies between the two researchers were resolved by discussing the issues and crosschecking the literature. Checklists were blinded — i.e., all elements that directly or indirectly referred to the hospital were removed.

The meeting was lead by a facilitator (JB) who introduced all checklists and mentioned the issues found during preparation. Simultaneously, the relevant checklist was displayed on a screen. This was followed by a discussion among the panel members in order to reach consensus on two questions : 1) are all 22 items included in the checklists as mentioned by the WHO, and 2) in case modifications were made, to assess whether or not these were in accordance with the WHO recommendations. In case no consensus was reached after five minutes following start of the discussion, the referee (DV) intervened and made, based on the arguments formulated by the panel, a final decision. A copy of the WHO's implementation manual and checklist was provided during the meeting as a reference. This process was repeated for all checklists.

Statistical analysis

The data of the survey and the conclusions appearing from the expert evaluation were anonymously analysed using descriptive statistics. Survey answers were reported as numbers and percentage. IBM® SPSS® statistics version 22 was used for managing the data and computing the statistics.

Ethical considerations

Given the methodology, the institutional review board waived the necessity of an informed consent. Consent was assumed when the CEO signed the declaration of intent.

Results

From all invited hospitals (n = 56), 33 signed the declaration of intent (response rate = 58.9%). As some hospitals have 2 or more sites, 40 invitations to fill out the survey were sent, of which 36 returned the survey. One hospital attached a 9-page structured patient record as checklist. Although it was a well-designed patient record, it was the experts' opinion that this could not be considered as a surgical safety checklist and was, consequently, excluded for further evaluation.

Survey results (36 hospitals)

The results concerning checklist usage are summarised in table 1. All hospitals (n = 36, 100%) reported the use of a surgical safety checklist in the operating theatre. Four hospitals (11.1%) reported usage of the original, non-modified, version of WHO surgical safety checklist. The majority of hospitals (80.6%, n = 29) reported to use a modified version of the WHO checklist. The use of a self-developed checklist was reported by 8.3 per cent of hospitals (n = 3).

Usage of the checklist was obliged during elective procedures under general-, and local anaesthesia, and during urgent procedures in 97.2 per cent (n = 35), 66.7 per cent (n = 24), and 75 per cent (n = 27) of hospitals, respectively. About a quarter of hospitals (22.2%, n = 8) reported procedures for which the checklist was not mandatory. These procedures included: ambulatory procedures (n = 5), endoscopies (n = 1), tooth extractions (n = 2), ophthalmologic surgery (n=3) and otolaryngology surgery (n = 1). Two hospitals reported to have developed a shorter version of the checklist for these procedures.

Most hospitals (94.4%, n = 34) use some kind of tool (for instance, leaflet, poster, or computer) to ensure every item is covered. In 69.4 per cent (n = 25) of hospitals one team member is responsible for completing the checklists ; 13.9 per cent (n = 3) of hospitals reported they did not dedicate one of the team members

for this job, and 16.7 per cent (n = 6) of the respondents did not know whether or not someone is responsible for checking items. Almost half of the respondents (44.4%) did not know whether verbal confirmation of all items was performed and whether the entire team stopped all other activities at the three critical points (i.e., sign in, time out, sign out) to discuss the checklist items.

Table 1 Survey questions and results regarding checklist usage

Question	Yes n(%)	No n(%)	Unsure n(%)
Does your hospital use a surgical safety checklist?	36 (100)	/	/
Is the use of the checklist obliged during elective procedures under general anaesthesia?	35 (97.2)	1 (2.8)	/
Is the use of the checklist obliged during elective procedures under local anaesthesia?	24 (66.7)	12 (33.3)	/
Is the use of the checklist obliged during urgent, unplanned procedures?	27 (75)	9 (25)	/
Are there particular procedures for which the use of the checklist is not required?	8 (22.2)	28 (77.8)	/
Does the checklist include at least all 22 items as proposed by the WHO checklist?	25 (69.4)	11 (30.6)	/
Does the entire team stop all other activity for a few moments at three critical points, i.e., pre-anaesthesia, pre-incision and before the patient leaves the OR? The goal is for the entire team to participate in each pause. (The surgeon may not have to be present for the pre-anaesthesia check.)	8 (22.2)	12(33.3)	16 (44.4)
Does the entire team verbally confirm each item on the WHO Checklist? The goal is for the entire team to participate. At a minimum, every item on the WHO Checklist should be confirmed. Other items may also be addressed.	7 (19.4)	13(36.1)	16 (44.4)
Are the items verified without reliance on memory? The goal is to use a tool for reference to ensure every item is covered, e.g., a form, poster, or computer screen.	34 (94.4)	2(5.6)	/
Is during the operation one person (nurse, surgeon or anaesthesiologist) responsible for the initiation of the checklist items?	25 (69.4)	5(13.9)	6 (16.7)

Content of the checklists (35 checklists)

Based on self-report, 69.4 per cent (n = 25) of hospitals stated that their checklist included all 22 items as mentioned by the WHO. After expert evaluation, though, it was found that only 17.1 per cent (n = 6) of the evaluated checklists included all 22 WHO items. Inclusion of WHO items ranged from 7 to 22 items (mean = 16.6, SD = 4.48). When detailing on the three functional parts of the checklist, it showed that 48.6 per cent (n = 17) of checklists contained all sign-in items, 25.7 per cent (n = 9) covered all time-out items and 37.1 per cent (n = 13) enclosed all sign-out items. Modifications, in terms of adding extra items to the checklist, were made by 60 per cent (n = 21) of hospitals. These items most often included : preoperative checks for ward nurses, availability of patient record,

anticoagulation status, patient positioning and checking for the availability of specific surgical materials.

Sign in : before induction of anaesthesia

Table 2 Inclusion of WHO surgical safety checklist sing in items

	Checklists fully including this item % (n)	Checklists partially including this item % (n)	Checklists not including this item % (n)
Sign in - Before induction - 48.6% of checklists included all items			
Has the patient confirmed his/her identity, site, procedure, and consent?	62.9 (22)	37.1 (13)	-
Is the site marked?	94.3 (33)	-	5.7 (2)
Is the anaesthesia machine and medication check complete?	74.3 (26)	8.6 (3)	17.1 (6)
Is the pulse oximeter on the patient and functioning?	71.4 (25)	8.6 (3)	20.0 (7)
Does the patient have a known allergy?	100 (35)	-	-
Does the patient have a difficult airway or aspiration risk?	71.4 (25)	2.8 (1)	25.7 (9)
Does the patient have a risk of > 500ml blood loss (7ml/kg in children)?	77.1 (27)	-	22.9 (8)

In total, 40 per cent (n = 14) of checklists included all sign-in items ; an additional 8.6 per cent (n = 3) included all sign-in items if partial uptake (i.e., including only a sub-set of item elements) was considered. A detailed overview of the inclusion and omission of sign-in items can be found in table 2. Items for which only specific parts of the item were included are described below.

The item '*Has the patient confirmed his/her identity, site, procedure, and consent ?*' was included in all checklists, although not all issues (i.e., identity, site, procedure and consent) of this question were included. All question issues were included in 62.9 per cent (n = 22) of checklists. For those not including all issues, the 'consent' part was most often missing (76.9%, n = 10). One hospital did not use 'consent and procedure', one 'consent and site' and one 'site'.

The item '*Is the anaesthesia machine and medication check complete?*' was included in 74.3 per cent (n = 26) of checklists, 8.6 per cent (n = 3) mentioned only to check the anaesthesia machine without specifically mentioning a medication check and 17.1 per cent (n = 6) did not include this item.

The item '*Is the pulse oximeter on the patient and functioning?*' was present in 71.4 per cent (n = 25) of checklists, 8.6 per cent (n = 3) included the item but did not specifically mention to control its functioning and 20.0 per cent (n = 7) did not include this item.

The item '*Does the patient have a difficult airway or aspiration risk ?*' was included in 71.4 per cent (n = 25) of checklists, one checklist partially included (difficult

airway) the item and 25.7 per cent (n = 9) did not include this item in the checklist.

Time out : before skin incision

Table 3 Inclusion of WHO surgical safety checklist items

	Checklists fully including this item % (n)	Checklists partially including this item % (n)	Checklists not including this item % (n)
Time out - Before skin incision - 25.7% of checklists included all items			
Confirm all team members have introduced themselves by name and role	45.7 (16)	-	54.3 (19)
Confirm the patient's name, procedure, and where the incision will be made	94.3 (33)	-	5.7 (2)
Has antibiotic prophylaxis been given within the last 60 minutes?	100 (35)	-	-
What are the critical or non-routine steps? [surgeon]	85.7 (30)	-	14.3 (5)
How long will the case take? [surgeon]	51.5 (18)	-	48.5 (17)
What is the anticipated blood loss? [surgeon]	71.4 (25)	-	28.6 (10)
Are there any patient-specific concerns? [anaesthetist]	71.4 (25)	-	28.6 (10)
Has sterility (including indicator results) been confirmed? [nursing team]	82.9 (29)	-	17.1 (6)
Are there equipment issues or any concerns?	77.1 (27)	-	22.9 (8)
Is essential imaging displayed?	74.3 (26)	-	25.7 (9)

In total, 25.7 per cent (n = 9) of checklists included all time-out items. A detailed overview of the inclusion and omission of time-out items can be found in table 3. Items for which only specific aspects of the item were included are described below.

The item *'Confirm all team members have introduced themselves by name and role'* was included in 45.7 per cent (n = 16) of checklists. Two checklists changed this item to *'Is the surgical team complete?'*, which was not interpreted as a suitable modification by the expert panel.

The three items regarding anticipation to potential critical events addressed to the surgeon occurred in two different ways: as a single item according to the first version of the WHO surgical safety checklist or divided in three separate items as suggested in the 2009 revised version of the checklist. Both forms were evaluated to be in accordance with the WHO checklist in case all three items were mentioned (e.g., if the item only covered the critical steps from the surgeons perspective this was evaluated to only include the item *'What are the critical or non-routine steps ? [surgeon]'*). The question '*What are the critical or non-routine steps ? [surgeon]*' was included in 85.7 per cent (n = 30) of checklists. The question '*How long will the case take ? [surgeon]*' was included in 51.5 per cent (n = 18) of checklists

and the question *'What is the anticipated blood loss ? [surgeon]'* was included in 71.4 per cent (n = 25) of checklists.

Sign out : before patient leaves operating theatre

Table 4 Inclusion of WHO surgical safety checklist items

	Checklists fully including this item % (n)	Checklists partially including this item % (n)	Checklists not including this item % (n)
Sign out - Before patient leaves operating theatre - 37.1% of checklists included all items			
Nurse verbally confirms the name of the procedure	65.7 (12)	-	34,3 (23)
Nurse verbally confirms completion of instrument, sponge and needle counts	51.5 (18)	37.1 (13)	11.4 (4)
Nurse verbally confirms specimen labelling (read specimen labels aloud, including patient name)	62.9 (22)	17.1 (6)	20.0 (7)
Whether there are any equipment problems to be addressed	77.1 (27)	-	22.9 (8)
What are the key concerns for recovery and management of this patient?	94.3 (33)	-	5.7 (2)

In total, 37.1 per cent (n = 13) of checklists included all sign-out items. A detailed overview of the inclusion and omission of sign-out items can be found in table 4. Items for which only specific aspects of the item were included are described below.

The item '*Nurse verbally confirms completion of instrument, sponge and needle counts*' was included in 51.5 per cent (n = 18) of checklists, 14.3 per cent (n = 5) included only sponge counts, 5.7 per cent (n = 2) did not include instrument count, 17.1 per cent (n = 6) did not include needle count and in 11.4 per cent (n = 4) of checklists this item was not included at all.

The item '*Nurse verbally confirms specimen labelling (read specimen labels aloud, including patient name)*' was present in 62.9 per cent (n = 22) of checklists. Further, 17.1 per cent (n = 6) of checklists included this item, however, they did not explicitly mention to read the specimen labels aloud. This item was excluded in 20 per cent (n = 7) of checklists.

Discussion

This study evaluated the content of 35 surgical safety checklists. An expert panel conducted a content-driven evaluation of the retrieved checklists by verifying the presence of the WHO items and evaluating any modifications made. Our findings showed that only a minority (17.1%) of checklists included all 22 items proposed by the WHO. About half of the hospitals included all sign-in items. Noteworthy,

only 62.9 per cent of hospitals included the item '*Has the patient confirmed his/her identity, site, procedure, and consent ?*' in their checklist. The most frequently omitted aspect of this item was verification of the patients' consent. A potential explanation might be found in the quite complex law regarding this theme. Although Belgian law obliges free and informed consent from the patient in specific circumstances, it is not obliged to use a written consent. Further, the most frequently omitted sign-in items concerned checks related to airway evaluation and blood loss. Items related to safe anaesthesia practice (machine, medication and pulse oximeter checks) were in 8.6 per cent only partially included. One could argue that this partial uptake (i.e., including a selection of aspects of an item) does not significantly jeopardise checklist performance.

A quarter of hospitals included all time-out items. Not even half of the checklists included a formal team introduction. However, research has shown that sharing the names and roles of all individuals involved is one of the most effective methods for promoting an individual's sense of participation and responsibility. Moreover, it has been demonstrated to increase the probability that individuals will speak up if they anticipate or detect a potential problem. This is especially relevant given that team membership is often not consistent from one day to another.[21] Further, it seems that not all hospitals have adapted the latest version of the WHO checklist. Various checklists aggregated the three questions directed to the surgeon to anticipated critical events, which is consistent with the first version of the WHO checklist. If all three aspects were clearly present, it was assumed to be in accordance with the content and intentions of the WHO checklist. Some even combined the items for surgeons, anaesthesiologists and nurses into one question. This has to be discouraged, as it is important to provide a formal point in which every team member involved can to speak up if necessary. If not, cultural or hierarchical aspects can prevent this from happening.

A third of hospitals included all sign-out items in their checklist. This appears to be comparable with the literature measuring checklist compliance.[22,23] These studies also show low compliance with sign-out items. This could be a reason why hospitals omitted some of the sign-out items.

Besides omitting items, 60 per cent of hospitals were found to add items to the WHO checklist. Most frequently added items included: checks carried out by ward nurses preparing the patient and checks supporting patient transfer between ward and operating theatre staff. Concerning the perioperative phase, clinical items (e.g., hypothermia, anticoagulation therapy or deep vein thrombosis prevention) and logistic items (e.g., completeness of the patient record, presence of implants, positioning of the patient) formed the most frequently added topics.

The invasive nature, combined with its risk prone conditions, make surgery one of the most important causes of healthcare related harm.[3] As patient safety is a persistent problem within the surgical context it is important to implement

evidence-based safety systems. Most errors leading to harm originate from the 'softer' aspects of surgery such as communication and teamwork.[3] It is often more challenging to influence these aspects than to influence aspects shaping individual performance (e.g., knowledge and technical skills). Other complex, high risk industries have recognised this challenge and have successfully introduced safety checklist to prompt team engagement by focusing on essential steps during critical moments within the process. Analogous to this checklist philosophy, the WHO developed its surgical safety checklist. The introduction of the checklist has been associated with a decrease in postoperative complications and mortality, although the underlying mechanisms causing this reduction remain unclear.[11,12] The publication of the study by Urbach *et al.* revived the discussion whether or not the WHO surgical safety checklist is capable to reduce operative mortality or complications.[17] This question can only be answered if the checklist can effectively be implemented and use as intended be ensured.

The WHO allows modifications of the checklist to improve the checklist's fitness to the local workflow. Based on the current literature, there is only evidence that the use of the WHO checklist in its original form is associated with significant better patient outcomes.[24] Consequently, from a quality perspective it is to be recommended that perioperative safety checklists should at least include all 22 WHO items. The present study demonstrates that 82.9 per cent of hospitals decided to omit one or more WHO items. This decision is likely the result of several interplaying factors (e.g., local work flow), influenced by the opinion of key stakeholders. As these opinions cannot sufficiently be captured by a survey, this study did not investigate stakeholder's opinions about the WHO checklist. Other, more in-depth methods should be applied to gain better insight into the reasoning behind these decisions. Besides attitude towards the checklist, other factors like knowledge of perioperative risks could explain why stakeholders decide to omit certain checklist items. In addition, it could be that one or more of the omitted items are registered using other systems (e.g., the patient record). In this case, one could argue that the individual item is covered, but an important aspect of a safe environment is missing: shared responsibility. When the individual safety checks are spread across multiple systems or forms it becomes easy to lose overview, making it tempting to degrade the shared responsibility into individual responsibility. Even though modifications are allowed to fit with local work flow, it is important to combine the safety checks in one system, which is accessible and visible to all team members.

The WHO provides healthcare professionals with a simple safety checklist based on evidence, established with the cooperation of many healthcare professionals. It seems, however, that this checklist does not fulfil the expectations of many Flemish hospitals. Encouraged, or blinded, by the recommendation to modify the checklist towards local work flow, most hospitals omitted one or more items. This led to a variety of checklists, with little to no resemblance to the original WHO

checklist. It needs to be questioned if some of the obtained checklists are capable of reproducing the proven reduction of post-operative complications, as some effective aspects may have been lost. Interventions can be conceptualized as having 'core components' (i.e., the essential and indispensable elements of the intervention) and an 'adaptable periphery' (i.e., adaptable elements, structures, and systems related to the intervention and organization into which it is being implemented).[19] The intervention's adaptable periphery allows it to be modified to the setting without undermining the integrity of that intervention.[19] To ensure the effectiveness of the checklist, more detailed recommendations and guidance for the modification of the WHO surgical checklist are required. Therefore, more insight is needed regarding the effect of individual items in order to support hospitals in the modification of their surgical safety checklist.

Limitations

When interpreting our findings, a number of limitations should be taken into account. The sampling strategy may have led to including more motivated hospitals, and thus better results. However, this bias is limited by the fact that the regional legislation requests the use of the WHO surgical safety checklist. This study is conducted in a strict geographical region. As such, our results cannot be extrapolated. This study only evaluated the checklists content. Its form and the way of using the checklist was no subject of the study. These aspects may also be relevant as they could prevent proper use of the checklist. Last, this study only described the modifications made without mentioning the underlying rationale for omitting specific items. To the best of our knowledge, this is the first study performing a content-driven evaluation of surgical safety checklists.

Conclusion

This study shows that modifications made to the WHO surgical safety checklist vary between hospitals. In contrast to the respondents' believe of using the WHO checklist, only a small number of hospitals included all 22 WHO items. It can be questioned if the modified checklists will result in an equal decrease in the number of preventable surgery related adverse events as previously demonstrated. Further research and more detailed, clear guidance for the modification of the WHO surgical checklist are required.

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Part III

Barriers and facilitators to checklist implementation

“When you translate a dream into reality, it’s never a full implementation. It is easier to dream than to do”

— Shai Agassi —

Chapter 5

Barriers and facilitators related to the implementation of surgical safety checklists: a systematic review of the qualitative evidence

This chapter was published as:

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Surgical safety checklists are intended to ensure consistency in patient perioperative safety and to introduce or maintain a culture that values achieving it.[1] The use of these checklists is associated with increased patient safety awareness, improved communication, reduction of surgical claims and reduction in the number of postoperative complications including mortality.[2–10] It cannot, however, be assumed that the mere application of the checklist will automatically lead to improved safety.[11–13] Reported compliance with checklist items is assumed to be correlated with the impact of surgical safety checklists.[10,14] Consequently, the clinical effectiveness of the checklist will vary with the implementation success.[15,16]

The implementation of new guidelines and safety interventions has been shown to be difficult in various healthcare sectors, which highlights the importance of the implementation process.[17–19] Several studies have reported high levels of participation and checklist completion (ranging from 12% to 100%).[20] However, the implementation is more than merely 'checking the box'. A discrepancy between ticking off checklist items and the performance of the actions results in poor fidelity as regards the checklist's intentions.[21–29] The implementation of a surgical safety checklist is a complex social intervention. Factors influencing the dissemination and uptake of evidence-based interventions or technological innovation may, therefore, not apply. In order to increase the understanding of the user-related barriers to, and facilitators of, the implementation of surgical safety checklists, we conducted a systematic review of the qualitative literature.

Methods

Design

A synthesis of the qualitative evidence synthesis was formulated by means of thematic synthesis.[30] The strength of this methodology is its potential to enable conclusions to be drawn on the basis of common elements of otherwise heterogeneous studies. Conclusions drawn from thematic analysis fulfil an important research aim of qualitative research by generating hypotheses for which traditional systematic reviews are poorly suited.[30]

Search strategy

The search was performed in MEDLINE (from inception to March 2015) using the following query: ("Surgical Procedures, Operative"[Mesh] OR "surgical" OR "surgery" OR "operative)" AND ("checklist"[MeSH] OR "checklist" OR "time-out)" AND ("fidelity" OR "implementation" OR "adherence" OR "compliance" OR "barriers" OR "facilitators" OR "incentives"). Broad search terms were applied without date restrictions in order to make the search strategy as sensitive as

possible. Methodological filters for study design were not used because they reduce the sensitivity of searches.[31,32] The reference lists of all of the papers were scrutinised, and a cited reference search was made in the Web of Science for additional papers on the subject.

Inclusion criteria

Qualitative studies that explored the perspectives and experiences of stakeholders with the implementation of surgical safety checklists were included. These stakeholders were nurses, surgeons, anaesthesiologists, residents, implementation leaders, administrators and any others directly involved in, or affected by, the implementation. Following the guidance of the Cochrane Qualitative Research Methods Group, which considers critical appraisal to be a technical and pragmatic exercise, we restricted the type of qualitative studies included in this review.[33] Only empirical studies with a description of the sampling strategy, the data collection procedures and the type of data analysis were included. These empirical studies had to report the methodology chosen and the methods or research techniques opted for since this facilitates the systematic use of critical appraisal as well as a more pragmatic appraisal process. Therefore, descriptive papers, editorials and opinion papers that were not based on actual experiences related to the implementation of surgical safety checklists were excluded. No language or country restrictions were applied.

Quality assessment

The primary goal of our quality assessment was to highlight the quality of the published literature on the subject. The full texts of the included articles were reviewed by two independent authors (JB and PS) using the Qualitative Assessment and Review Instrument (QARI).[34] The 10 QARI criteria do not relate to validity or bias in the process-orientated methods as regards the reviews of effects, their purpose being to establish the nature and appropriateness, the methodological approach, the specific methods and the representation of the voices or meanings of the study participants.[35] However, given that there is no accepted method for excluding qualitative studies from the syntheses on the basis of their quality, we did not exclude studies based on the QARI scoring.[36,37]

Extracting data from studies

A data extraction form was developed cataloguing the author, year of publication, journal, method of data collection, phenomena of interest, study setting, country of study, data analysis and main conclusions. In syntheses of qualitative research, the 'informants' are the authors of the individual studies rather than the participants in these studies. Therefore, the authors' interpretations — presented, for example, by themes and categories — constitute our data. While the authors'

interpretations were collected primarily from the results sections, data found in the discussion sections were also extracted when relevant and well supported by data.

Thematic synthesis

Thomas and Harden described thematic synthesis as *"a tried and tested method that preserves an explicit and transparent link between the conclusions and text of the primary studies; as such it preserves principles that have traditionally been important to systematic reviewing"*.[30] Thematic analysis has three stages: (a) line-by-line coding of the findings of primary studies to extract the key concepts, (b) organisation of these key concepts into related areas to construct 'descriptive' themes that formed the backbone of the structure of the analysis and (c) development of 'analytical' themes based on the synthesis of the experiences and recommendations of authors of the original articles. While the development of descriptive themes remains close to the primary studies, the analytical themes represent a stage of interpretation in which the reviewers go beyond the primary studies and generate new interpretive constructs, explanations or hypotheses.

QSR International's NVivo 10 software was used to organise the codes into hierarchical structures.[38] The text of each included study (results and discussion section) was imported into the software verbatim. One of us (JB) developed a set of descriptive codes inductively by coding each line of the text of all of the included studies. We looked for similarities and differences between the codes in order to start grouping them into a hierarchical tree structure, and new codes were created to catalogue the meaning of groups of initial codes. This process resulted in a tree structure with several layers in order to organise the descriptive themes. The groupings were then further refined by discussion and rechecking of the original studies (JB, FL and PS). Successive drafts of a narrative that described the themes seen in the findings were then discussed by the wider study group (JB, FL, PS, AV and DV) and further refined. All of the stages of the process were checked by various experts (an organisational psychologist, safety culture experts and patient safety experts) to ensure accuracy and control of bias in the analysis.

Results

The search strategy yielded 535 papers. Screening for eligible and inconclusive abstracts reduced this list to 45 papers. After full-text review, 27 studies were excluded from the final analysis (see supplementary appendix 1 for further explanation).[21,22,27–29,39–60] We included 18 studies involving >700 healthcare professionals (see figure 1).[25,61–77] The studies involved 18 different countries. The data in these studies had been collected using interviews, focus groups,

observations and open-ended surveys. A detailed overview of the study characteristics is provided in supplementary appendix 2.

Quality assessment

Overall, the selected studies scored well on the QARI (see supplementary appendix 3 for an overview of QARI scoring). Nevertheless, only 4 of the 18 papers stated the cultural and/or theoretical location of the researcher, so it was difficult to appraise his/her potential influence on the study findings and vice versa. Adequate representation of the participants, and their opinions, was not provided in five studies, and the congruity between the stated philosophical perspective and the research methodology was often difficult to evaluate. No additional exclusions were made after the technical appraisal.

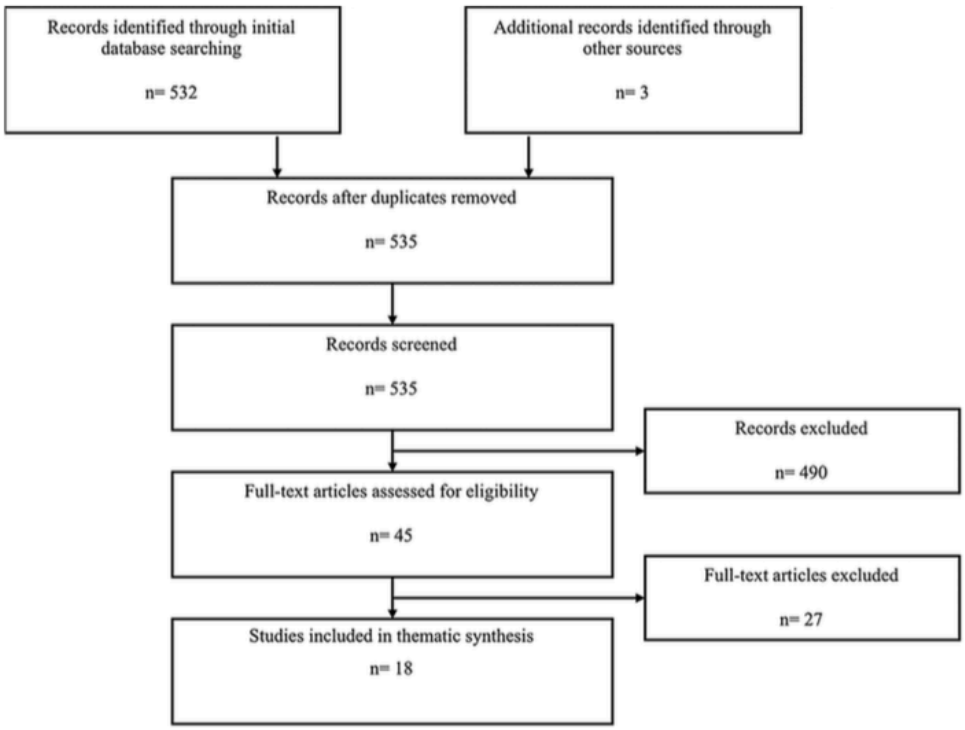

Figure 1 PRISMA diagram

Synthesis findings

The thematic analysis of the primary articles revealed five main themes with respective subthemes. Two of these main themes — staffs' perception of the checklist and patient safety, and workflow adjustments — represent user-related changes required to conduct the checklist as intended (dimension one). The other three main themes — checklist, implementation process and local context —

constitute factors affecting the user-related changes (dimension two). Figure 2 shows our data structure. It provides a graphical representation of how we progressed from subthemes (the result of grouping key concepts from the primary studies) to main themes describing the two dimensions.

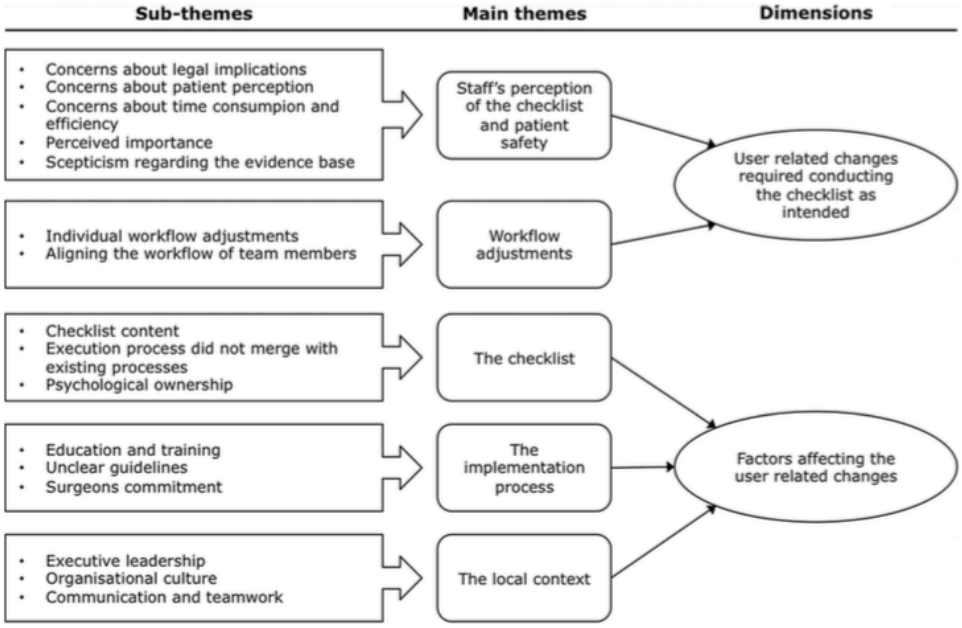

Figure 2 Data structure

User-related changes required to conduct the checklist as intended

In order to implement the checklist and assure it is used as intended, changes on the user level (i.e., physicians and nurses) are needed. In what follows, we describe the main themes and subthemes related to this first dimension. Illustrative quotations for each of the themes are provided in table 1.

Staffs' perception of the checklist and patient safety. The perception of the staff of the checklist and its items, and the perception of patient safety in general, determines the individual willingness to use the checklist. Healthcare providers expressed *concerns about legal implications*, which hampered their willingness to use the checklist. Participants, especially nurses, expressed *concerns about patient perception*, which led to the omission of items they perceived as causing stress in patients (e.g., expected blood loss) or performing the checks without verifying out loud. Most of the studies reported *concerns about time consumption and efficiency*. Participants felt, or presumed, that checklist execution consumed too much time and thereby hampered operating theatre efficiency. The *perceived importance* of the checklist items varied across professions and individuals, which led to varying usage and support among surgeons, anaesthesiologists and nurses.

Table 1 Themes describing user-related changes required conducting the checklist as intended with exemplary citations from the study findings

Main theme	Subtheme	Exemplary citations from the study findings
Staffs' perception of the checklist and patient safety	Concerns about legal implications	*Nurses were therefore concerned about the legal implications of signing the checklist as they might be held accountable for errors.*[68]
	Concerns about patient perception	*For example, some stated that patients often did not understand why they had to confirm their ID/procedure, etc., so many times during their surgical pathway, and others felt that specific questions around blood loss and difficult airway (part of the sign-in checks) would anxiety provoking for certain patients (this was a particular concern if the patient was undergoing a local anaesthetic procedure and therefore witnessed all of the checks).*[76]
	Concerns about time consumption and efficiency	*...respondents had significant concern about its perceived effect on OR efficiency.*[70]
	Perceived importance	*Confirming the team members by name and role was the most missed check. The explanation given for this was that a lack of staff turnover and degree of familiarity with each other made this check appear less important.*[73]
	Scepticism regarding the evidence base	*Scepticism regarding the evidence base: The evidence base behind the checklist is weak and/or not applicable to the current context.*[76]
Workflow adjustments	Individual workflow adjustments	*Two participants expressed concern about the interruption in workflow that was sometimes required to complete the checklist discussion.*[61]
	Aligning the workflow of team members	*These asynchronous workflows impacted on a healthcare professional's ability to halt their work and collaboratively meet to communicate at a time-out procedure: Time out was about to commence and the nurse initiating it asked the anaesthetist "Are you joining us?" The anaesthetist replies, "No, we have things to do". [Obs_circnurs_125]*[25]

The perceived importance is strongly related to understanding the intentions and aims of the checklist. In addition, risk perception plays an important role in the conviction that risks assumed by the checklist exist in the immediate work environment. Finally, *scepticism regarding the evidence base* was expressed. Surgeons and anaesthetists, in particular, believed that the existing evidence was inconclusive and did not support general implementation of surgical safety checklists.

Workflow adjustments. Implementation of the checklist requires modification of operating theatre staffs' workflow. Proper execution of the safety checks

introduced by the checklist involves changes in the workflow of the operating theatre staff, which was often experienced as an increased workload. Besides individual workflow adjustments, alignment between the workflows of surgeons, anaesthesiologists and nurses is needed in order to execute the brief stops (i.e., sign in, time out and sign out) required to complete the checklist. Aligning the workflow of team members is difficult to achieve. In addition, the checklist sometimes entails the repetition by nurses or physicians of one or more safety checks — as some are already included in existing procedures — the redundant registration thus creating an administrative burden. As a result, physicians and nurses might experience the checklist as an additional, often unnecessary, task.

Factors affecting the user-related changes

Several factors act as a barrier or facilitator to the user-related changes required to precede checklist usage. In what follows, we describe the main themes and subthemes related to this second dimension. Illustrative quotations for each of the themes are provided in table 2.

The checklist. A first theme emerged around *design problems* influencing staff perception and workflow. Many healthcare providers found the content somehow irrelevant to their setting or suggested rewording certain items to create a better fit with actual usage. Layout and form factor issues (e.g., inconvenient format or complex computer applications) were also expressed. Second, respondents found that the *execution process did not merge with existing processes*. This created redundant safety checks and administration or even conflicting workflows. Linked to beliefs and prejudices, as previously mentioned, professionals need to experience *psychological ownership*, meaning that they must have the feeling that the intervention is created, or at least tailored, to their needs. This sense of ownership seems crucial in convincing physicians to use the checklist. Even though the checklist is supported by evidence and is endorsed by leading organisations (e.g., professional associations), individuals may have a different opinion on its usefulness and importance. Some parts or items of the checklist are perceived as relevant only to specific professionals, which diluted the sense of shared responsibility.

The implementation process. The implementation process refers to the joint activity of implementing the checklist by actors who, in relation to checklist implementation, engage in particular ways of relating over time.[78] This process must create a clear transition period supporting the acquisition of the new workflow. A large part of the implementation effort entails *education and training*. Participants from the original studies found explaining why the checklist is necessary, providing clear communication on organisational intentions, and addressing the concerns expressed by staff to be of vital importance for creating support and willingness prior to the actual implementation. In addition, participants found it important to show them how they must use the checklist.

Table 2 Themes describing the factors affecting the user-related changes with exemplary citations from the study findings

Main theme	Subtheme	Exemplary citations from the study findings
The checklist	Checklist content	*The binary (yes/no) response system was ambiguous and confusing.*[68]
	Execution process did not merge with existing processes	*... duplication with existing processes that already covered several of the items in the surgical checklist.*[68]
	Psychological ownership	*... they [surgeons] did not necessarily agree with it, albeit this protocol was endorsed by the College of Surgeons.*[62]
		staff should have been involved in adapting and implementing the SSC as a means of fostering ownership.[74]
The implementation process	Education and training	*Many participants said that they did not receive information or training on how to use the SSC....* [74]
	Unclear guidelines	*Many participants said that staff were uncertain about how to use the SSC and who was responsible for leading it.*[74]
	Surgeons commitment	*Physician's support and motivation were crucial for implementing the checklist.*[63]
The local context	Executive leadership	*... lack of clarity and agreement with protocol specifics, and inadequate executive leadership primarily resulted in reduced ownership and acceptance of the protocol by physicians.*[68]
		Hospital leadership was not seen as involved in either promoting or actively implementing the SSC.[74]
	Organisational culture	*The same proportion of staff held the perception that the culture within their hospital was that of a general resistance to the introduction of change, whatever form it takes, particularly from more senior members of staff.*[76]
	Communication and teamwork	*We often talk about being one team, but it is in itself three teams. The surgeons don't see themselves as part of the team; they see the others forming the team, but they invite in so to speak.*[62]

Healthcare providers found that *unclear guidelines* hampered checklist execution. Therefore, the introduction needs to be supported with clear guidelines and training on how, when and who will execute the checklist. During the implementation process, the commitment of all of the professionals is required to sustain checklist usage. Nurses found *surgeons' commitment* to be imperative. Given the hierarchical context within the operating theatre, senior surgeons' leadership is of undeniable importance.

The local context. The local context refers to the local historical-relational context of checklist implementation that is always partly created in the joint

activity that the actors engage in.[78] Participants expressed that, in addition to general leadership, *executive leadership* is needed to communicate the importance of the checklist and patient safety in general. Executive leadership needs to be exercised in order to create a context in which physicians and nurses feel supported. Across studies, respondents saw the organisational culture as a major barrier but also as a potential facilitating element. Both the hospital-wide and the immediate *organisational culture* play a mediating role. Although checklist usage is expected to change the safety culture, there is a very complex relationship between the checklist, the procedures, the context, the culture and the behavioural changes.[72] With the deepening of the culture, respondents found that *communication and teamwork* issues hamper checklist execution. These issues often stem from a hierarchical team culture that obstructs the open culture and communication required to execute the checklist correctly. The social interaction between team members has a great impact on nurses' decision to participate in checklist usage. They seem to adjust their team involvement according to the practical, social and professional conditions in their work environment.

Analytical themes

Up to this point, we have produced a synthesis that kept very close to the original findings of the studies. 'Going beyond' the content of the original studies has been identified by some as the defining characteristic of synthesis.[30] With the development of analytical themes, we 'went beyond' the findings of the primary studies and generated additional concepts, understandings or hypotheses.

Disrupted routines and conflicting priorities. The introduction of a checklist in the operating theatre involves physicians and nurses changing existing routines.[25] Workflows on the individual, professional or team level have to be altered and aligned in order to create a brief moment of reflection to review the safety checks collectively.[25,61–63,74,76,77] The workflow introduced by the checklist often collides with existing routines.[61,63] This creates conflicts as existing workflows are established in function of different priorities (e.g., efficiency or productivity).[61,62,66,68,77] Hence, the priority of patient safety, introduced by the checklist, has to compete with the already existing clinical and organisational priorities. Conflicts between priorities compel physicians and nurses to weigh using the checklist against other priorities. When a conflict in priorities emerges, the perceptions of operating theatre staff regarding patient safety drive their ultimate decision about whether or not to use the checklist.[66]

Different perspectives and motives. The motivation for implementing a surgical safety checklist differs between healthcare providers and hospital management.[62,70,75,77] The use of a surgical safety checklist is often part of hospital-accreditation requirements or other quality-improving programmes. Management feels, with the perspective of obtaining accreditation, that it is

necessary to apply the checklist very strictly. Healthcare providers, however, feel that some of the checklist items have little or no relevance in their specific setting. Without clear communication about the motives of hospital management, perspectives drift apart and resistance towards the checklist develops. The perspective and motivation of the physicians may also differ from those of the nurses. Because of organisational requirements, nurses feel it necessary to use the checklist while physicians may not always concur with these requirements.[66]

The checklist is implemented as a simple technical intervention. The implementation of checklists is more than requiring that box be checked off: it is a complex social intervention with an expectation of interaction and cooperation between surgeons, anaesthetists and nurses.[63,66,75] However, this important aspect is often poorly addressed during implementation. Implementation teams should, therefore, promote and support inter-professional communication when introducing the checklist. If not, the checklist will be used as a tick-off exercise.[79]

Discussion

This systematic review comprehensively investigates user barriers and facilitators to the implementation of surgical safety checklists. Although the themes have been presented separately, implementation problems are multifactorial, highly interdependent and affected by considerable clinical complexity. Many themes were common to papers regardless of interstudy differences in geographical or clinical setting.

It was found that the implementation of a surgical safety checklist requires change in perception of the operating theatre staff regarding the checklist and its items, and the perception of patient safety in general. In addition, physicians and nurses need to adjust their workflows. These changes are impeded or advanced by characteristics of the checklist, the implementation process and the local context.

Based on the experience of high-reliability organisations, characteristics of the checklist (e.g., length, layout and design, and content) are important.[44] The content of the checklist needs to be supported by scientific evidence and written in clear, understandable words preferably embedded within existing processes. The checklist must precisely mirror the intended operation without creating ambiguity or confusion. The checklist and its items must be relevant to the applied setting. Exporting a checklist to situations in which it was not meant to be used may impede further checklist implementation.[63] Obstacles stemming from the checklist apply not only to the content but also to psychological ownership. Physicians and nurses need to feel as though the checklist has become a part or an extension of their selves. In other words, they have to feel that it is ‘mine’ or

'ours'.[80] Even better is collective psychological ownership, with the entire operating theatre staff feeling that the checklist is part of them and their work.[81]

The implementation process itself can act as a barrier and so create aversion. As with any new procedure or guideline implementation, the checklist creates uncertainty and questions. Lack of consensus guidelines will lead to personal interpretations and enhance confusion. Therefore, the introduction needs to be supported by clear guidelines on how, when and who will execute the checklist. These guidelines need to be formalised in a written procedure, and the execution of the checklist also needs to be demonstrated. Small-scale tests can familiarise physicians and nurses with the checklist and experiment with workflow adjustments. Reactions to these tests can be used to alter or clarify checklist guidelines and procedures. Surgeons, who play the central role during the procedure, are often seen as leaders in the operating theatre. Research on the broader context of patient

safety has shown that senior staff may not always be the best source of patient safety knowledge and skills.[82] This suggests that surgeons not only need to be supported but also to be educated. A promising approach to deal with the difficulties associated with changing routines can be found in team learning.[83] Successful implementers used enrolment to motivate the team, designed preparatory practice sessions and early trials to create psychological safety (i.e., a shared belief that the team is safe for interpersonal risk taking) and encourage new behaviours, and thus promote shared meaning and process improvement through reflective practices.[83,84]

The local context in which the checklist has to be implemented is important. The organisational culture — that is, a social-organisational phenomena, in terms of behaviour or attitudes, that emerges from a common way of sense making, based on shared values, beliefs, assumptions and norms — influences the behaviour and perception of physicians and nurses.[85] People often view themselves as members of a community of practice with established norms and processes that can change only when the entire group changes. For example, a new workflow practice or technology standard may be difficult to adopt unless the entire group agrees at the same time to use the system. To improve the safety culture in the operating theatre, interventions should aim at minimising the hierarchy and empowering nursing staff in addition to standardising and structuring the practicalities concerning the use of the checklist. Such initiatives need to be performed by the operating theatre management.[66] Second, leadership (i.e., the process of social influence in which one person can enlist the aid and support of others in the accomplishment of a common task[86]) from senior staff and the chief surgeon has been frequently presented as a key to successful implementation.[25,62–64,66,68,69,72] In addition, participants found executive leadership equally important. It is important to show that patient safety is regarded as a priority in the

hospital.[62,64,66,69,72] Finally, communication and teamwork have a profound influence on checklist usage. The existence of a professional hierarchy in medicine and the differential status accorded to those in different disciplines hampers teamwork and communication. Profession-derived status is associated with psychological safety, so it is important to have a sense of confidence that the team will not embarrass, reject or punish someone for speaking up when noticing a real or potential safety problem. Psychological safety is a key antecedent of speaking up and learning behaviour in healthcare teams.[87] It is suggested that leader inclusiveness moderates the relationship between status and psychological safety.[87]

We found that the workflow introduced by the checklist often collides with existing routines.[61,63] This creates conflicts as existing workflows are established to achieve different priorities (e.g., efficiency or productivity). The effect of disrupted routines has previously been recognised during the implementation of new technology in hospitals.[83] Conflicts between priorities compel physicians and nurses to balance using the checklist against other priorities. When a conflict in priorities emerges, the perceptions of the operating theatre staff regarding patient safety drives their ultimate decision whether or not to use the checklist. We found that stakeholders' perspectives and motives towards the checklist often differ. These different views create tension and aversion. In order for a checklist to be considered a priority, staff's perceptions and attitudes regarding it and patient safety in general must be supportive. Therefore, the safety checklist will be of little value if disruptive attitudes and behaviours are not addressed.[88] This is in line with the establishment of a climate of safety (i.e., shared perceptions among the staff concerning the policies, procedures, practices and kinds of behaviours that will be rewarded and supported with regard to safety).[89,90] This requires that a good safety climate must be established prior to, and during, implementation. New routines require adjustment and training. An important feature of checklists is the combination of checks ensuring adherence to proven practices (e.g., administration of antibiotics and use of pulse oximeters) and other non-technical items (e.g., team introductions and confirmation of procedures). The principal purpose of these non-technical items is to promote specific aspects of teamwork, communication and situational awareness.[72] However, education and training during checklist implementation often neglects these non-technical items. The importance of team learning and training in order to modify teamwork and communication has been implemented with positive effects.[91]

The checklist is in essence a complex social intervention aimed to improve communication and teamwork in a strictly hierarchical context. Even when initial perceptions and attitudes regarding the checklist are positive,[92] it does not guarantee long-term improvement.[93] The existing hierarchies and the tribal affiliations of professional groups must be altered in order to create psychological safety. Each member has to be allowed to take interpersonal risk by speaking up

if any concern about safety arises without being afraid of being embarrassed, rejected or punished.[87,94] Implementation is much more complex than addressing the barriers and enabling the facilitators found in this review. Implementation is an ever-changing process for change in one aspect can generate a reaction in one or several other aspects and thereby create a wholly new environment. Hence, it is not enough to have a list of barriers and facilitating factors: we also need to deal with the interaction between them.

Strengths and limitations of this study

The results of this thematic synthesis should be interpreted within certain limitations. First, only one electronic database (MEDLINE) was consulted. To mitigate the potential loss of relevant articles, a cited and citing reference study in Web of Science was conducted. Second, assessing the quality of the included studies remains controversial in qualitative reviews. The QARI was selected because it is referred to as the most coherent instrument for evaluating the validity of qualitative research.[34] Last, this review specifies a list of themes that are believed to influence checklist implementation but does not specify the interactions between them.

The current research also has some notable strengths. First, to the best of our knowledge, this is the first overview of qualitative research on the barriers and facilitating factors regarding the implementation of checklists. The results of this study present the barriers and facilitators that play during the implementation of many patient safety initiatives in healthcare and, therefore, present a valuable learning opportunity. Second, the use of thematic synthesis enabled the synthesis of the results of otherwise heterogeneous studies.

Conclusions

Implementation of a checklist requires structural changes in workflow of the operating theatre staff workflow, as well as in their perceptions regarding the checklist and patient safety in general. The required changes are impeded or advanced by three main factors: the checklist, the implementation process and the local context. However, the complex reality in which the checklist is implemented requires an approach that includes more than getting rid of the barriers and supporting facilitating factors. Implementation leaders must facilitate team learning to foster mutual understanding of the perspectives and motivation and the adaptation of existing routines. This paper provides a pragmatic overview of the constructs upon which theories, hypothesising potential change strategies and interactions, can be developed and tested empirically.

Appendix 1 Article selection

	Reference	Included	Reason exclusion
1	Lingard L, Espin S, Rubin B, Whyte S, Colmenares M, Baker GR, et al. Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. Qual Saf Health Care. 2005;14(5):340–6.	•	
2	Verdaasdonk EGG, Stassen LPS, Widhiasmara PP, Dankelman J. Requirements for the design and implementation of checklists for surgical processes. Surgical endoscopy. 2009;23(4):715–26.	☐	Review on design elements, no qualitative content
3	Paull DE, Mazzia LM, Izu BS, Neily J, Mills PD, Bagian JP. Predictors of successful implementation of preoperative briefings and postoperative debriefings after medical team training. Am J Surg. 2009;198(5):675–8.	☐	Quantitative analyses attendance and participation of team members
4	Gillespie BM, Chaboyer W, Wallis M, Fenwick C. Why isn't 'time out' being implemented? An exploratory study. Qual Saf Health Care. 2010;19(2):103–6.	•	
5	Sivathasan N, Rakowski KRM, Robertson BFM, Vijayarajan L. The World Health Organization's 'Surgical Safety Checklist': should evidence-based initiatives be enforced in hospital policy? JRSM Short. 2010 ed. 2010;1(5):40–0.	☐	No qualitative analysis
6	Robinson LD, Paull DE, Mazzia LM, Falzetta L, Hay J, Neily J, et al. The role of the operating room nurse manager in the successful implementation of preoperative briefings and postoperative debriefings in the VHA Medical Team Training Program. J Perianesth Nurs. 2010 Oct;25(5):302–6.	☐	No qualitative analysis
7	Thomassen O, Brattebø G, Heltne J-K, Søfteland E, Espeland A. Checklists in the operating room: Help or hurdle? A qualitative study on health workers' experiences. BMC Health Serv Res. 2010 Dec 31;10:342–2.	•	
8	Weiser TG, Lipsitz SR, Dziekan G, Lapitan MCM, Reznick RK, Vats A, et al. Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention. BMJ Qual Saf. 2010 Dec 31;20(1):102–7.	☐	No qualitative analysis
9	Thomassen O, Espeland A, Søfteland E, Lossius HM, Heltne J-K, Brattebø G. Implementation of checklists in health care; learning from high-reliability organisations. Scand J Trauma Resusc Emerg Med. 2011;19(1):53–3.	☐	High-reliability organisations
10	Conley DM, Singer SJ, Edmondson L, Gawande AA. Effective surgical safety checklist implementation. J Am Coll Surg. 2011;212(5):873–9.	•	
11	Lingard L, Regehr G, Cartmill C, Orser B, Espin S, Bohnen J, et al. Evaluation of a preoperative team briefing: a new communication routine results in improved clinical practice. BMJ Qual Saf. 2011;20(6):475–82.	☐	Quantitative data on antibiotics
12	Cunat C, Flatin V, Viale J-P. [Implementation strategy of the HAS French surgical check-list in a university hospital]. Ann Fr Anesth Reanim. 2011 Jun;30(6):484–8.	•	
13	Ali M, Osborne A, Bethune R, Pullyblank A. Preoperative surgical briefings do not delay operating room start times and are popular with surgical team members. Journal of patient safety. 2011;7(3):139–43.	☐	No qualitative analysis
14	Calland JF, Turrentine FE, Guerlain S, Bovbjerg V, Poole GR, Lebeau K, et al. The surgical safety checklist: lessons learned during implementation. Am Surg. 2011;77(9):1131–7.	☐	No qualitative analysis
15	Vogts N, Hannam JA, Mitchell SJ. Compliance and quality in administration of a Surgical Safety Checklist in a tertiary New Zealand hospital. N Z Med J. 2011 Sep 9;124(1342):48–58.	☐	No qualitative analysis
16	Styer KA, Ashley SW, Schmidt I, Zive EM, Eappen S. Implementing the World Health Organization surgical safety checklist: a model for future perioperative initiatives. AORN journal. 2011;94(6):590–8.	☐	No qualitative analysis
17	Wæhle HV, Søfteland E, Hjälmhult E. Adjusting team involvement: a grounded theory study of challenges in utilizing a surgical safety checklist as experienced by nurses in the operating room. BMC Nurs. 2012;11(1):16.	•	
18	Delgado Hurtado JJ, Jiménez X, Peñalonzo MA, Villatoro C, de Izquierdo S, Cifuentes M. Acceptance of the WHO Surgical Safety Checklist among surgical personnel in hospitals in Guatemala city. BMC Health Serv Res. 2012;12(1):169.	☐	No qualitative analysis
19	Healy JM. How hospital leaders implemented a safe surgery protocol in Australian hospitals. Int J Qual Health Care. 2012 Feb;24(1):88–94.	•	
20	Bragg K, Schlenk EA, Wolf G, Hoolahan S, Ren D, Henker R. Time out! Surveying surgical barriers. Nurs Manage. 2012 Mar;43(3):38–44.	☐	No qualitative analysis

21	Fourcade A, Blache J-L, Grenier C, Bourgain J-L, Minvielle E. Barriers to staff adoption of a surgical safety checklist. BMJ Qual Saf. 2012 Mar;21(3):191–7.	•	
22	Helmio P, Takala A, Aaltonen L-M, Pauniaho SL, Ikonen TS, Blomgren KK. First year with WHO Surgical Safety Checklist in 7148 otorhinolaryngological operations: use and user attitudes. Clin Otolaryngol. 2012 Jul 31;37(4):305–8.	☐	Extensive letter, No qualitative analysis
23	Levy SM, Senter CE, Hawkins RB, Zhao JY, Doody K, Kao LS, et al. Implementing a surgical checklist: more than checking a box. Surgery. 2012 Sep;152(3):331–6.	☐	No qualitative analysis
24	Sheena Y, Fishman JM, Nortcliff C, Mawby T, Jefferis AF, Bleach NR. Achieving flying colours in surgical safety: audit of World Health Organization "Surgical Safety Checklist" compliance. J Laryngol Otol. 2012 Oct;126(10):1049–55	☐	No qualitative analysis
25	O'Connor P, Reddin C, O'Sullivan M, O'Duffy F, Keogh I. Surgical checklists: the human factor. Patient Saf Surg. 2013;7(1):14.	•	
26	Papaconstantinou HT, Jo C, Reznik SI, Smythe WR, Wehbe-Janek H. Implementation of a surgical safety checklist: impact on surgical team perspectives. Ochsner J. 2012 Dec 31;13(3):299–309.	•	
27	Haugen AS, Murugesh S, Haaverstad R, Eide GE, Søfteland E. A survey of surgical team members' perceptions of near misses and attitudes towards Time Out protocols. BMC Surg. 2013 Dec 31;13:46–6.	☐	No qualitative analysis
28	Kaderli R, Seelandt JC, Umer M, Tschan F, Businger AP. Reasons for the persistence of adverse events in the era of safer surgery--a qualitative approach. Swiss Med Wkly. 2013;143:w13882.	•	Qualitative analysis perception of clinical directors
29	Rydenfält C, Johansson G, Odenrick P, Akerman K, Larsson PA. Compliance with the WHO Surgical Safety Checklist: deviations and possible improvements. Int J Qual Health Care. 2013 Apr;25(2):182–7.	☐	No qualitative analysis on stakeholder perspective, observational studie
30	Braaf S, Manias E, Riley R. The "time-out" procedure: an institutional ethnography of how it is conducted in actual clinical practice. BMJ Qual Saf. 2013 Jul 31;22(8):647–55.	•	
31	Hannam JA, Glass L, Kwon J, Windsor J, Stapelberg F, Callaghan K, et al. A prospective, observational study of the effects of implementation strategy on compliance with a surgical safety checklist. BMJ Qual Saf. 2013 Oct 31;22(11):940–7.	☐	No qualitative analysis
32	Pickering SP, Robertson ER, Griffin D, Hadi M, Morgan LJ, Catchpole KC, et al. Compliance and use of the World Health Organization checklist in U.K. operating theatres. Brit J Surg. 2013 Oct 31;100(12):1664–70.	☐	Compliance, No qualitative analysis
33	Aveling EL, McCulloch P, Dixon-Woods M. A qualitative study comparing experiences of the surgical safety checklist in hospitals in high-income and low-income countries. BMJ Open. 2013 Dec 31;3(8):e003039–9.	•	
34	Cullati S, Licker M-J, Francis P, Degiorgi A, Bezzola P, Courvoisier DS, et al. Implementation of the surgical safety checklist in Switzerland and perceptions of its benefits: cross-sectional survey. Warburton D, editor. PLoS ONE. 2013 Dec 31;9(7):e101915–5.	☐	No qualitative analysis
35	van Schoten SM, Kop V, de Blok C, Spreeuwenberg P, Groenewegen PP, Wagner C. Compliance with a time-out procedure intended to prevent wrong surgery in hospitals: results of a national patient safety programme in the Netherlands. BMJ Open [Internet]. 2014;4(7):e005075–5. Available from: http://bmjopen.bmj.com/content/4/7/e005075.full	☐	Compliance, No qualitative analysis
36	Bashford T, Reshamwalla S, McAuley J, Allen NH, McNatt Z, Gebremedhen YD. Implementation of the WHO Surgical Safety Checklist in an Ethiopian Referral Hospital. Patient Saf Surg [Internet]. 2014;8:16.	•	
37	Gagliardi AR, Straus SE, Shojania KG. Multiple interacting factors influence adherence, and outcomes associated with surgical safety checklists: a qualitative study. Courvoisier DS, editor. PLoS ONE [Internet]. 2014;9(9):e108585. Available from: http://dx.plos.org/10.1371/journal.pone.0108585	•	
38	Saturno PJ, Soria-Aledo V, Da Silva Gama ZA, Lorca-Parra F, Grau-Polan M. Understanding WHO surgical checklist implementation: tricks and pitfalls. An observational study. World J Surg [Internet]. 2014 Feb;38(2):287–95. Available from: http://link.springer.com/10.1007/s00268-013-2300-6	☐	No qualitative analysis
39	Norton EK, Singer SJ, Sparks W, Ozonoff A, Baxter J, Rangel S. Operating Room Clinicians' Attitudes and Perceptions of a Pediatric Surgical Safety Checklist at 1 Institution. Journal of patient safety. 2014 Jul.		No qualitative analysis
40	Putnam LR, Levy SM, Sajid M, Dubuisson DA, Rogers NB, Kao LS, et al. Multifaceted interventions improve adherence to the surgical checklist. Surgery. 2014 Jul 31;156(2):336–44.	☐	Compliance, No qualitative analysis

41	Patel J, Ahmed K, Guru KA, Khan F, Marsh H, Khan MS, et al. An overview of the use and implementation of checklists in surgical specialities - a systematic review. International Journal of Surgery. 2014 Nov 30;12(12):1317–23.	□	Review, No qualitative analysis
42	Rönnberg L, Nilsson U. Swedish Nurse Anesthetists' Experiences of the WHO Surgical Safety Checklist. Journal of PeriAnesthesia Nursing. Elsevier Inc; 2014 Dec 5;:1–8.	•	
43	Sendlhofer G, Mosbacher N, Karina L, Kober B, Jantscher L, Berghold A, et al. Implementation of a surgical safety checklist: interventions to optimize the process and hints to increase compliance. PLoS ONE. 2014 Dec 31;10(2):e0116926–6.	□	No qualitative analysis
44	Russ SJ, Sevdalis N, Moorthy K, Mayer EK, Rout S, Caris J, et al. A qualitative evaluation of the barriers and facilitators toward implementation of the WHO surgical safety checklist across hospitals in England: lessons from the "Surgical Checklist Implementation Project". Ann Surg. 2015 Jan;261(1):81–91.	•	
45	Haugen AS, Høyland S, Thomassen O, Aase K. "It"s a State of Mind': a qualitative study after two years' experience with the World Health Organization's surgical safety checklist. Cogn Tech Work. 2015 Sep 30;17(1):55–62.	•	

Appendix 2 Characteristics of included studies

Author	Year	Journal	Methodology	Data collection	Phenomena of interest	Setting	Specialism	Geographical	Participants	Data analysis
Lingard et al.	2005	Quality & safety in healthcare	Grounded theory	Interviews	describe how the checklist was used by participants from different professions		Vascular surgery	Canada	3 staff surgeons 1 surgical fellow 3 nurses 1 anesthesia resident 3 staff anesthesiologists	modified grounded theory approach that combined emergent theme analysis with attention to preselected issues identified in our previous work on teamwork and communication. Using a constant comparative analysis process
Thomassen et al.	2010	BMC Health Services Research	Content analysis	Focus group interviews	nurses' and physicians' acceptance and experiences with the a surgical safety checklist	seven operating theatres	neurosurgery, plastic surgery, burn surgery, and otolaryngological surgery	Norway	9 nurses (2-23 years experience; 2 men) 4 residents (1-4 years experience; 2 men) 1 experienced female consultant	Thematic analysis: systematic tekst condensation
Conley et al.	2011	J Am Coll Surg	Content analysis	Interviews	factors that distinguished highly effective checklist implementation processes	5 State hospitals		USA, Washinton	5 Implementation leaders 5 Surgeons no member of implementation team	Thematic analysis: question by question to identify factors distinguishing hospitals.
Wæhle et al.	2012	BMC Nursing	Grounded theory	1) observation 2) a single interview with an OR nurse 3) focus group interviews of operating room nurses and nurse anesthetists.	explore the nurse anesthetists and operating room nurses' challenges and strategies used when utilizing the WHO's checklist	tertiary hospital		Norway	7 OR nurse 7 nurse anesthesists	constant comparative method line-by-line open coding
Healy	2012	Int J Qual Health Care	Ethnographic study	in-depth interviews using a semi-structured questionnaire	explore the range of mechan-isms used by leaders to embed the safety protocol in their hospital	20 hospitals in Australian state capitals		Australia	72 heath sector leaders	analysed according to keywords and themes using qualitative analysis methods
Fourcade et al.	2012	BMJ Qual Saf	Content analysis	1) collective interviews 2) individual interviews 3) email questionnaire sent to surgical staff 4) Direct observations on all the barriers that had cropped up during the interviews and in the completed questionnaires	identify and compare barriers to effective use in these centres; and to develop a strategy for effective use	18 National Federation of Cancer Centres	Cancer surgery	France	1) collectively interviewed: 4 surgeons, 3 anaesthetists, 2 nurses, 6 senior nurses and 1 quality manager 2) individual interviews: 2 surgeons, 3 anaesthetists and 3 senior nurses 3) email questionnaire: 18 centers 4) Direct observations: two centers (20h)	Thematic analysis: Axial coding to relate responses and create a typology of the barriers hindering effective checklist use of each barrier Vertical coding was used to better define the content of
O'Connor et al.	2013	Patient Safety in Surgery	Content analysis	Questionair with 5 items adressing barriers to the use of the checklist (likert style) Open ended question about barriers	beliefs about levels of compliance and support, impact on patient safety and teamwork, and barriers to the use of the checklist.	One hospital		Ireland	41 surgeon's 33 anaesthesits 33 nurses	Thematic analysis: analysed according to keywords and themes using qualitative analysis methods
Gillespie et al.	2010	Quality & safety in healthcare	Grounded theory	Individual and group, semistructured interviews using a collation of issues based around 'time out' and communication explored wider organisational and end-user perspectives of 'time out'.	Implementation and practice issues associated with the introduction and ongoing use of a 'time out' protocol	One large metropolitan hospital	various surgical subspecialities	Australia, Southern Queensland	Eight interviews were conducted with a total of 16 participants. 4 individual interviews (physicians) 4 group interviews were conducted (3 nurse managers and 9 registerd nurses)	inductive and deductive approaches underpinned by grounded theory methods

Aveling et al.	2013	BMJ Open	Ethnographic study	(1) semi- structured interviews with anaesthetists, surgeons, theatre staff, management and administrative staff and covered experiences of checklist implementation, institutional context and management of patient safety. Interviews were conducted with informed consent from participants and were recorded, translated (where required) and tran- scribed; (2) non-standardised observations and informal discussions with staff in operating rooms were recorded as field-notes in notebooks and later elaborated more fully and (3) collation of relevant documentation.	identify and compare influences on checklist implementation and compliance in operating theatres in hospitals in high-income and low-income countries	Three hospitals: two in the UK in a low- income sub-Saharan African country.		UK & sub-saharan African country	39 staff: 19 in Mbile 4 anesthesthesists 6 surgeons 4 managers 5 nurses 20 across the two UK hospitals 4 anaesthetists 3 surgeons 4 managers 9 nurses	Data were analysed thematically and guided but not constrained by sensitising concepts derived from the research questions. A single coding framework was iteratively developed, refined and applied to all three data sets. Data were initially coded into basic themes within three global categories—implementation barriers, facilitators and contextual characteristics. In each category, basic codes were grouped into organising themes, and patterns in different sites were identified, compared and contrasted, paying attention to interrelations between themes. In addition, we analysed data from each site to identify patterns of use, completeness and fidelity of checklist compliance.
Braaf et al.	2013	BMJ Qual Saf	Ethnographic study	participant observation two focus groups 20 semi-strutured interviews	explorer how the time-out procedure is implemented in clinical practice	Three public, university hospitals		Australia, Melbourne	107 informants were observed Focus groupes and interviews: 30 participants	Institutional ethnography
Kaderli et al.	2013	Swiss Medical Weekly	Content analysis	Electronic questionnaire consisted of multiple-choice and free-response items	potential reasons for the persistence of adverse events despite efforts to improve patient safety in Switzerland by analysing the advantages and disadvantages of introducing and implementing surgic- al safety checklists using free-reply arguments from direct- ors of clinics in operative medicine.			Switzerland	237 directors of clinics in operative medicine	Content analysis following Mayring
Gagliardi	2014	PLOS one	Grounded theory and thematic analysis	Interviews via telephone	The overall objective of this study was to understand and compare the processes and factors influencing SSC adherence in multiple hospitals of different types that had been exposed to the SSC for various lengths of time.	61 hospitals (small and large community, and teaching hospitals)		Canada	29 nurse 13 surgeons 9 anaesthetists	Inductive iterative approach underpinned by grounded theory methods Interpretation according to a conceptual framework of implementation fidelity
Bashford et al.	2014	Patient safety in surgery	not specificly mentioned	Questionnaire with free-response items Semistructured interviews	demonstrate how the Checklist may be implemented in Ethiopia, building on those strategies developed from experience in both high and low-resource settings, and provide further lessons for other low-resource centres.	Low-resource center	Plastic & reconstructive surgery	Ethiopia	3 nurses 2 surgeons 2 anaesthetists	not specificly mentioned
Papaconstantinou et al.	2013	The Ochner Journal	Content analysis	Questionnaire with free-response items	provider perspectives of team communication, patient safety, patient care, and operative efficiency before and after implementation of a WHO-adapted surgical safety checklist in an effort to enhance surgical safety at our institution.	One tertiary care hospital		USA, Texas	86 respondents	Thematic analysis: iterative thematic qualitative approach
Cunat et al.	2011	Annales Françaises d'Anesthésie et de Réanimation	Content analysis	Interviews	Experiance regarding implementation of a surgical safety checklist	5 hospitals		France	Doctors and nurses	not specificly mentioned

Rönnberg et al.	2015	Journal of PeriAnesthesia Nursing	Content analysis	Questionnaire with free-response items	Nurse anesthetists experience with the WHO surgical safety checklist		Sweden	47 nurse anesthetists	Content analysis following Graneheim and Lundman
Russ et al.	2015	Annals of Surgery	Content analysis	Interviews via telephone	1) How was the WHO checklist initially implemented within English hospitals? 2) What were the key barriers and facilitators to its implementation? 3) What lessons can we extract for informing how to optimize the diffusion and uptake of improvement initiatives in surgery and wider health care systems?	10 Hospitals	UK	23 nurses 37 surgeons 31 anesthesiologists 18 OR practitioners 10 radiographers	Thematic analysis
Haugen et al.	2015	Cognition, Technology & Work	Content analysis	Focus group interviews	explore surgical personnel experiences with the World Health Organization's Surgical Safety Checklist, 2 years after implementation.	tertiary hospital	Norway	4 Surgeons 3 Nurses 4 anaesthetists 3 nurse anaesthetists	Content analysis following Graneheim and Lundman

Appendix 3 The Qualitative Assessment and Review Instrument

	There is congruity between the stated philosophical perspective and the research methodology.	There is congruity between the research methodology and the research question or objectives.	There is congruity between the research methodology and the methods used to collect data.	There is congruity between the research methodology and the representation and analysis of data.	There is congruity between the research methodology and the interpretation of results.	There is a statement locating the researcher culturally or theoretically	The influence of the researcher on the research, and visa versa, is addressed.	Participants, and their voices, are adequately represented.	The research is ethical according to current criteria or, for recent studies, there is evidence of ethical approval by an appropriate body.	Conclusions drawn in the research report do appear to flow from the analysis, or interpretation, of the data.
Lingard et al.	●	●	●	●	●	●	●	●	●	●
Thomassen et al.	●	●	●	●	●	○	○	●	●	●
Conley et al.	●	●	●	●	●	○	○	●	●	●
Wæhle et al.	●	●	●	●	●	●	●	●	●	●
Healy	●	●	●	●	●	○	○	●	●	●
Fourcade et al.	●	●	●	●	●	○	○	○	●	●
O'Connor et al.	●	●	●	●	●	○	○	○	●	●
Gillespie et al.	●	●	●	●	●	○	○	●	●	●
Aveling et al	●	●	●	●	●	●	●	●	●	●
Braaf et al.	●	●	●	●	●	●	●	●	●	●
Kaderli et al.	?	●	●	●	●	○	○	●	●	●
Gagliardi et al.	?	●	●	●	●	○	○	●	●	●
Bashford et al.	?	●	●	○	●	○	○	○	●	●
Papaconstantinou et al.	?	●	●	○	●	○	○	○	●	●
Cunat et al.	?	●	●	●	●	○	○	○	●	●
Rönnberg et al.	●	●	●	●	●	○	○	●	●	●
Russ et al.	●	●	●	●	●	○	○	●	●	●
Haugen et al.	●	●	●	●	●	○	○	●	●	●

Legend: ● yes; ○ no; ? unclear

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1. Bergs J, Hellings J, Simons PAM, et al. Surgical safety checklists: an update. Acta Chir Belg 2014;114:219–24.
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3. Weiser TG, Haynes AB, Dziekan G, et al. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. Ann Surg 2010;251:976–80.
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Chapter 6

What nurses and physicians really think about checklists: a mixed methods study of clinicians' perceptions and attitudes towards surgical safety checklists in the operating theatre

This chapter is submitted for review:

Bergs J, Lambrechts F, Desmedt M, Vlayen A, Marneffe W, Hellings J, Vandijck D. What nurses and physicians really think about checklists: a mixed methods study of clinicians' perceptions and attitudes towards surgical safety checklists in the operating theatre.

Worldwide approximately 234 million operations are performed annually, making surgery an important aspect of healthcare.[1] Although there is extended expertise, knowledge, and skills amongst clinicians complications and errors still occur.[2] Most factors leading to surgical adverse events are often unrelated to surgical techniques, but rather to non-operative management. These reasons include, inter alia: inadequate teamwork, poor relationships with patients, poor understanding of human factors, and inadequate knowledge of the complexity of healthcare.[2-4] Other high-risk industries — such as aviation and the nuclear industry — have a long tradition in analysing the complex mechanisms underlying the occurrence of undesirable events and the design of solutions to improve safety. The use of safety checklists is one of the suggested methods to improve safety in complex environments. Safety checklists appear to be effective tools for improving patient safety in various clinical settings.[5] Their use is linked to strengthening compliance with guidelines, improving human factors, reducing the incidence of adverse events, and decreasing mortality and morbidity.[5] The use of checklists in healthcare gained momentum following the introduction of the WHO surgical safety checklist (SSC). The purpose of this checklist is to help operating theatre (OT) teams remember important details (e.g., antibiotic prophylaxis) that may be missed during an operation. In addition, it serves as a tool to encourage teamwork and communication.[6] The use of surgical safety checklists is associated with increased patient safety awareness, improved communication, reduction of surgical claims, and reduction in the number of postoperative complications including mortality.[7-11] A growing body of literature points out that, while the physical act of ''checking the box'' may not necessarily prevent all adverse events, the checklist is a scaffold on which attitudes towards teamwork and communication can be encouraged and improved. Recent evidence reinforces the fact that compliance with the checklist is crucial to realize its effects on patient safety.[12]

The implementation of new guidelines and safety interventions has shown to be difficult in various healthcare sectors, which highlights the importance of the implementation process.[12-15] Several studies have reported high levels of participation and checklist completion.[7,16] However, implementation requires more than installing individual verification of certain key issues followed by the physical act of ''checking the box''.[17] The checklist is essentially a tool to facilitate communication and teamwork. As a result, its implementation can be seen as a complex social intervention. Factors influencing the dissemination and uptake of evidence-based interventions or technological innovations may, therefore, not apply. The use of checklists makes eminent sense from a safety point of view. However, research has shown that the perceptions of physicians and nurses show otherwise.[18] Individual and collective willingness to use the checklist depends, at least partially, on clinicians perceptions of the checklist and by extension to their perception of patient safety in general.[12]

The overall objective of this study was to understand and compare clinicians' perceptions and attitudes towards patient safety and the surgical safety checklist in multiple hospitals of different types, which have been exposed to the WHO surgical safety checklist for various lengths of time. In particular, we surveyed nurses, surgeons, and anaesthetists from four hospitals in Belgium. This may reveal approaches for optimizing checklist implementation, which could be tested in future research and, if widely adopted, lead to more consistent checklist use, and improved outcomes among surgical patients.

Methods

This survey study makes part of a larger study evaluating the implementation of the WHO surgical safety checklist in Flanders (Belgium's Dutch speaking part). We surveyed surgical team members' perception of patient safety and surgical safety checklists using a cross-sectional design. This survey was performed among a voluntary sample of clinicians (including surgeons, operating theatre nurses, anaesthetists, and nurse anaesthetists) actively working in the designated study operating theatres at four hospitals. The study was primarily quantitative, with complementary qualitative strands. The questionnaire included existing validated metrics from multiple instruments (detailed below) and open-ended questions.

Sampling and recruitment

A random sample of four acute hospitals — taken from a lager sample of 33 hospitals who participated in a national survey on the use of the surgical safety checklist in Belgium[18] — was used to identify practicing clinicians with different characteristics including: clinical profession, geographical region (provinces), and type of hospital (teaching, large community, and small community). With the aid of a local contact person all clinicians working in the operating theatre (i.e., nurses, surgeons, and anaesthetists) of each hospital included were invited to participate by regular mail or email with an invitation letter and consent form. A general reminder was sent at four and eight weeks from initial contact.

Questionnaire

We designed the survey to obtain insight in surgical team members' perceptions and attitudes towards patient safety and surgical safety checklists. The survey consisted of three parts: (1) the Safety Attitudes Questionnaire**,** (2) factors affecting the correct use of surgical safety checklists, and (3) perception and attitudes towards the WHO surgical safety checklist. The survey also included questions about participant characteristics such as profession, experience, and gender.

The Safety Attitudes Questionnaire

The Safety Attitudes Questionnaire (SAQ) is a validated instrument used to measure attitudes and perceptions in various healthcare settings.[19] The SAQ was derived from the Flight Management Attitude Questionnaire (FMAQ), a human factors survey used to measure cockpit culture in commercial aviation. The SAQ focuses on safety climate and asks healthcare teams to describe their attitudes to six domains, using a five-point Likert scale to score. Table 2 provides the types of questions included. This survey instrument was chosen because of its well-established validity and previous use in research to better understand issues of safety and teamwork in the surgical environment.[19] The SAQ has been adapted for use in intensive care units, operating theatres, general inpatient settings (such as medical and surgical wards), emergency medical services, ambulatory clinics/primary care and nursing homes, and long term care facilities. The SAQ distinguishes itself from other surveys in that it maintains continuity with the FMAQ, which has been used for over 20 years. This allows comparisons between industries as well as identification of common human factors issues. It can also be used to compare the attitudes of different types of staff within healthcare and is fully validated for this purpose. Another strength of this tool is that it is relatively short and quick to complete, and can be used to monitor changes over time with repeated implementation.

The full version of the questionnaire included 60 items, of which only 30 were scaled. The generic SAQ Short Form version, used for hospital-wide administration, uses the 30 scaled items. Non-scaled items are used in addition so that additional information can be collected during the same survey administration. The SAQ short form comprises 41 items which load on six factors: *Teamwork Climate, Safety Climate, Job Satisfaction, Perceptions of Management* (unit and hospital level), *Stress Recognition*, and *Working Conditions*, and it has been demonstrated to have good psychometric properties. All responses were recorded on a five-point Likert scale (1=disagree strongly, 2=disagree slightly, 3=neutral, 4=agree slightly, 5=agree strongly, and not applicable as scores). In those instances, where no answer was provided for a specific item, the item was scored as neutral although non-response rates were measured. Negatively worded items were reversed scored so that their valence matched the positively worded items to calculate summary statistics.

The translation of the generic SAQ Short Form version into Dutch was performed in several steps. First, the questionnaire was translated in Dutch by an independent translator (researcher with Dutch as native language and proficient in English). The translated version was than discussed within the research group. Following consensus of the wording, face validity was established by testing the resulting preliminary Dutch version of the SAQ questionnaire on a sample of clinicians (n = 10) with varying education and age.

Factors affecting the correct use of surgical safety checklists

Perceptions of factors affecting the correct use of surgical safety checklists were surveyed using two open-ended questions: '*What do you think are the main impediments to the correct use of the safe surgery checklist? (in order of importance)*' and '*What do you think are the main facilitating factors to the correct use of the safe surgery checklist? (in order of importance)*'. In addition to these open-ended questions, we assessed if factors found in other settings applied to the current study settings. We used the framework of Russ *et al*., because it is the most comprehensive framework to date.[20] The framework contains 11 themes which describe the barriers to checklist implementation and 9 themes describing potential facilitators. (see table 4 and 5) Respondents were asked to what extent each of the 20 proposed themes applied to their work environment, using a five-point Likert scale (1=disagree strongly, 2=disagree slightly, 3=neutral, 4=agree slightly, 5=agree strongly, and not applicable as scores).

Perceptions and attitudes towards the surgical safety checklist

Clinicians' perceptions and attitude towards implementation support, usage, and importance of surgical safety checklists was surveyed using 24 items. (see table 6-9) The items were selected following a comprehensive literature review on the topic. A team of patient safety and change management experts selected the most relevant items in addition to the previously mentioned items and the Safety Attitudes Questionnaire. Respondents were asked to what extent they agreed with each of the items, using a five-point Likert scale (1=disagree strongly, 2=disagree slightly, 3=neutral, 4=agree slightly, 5=agree strongly, and not applicable as scores).

Solutions to the implementation problem

The survey also contained an open-ended question that allowed respondents to offer their proposed solutions for solving the implementation problem on the one hand and on how to improve the correct use of the checklist on the other hand.

Data collection

The survey was distributed to all eligible clinicians through the hospitals' email system. We used a web-based questionnaire with an information letter and a direct link to the questionnaire itself. To increase the interest of potential respondents prior to distribution, we also promoted the survey on the hospital intranet page and on wall posters in the operating theatre. The hospital managers provided access for survey recruitment at staff meetings.

Data analysis

Respondent characteristics were summarised using proportions for discrete variables, average scores for ordered categorical variables, and means with

standard deviations and ranges for continuous variables. Analysis of differences in SAQ factor scoring between professions and study sites was performed with the analysis of variance (ANOVA). Analysis of differences in perceptions and attitudes regarding the checklist and factors influencing implementation between study sites and professions, was performed with the Pearson's chi-squared test or analysis of variance (ANOVA) as appropriate. Alpha was set at 0.05, and all *P*-values were two-sided. R version 3.2.2 was used for all analyses.

Qualitative analysis was used to evaluate the suggested solutions and to assess barriers and facilitators reported in the open-ended question. The analytic approach involved reading an initial group of responses, identifying possible themes through observation of patterns and repetitions, and then comparing and contrasting these themes within and across respondents to generate codes. Codes were then applied to a new group of responses, modified when needed, and newly created codes were applied to the previous set of coded responses. Saturation of themes was determined when no new themes emerged.

Ethics

The study was approved by the Human Subjects Committee of Hasselt University (Ref. B117201421085), as well as by the equivalent body at each of the study sites. No incentives were provided for return of the survey and all demographic questions were explicitly optional to assist in protecting anonymity.

Results

Participants

The respondents' characteristics vary considerably from site to site. A detailed overview is provided in table 1. Globally, respondents had a mean age of 41.79 (*SD* = 10.76) years, with on average 12.24 years of working experience in their current position (*SD* = 10.05) and 17.15 years in their respective profession (*SD* = 10.76). The majority of respondents were female (n = 87, 64.4%). Further, the major part of the sample consisted of nurses (n = 98, 72.6%). Participating physicians were mainly surgeons (n = 23, 17.0%). Anaesthesiologists constituted the minority in this study (n = 14, 10.4%).

Table 1 Characteristics of respondents (N = 134)

	Hospital 1 N=34	Hospital 2 N=36	Hospital 3 N=48	Hospital 4 N=17	Total N=135
Age, mean(SD)	43.71(9.81)	44.75(11.47)	38.21(10.41)	41.82(9.98)	41.79(10.76)
Gender, n(%)					
Male	12(35.3)	8(22.2)	18(37.5)	10(58.8)	48(35.6)
Female	22(64.7)	28(77.8)	30(62.5)	7(41.2)	87(64.4)
Profession, n(%)					
Nurse	17(50.0)	29(80.6)	44(91.7)	8(47.1)	98(72.6)
Anaesthesiologist	7(20.6)	2(5.6)	1(2.1)	4(23.5)	14(10.4)
surgeon	10(29.4)	5(13.9)	3(6.3)	5(29.4)	23(17.0)
Working experience, years mean(SD)	17.41(10.99)	20.92(10.71)	15.06(10.50)	15.41(9.22)	17.15(10.76)
Experience in current position, years mean(SD)	12.50(9.42)	14.25(10.86)	11.73(10.52)	9.82(7.72)	12.24(10.05)

Safety Attitude Questionnaire

A detailed overview of individual SAQ item scores is provided in table 2. The six aggregated factor scores were used for further description and analysis. Table 3 provides a detailed overview of the SAQ factor scores for each hospital.

There was a significant difference in *Teamwork Climate* scores amongst professions ($F(2,132) = 6.23$, $P = .003$) with highest scores given by surgeons ($M = 72.46$, SD = 6.37), compared to anaesthesiologists ($M = 68.76$, SD = 11.76) and nurses ($M = 65.46$, SD = 12.63). There was also a significant difference in the *Perception of Management* between professions ($F(2,132) = 10.07$, $P = .000$). Anaesthesiologists perceived management most positive ($M = 68.01$, SD = 18.15), followed by surgeons ($M = 62.85$, SD = 12.76) and nurses ($M = 53.11$, SD = 13.52). Finally, a parallel difference was found for *Working Conditions* scores ($F(2,132) = 8.13$, $P = .000$). Anaesthesiologists gave the highest score ($M = 67.86$, SD = 11.25), followed by surgeons ($M = 64.85$, SD = 16.08) and nurses ($M = 55.36$, SD = 13.60). There was no statistically significant difference for *Safety Climate*, *Job Satisfaction*, or *Stress Recognition* scores between professional roles.

There was a significant difference in *Job Satisfaction* ($F(3,131) = 3.90$, $P = .010$), P*erceptions of Management* ($F(3,131) = 10.27$, $P = .000$), and *Working Conditions* ($F(3,131) = 8.05$, $P = .000$) scores between study sites. There was no significant difference between study sites for *Teamwork Climate* ($F(3,131) = 2.59$, $P = .055$), *Safety Climate* ($F(3,131) = 1.95$, $P = .125$), and *Stress Recognition* ($F(3,131) = 0.88$, $P = .455$) scores.

Table 2 Safety Attitude Questionnaire (N = 135)

	n	Mean(SD)	%positive	Skewness	Kurtosis
Teamwork Climate					
My input is well received in this clinical area.	135	3.54(0.79)	65.2	-1.20	1.20
In this clinical area, it is difficult to speak up if I perceive a problem with patient care.[a]	135	3.48(0.77)	59.2	-0.90	0.13
Disagreements in this clinical area are resolved appropriately (i.e., not who is right, but what is best for the patient).	135	3.39(0.82)	51.9	-0.74	0.28
I have the support I need from other personnel to care for patients.	135	3.84(0.55)	81.5	-1.17	2.83
It is easy for personnel here to ask questions when there is something that they do not understand.	135	3.79(0.71)	80.0	-1.22	1.63
The physicians and nurses here work together as a well-coordinated team.	135	3.67(0.73)	65.2	-0.45	0.11
Safety Climate					
I would feel safe being treated here as a patient.	135	4.02(0.49)	90.4	-0.32	2.79
Medical errors are handled appropriately in this clinical area.	135	3.61(0.74)	66.7	-1.18	1.72
I know the proper channels to direct questions regarding patient safety in this clinical area.	135	3.72(0.78)	74.8	-1.09	1.25
I receive appropriate feedback about my performance.	135	3.15(0.97)	43.0	-0.40	-0.58
In this clinical area, it is difficult to discuss errors.[a]	135	3.49(0.83)	61.4	-0.75	-0.13
I am encouraged by my colleagues to report any patient safety concerns I may have.	135	3.36(0.83)	51.8	-0.77	0.11
The culture in this clinical area makes it easy to learn from the errors of others.	135	3.38(0.77)	51.9	-0.67	-0.30
Job Satisfaction					
I like my job.	135	4.25(0.65)	91.2	-0.64	0.81
Working here is like being part of a large family.	135	3.23(0.93)	43.0	-0.36	-0.30
This is a good place to work.	135	3.86(0.68)	78.6	-0.96	2.52
I am proud to work in this clinical area.	135	4.00(0.61)	83.0	-0.19	0.41
Morale in this clinical area is high.	135	3.39(0.81)	51.1	-0.84	0.77
Stress reduction					
When my workload becomes excessive, my performance is impaired.	135	3.33(0.94)	52.6	-0.47	-0.61
I am less effective at work when fatigued.	135	3.51(0.86)	64.5	-0.78	-0.25
I am more likely to make errors in tense or hostile situations.	135	2.90(0.99)	34.9	0.10	-1.09
Fatigue impairs my performance during emergency situations (e.g. emergency resuscitation, seizure).	135	2.74(0.94)	25.2	0.21	-0.82

Perceptions of Management					
Hospital management supports my daily efforts.	135	3.00(0.94)	35.6	-0.27	-0.79
Hospital management doesn't knowingly compromise patient safety.	135	3.51(0.87)	54.1	-0.38	0.02
Hospital management is doing a good job.	135	3.21(0.81)	38.5	-0.65	0.41
Problem personnel are dealt with constructively by our hospital management.	135	2.93(0.91)	25.9	-0.27	-0.17
I get adequate, timely info about events that might affect my work, from hospital management.	135	3.15(0.82)	38.5	-0.44	-0.54
Unit management supports my daily efforts.	135	3.40(0.77)	49.6	-0.62	0.39
Unit management doesn't knowingly compromise patient safety.	135	3.71(0.70)	65.9	-0.33	0.11
Unit management is doing a good job.	135	3.50(0.89)	57.8	-0.90	0.99
Problem personnel are dealt with constructively by our unit management.	135	3.15(0.88)	37.0	-0.36	-0.17
I get adequate, timely info about events that might affect my work, from unit management.	135	3.31(0.81)	46.7	-0.63	0.07
The levels of staffing in this clinical area are sufficient to handle the number of patients.	135	2.92(1.08)	34.1	-0.05	-0.84
Working Conditions					
This hospital does a good job of training new personnel.	135	2.96(1.05)	39.3	-0.40	-0.93
All the necessary information for diagnostic and therapeutic decisions is routinely available to me.	135	3.53(0.71)	57.0	-0.44	-0.13
Trainees in my discipline are adequately supervised.	135	3.50(0.81)	58.5	-1.23	2.58
Additional items					
My suggestions about safety would be acted upon if I expressed them to management.	135	3.31(0.77)	52.9	-0.69	-0.08
I experience good collaboration with nurses in this clinical area.	135	3.96(0.58)	84.4	-0.47	1.59
I experience good collaboration with anaesthesiologists in this clinical area.	135	3.96(0.62)	83.7	-0.56	1.49
I experience good collaboration with surgeons in this clinical area.	135	3.78(0.63)	73.3	-0.87	2.55
Communication breakdowns that lead to delays in delivery of care are common.[a]	135	2.90(0.95)	44.5	0.32	-1.13

[a]inverted scoring

Table 3 Safety Attitude Questionnaire factor scores for study sites (N=135)

	Hospital 1 (N=34)	Hospital 2 (N=35)	Hospital 3 (N=48)	Hospital 4 (N=17)	Total (N=135)
Teamwork Climate, mean(SD)	69.12 (11.15)	66.11 (9.51)	61.89 (13.77)	66.91 (12.18)	65.56 (12.18)
Safety Climate, mean(SD)	66.49 (11.26)	63.29 (12.45)	60.27 (13.89)	65.75 (8.93)	63.33 (12.47)
Job Satisfaction, mean(SD)	75.29 (10.65)	66.11 (13.37)	65.83 (15.68)	68.82 (11.39)	68.66 (13.86)
Stress Recognition, mean(SD)	52.57 (18.79)	56.94 (15.72)	51.43 (18.38)	50.00 (18.62)	53.01 (17.82)
Perceptions of Management, mean(SD)	66.77 (12.66)	53.09 (11.00)	50.76 (15.32)	57.88 (14.42)	56.31 (14.84)
Working Conditions, mean(SD)	65.44 (13.16)	57.87 (13.05)	51.56 (14.75)	63.72 (11.38)	58.27 (14.56)

Barriers and facilitators to checklist implementation of surgical safety checklists

An overview of the perceived relevance of the barriers and facilitating factors described in the literature is provided in Tables 4 and 5.

Comparison by profession showed a significant difference in scoring for the theme *Resistance and Noncompliance* — stating that certain individuals within the team make it very difficult to complete the checklist without confrontation or that certain individuals are not engaged in the checks ($F(2, 132) = 3.51$, $P = .033$). Nurses ($M = 3.82$, SD = 1.02) and anaesthesiologists ($M = 3.64$, SD = 1.22) were more likely to agree with this statement compared to surgeons ($M = 3.17$, SD = 1.01). Scores for other themes did not significantly differ between professions.

Comparison by study sites on the other hand, showed a significant difference in scoring for several themes. Perception of relevance to four themes describing possible barriers to checklist implementation differed significantly between sites — one systems factor: *Time Wasting* ($F(3, 131) = 4.76$, $P = .003$); and three tool-specific factors: *Unintended Negative Effects* ($F(3, 131) = 3.88$, $P = .011$), *Patient Perceptions* ($F(3, 131) = 2.74$, $P = .046$), and *Scepticism Regarding the Evidence Base* ($F(3, 131) = 2.88$, $P = .038$). Furthermore, perception of relevance for two facilitating factors were found to significantly differ between study sites — one system factor: *Integration with Existing Processes* ($F(3, 131) = 4.50$, $P = .005$) and one tool-specific factor *Modification/Adaptation* ($F(3, 131) = 3.25$, $P = .024$).

In general, relevance of *Time Wasting* was perceived relatively low ($M = 2.53$, SD = 1.03). A more detailed analysis showed that only a minority of respondents (n = 26, 19.3%) slightly or strongly agreed with the statement that the checklist causes unnecessary delay to the operation list. Most of the agreeing respondents (n = 19) worked in hospital 3 or 4, resulting in higher mean scores for hospital 3

Table 4 Perception of barriers to checklist implementation (N=135)

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly
ORGANISATIONAL FACTORS					
Implementation approach: The manner in which the checklist was introduced prevented buy-in and created adversity.	5(3.7)	51(37.8)	50(37.0)	23(17.0)	6(4.4)
Lack of culture for change: The culture within the hospital is that of a general resistance to change and new practice.	11(8.1)	42(31.1)	37(27.4)	30(22.2)	15(11.1)
SYSTEMS FACTORS					
Time wasting: The checklist causes unnecessary delay to the operating list.	17(12.6)	62(45.9)	30(22.2)	20(14.9)	6(4.4)
Repetition: The checklist duplicates existing safety procedures, failing to add anything to the system.	11(8.1)	69(51.1)	31(23.0)	20(14.8)	4(3.0)
TEAM FACTORS					
Resistance and noncompliance: Certain individuals within the team make it very difficult to complete the checklist without confrontation, or certain individuals are not engaged in the checks.	6(4.4)	17(12.6)	17(12.6)	68(50.4)	27(20.0)
TOOL-SPECIFIC FACTORS					
Design problems—content: The content of the checklist is inappropriate, irrelevant and/or illogical.	13(9.6)	68(50.4)	27(20.0)	21(15.6)	6(4.4)
Design problems—structure: The structure of the checklist is inappropriate, irrelevant and/or illogical.	7(5.2)	74(54.8)	35(25.9)	16(11.9)	3(2.2)
Not applicable to all surgeries: The checklist is not suitable for use in certain specialties and/or certain types of procedure (i.e., emergencies, day-case).	2(1.5)	23(17.0)	15(11.1)	64(47.4)	31(23.0)
Unsuitable timing of checks: Sections of the checklist and/or individual items are ill-timed.	4(3.0)	57(42.2)	25(18.5)	35(25.9)	14(10.4)
Unintended negative effects: The checklist can have unintended negative effects on surgical safety if used as a tick-box exercise or if it creates friction within the team	5(3.7)	46(34.1)	35(25.9)	40(29.6)	9(6.7)
Patient perceptions: Too many checks in general make patients concerned that the system isn't safe, and some of the specific checks are anxiety provoking.	8(5.9)	50(37.0)	18(13.3)	44(32.6)	15(11.1)
Scepticism regarding the evidence base: The evidence base behind the checklist is weak and/or not applicable to the current context.	11(8.1)	58(43.0)	45(33.3)	20(14.8)	1(0.7)

Table 5 Perception of facilitators to checklist implementation (N=135)

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly
ORGANISATIONAL FACTORS					
Education/training: Staff buy-in and ownership of the checklist is improved by education and training around its evidence base, its local relevance and best practice.	1(0.7)	10(7.4)	35(25.9)	75(55.6)	14(10.4)
Feedback on local data: Regular feedback of local data and anecdotal evidence supporting a beneficial impact of the checklist reinforces that it is not just a tick-box exercise.	1(0.7)	4(3.0)	30(22.2)	84(62.2)	16(11.9)
Accountability for non-compliance: Ramifications for active noncompliance with the checklist are desired and thought to improve effectiveness of the tool.	5(3.7)	46(34.1)	37(27.4)	43(31.9)	4(3.0)
Support from hospital management: Visible, flexible and active support from hospital management during implementation and beyond reinforces the importance of using the checklist.	2(1.5)	7(5.2)	41(30.4)	65(48.1)	20(14.8)
SYSTEMS FACTORS					
Integration with existing processes: The checklist should be incorporated into existing paperwork/processes to streamline and remove repetition.	1(0.7)	12(8.9)	27(20.0)	74(54.8)	21(15.6)
TEAM FACTORS					
Senior clinical buy-in: When senior surgeons and anaesthesiologists drive use of the checklist it is used more effectively.	1(0.7)	10(7.4)	9(6.7)	68(50.4)	47(34.8)
Leadership skills: Strong individual leadership skills and passionate leaders engender participation from the rest of the team.	1(0.7)	8(5.9)	18(13.3)	82(60.7)	26(19.3)
Involving the entire OR team: Involvement of all team members in the implementation and modification of the checklist improves uptake.	0(0.0)	3(2.2)	13(9.6)	79(58.5)	40(29.6)
TOOL-SPECIFIC FACTORS					
Modification/adaptation: Ownership and effective use of the checklist improved by customization of the layout and/or content to the specific surgical context.	2(1.5)	8(5.9)	44(32.6)	57(42.2)	24(17.8)

(M = 2.85, SD = 0.99) and hospital 4 (M = 2.88, SD = 1.41) compared to hospital 1 (M = 2.21, SD = 0.84) and 2 (M = 2.22, SD = 0.91). The statement that the checklist can have *Unintended Negative Effects* on surgical safety if used as a tick-box exercise or if it creates friction within the team was agreed upon, slightly or

strongly, by more than 1/3 of respondents (n = 49, 36.3%). In percentage terms, there is one hospital (hospital 4) where more then half of the respondents (58.5%) supported this statement. This resulted in significant differences between study sites, mean scores varied between 2.65 (SD = 1.10) and 3.65 (SD = 1.06). Concerns regarding *Patient Perceptions* was perceived as a barrier by almost half of the respondents (n = 59, 43.7%), who slightly or strongly agreed with the statement '*Too many checks in general make patients concerned that the system isn't safe, and some of the specific checks are anxiety provoking'*. Mean scores for the hospitals varied between 2.76 (SD = 1.25) and 3.44 (SD = 1.16). Perceived relevance of the theme *Scepticism Regarding the Evidence Base* was low (*M* = 2.57, SD = 0.87). Only a minority of the respondents (n = 21, 15.7%) slightly or strongly agreed to the statement '*The evidence base behind the checklist is weak and/or not applicable to the current context*'. Almost half of the agreeing respondents (n = 10) worked in hospital 2, resulting in a higher mean score (*M* = 2.92, SD = 0.84) compared to other hospitals (hospital 1 *M* = 2.53, SD = 0.82; hospital 3 *M* = 2.40, SD = 0.74; hospital *M* = 4 2.41, SD = 1.18). Relevance of the theme *Integration with Existing Processes* was perceived as high (*M* = 3.76, SD = 0.85); the statement '*The checklist should be incorporated into existing paperwork/processes to streamline and remove repetition*' was, slightly or strongly, agreed upon by 70.4% (n = 95) of respondents. In two hospitals (1 and 2) some respondents disagreed with this statement (23.5%, n = 8; 13.9%, n = 5). Mean scores per hospital varied slightly but was statistically significant (hospital 1 *M* = 3.44, SD = 0.96; hospital 2 *M* = 3.58, SD = 0.91; hospital 3 *M* = 3.98, SD = 0.63; hospital 4 *M* = 4.12, SD = 0.78). Last, perception of relevance for the theme *Modification/adaptation* was strongly present amongst respondents (*M* = 3.69, SD = 0.88); 60% (n = 81), agreed with the statement '*Ownership and effective use of the checklist improved by customization of the layout and/or content to the specific surgical context*'. There was considerable variation in mean scores between hospitals (hospital 1 *M* = 3.44; SD = 0.89; hospital 2 *M* = 3.56, SD = 0.73; hospital 3 *M* = 3.79, SD = 0.92; hospital 4 *M* = 4.14, SD = 0.88).

The open-ended question in the survey, including respondents' reflections on the barriers and facilitating factors to checklist usage, was answered by 121 respondents (89.6%). The major themes identified regarding potential barriers were *Time Pressure* (78.5%, n=95), *Workflow Problems* (45.5%, n = 55), and *Team Member Attitude/Perception* (39.7%, n = 48). *Team Member Attitude/Perception* was further divided into subcategories, with the most common themes in decreasing frequency related to *Surgeons Cooperation, Anaesthesiologist Cooperation*, and *Personal Perceptions' Regarding the Checklist*. Further, 19% (n = 23) of respondents recommended changes to the checklists content (e.g., removing certain items).

Suggested facilitating factors often (n = 107, 88.4%) contained examples and statements of *Perceived Benefits* associated with checklist usage (e.g.,

statements that the checklist improved safety and examples of how the checklist avoided specific adverse events). Other themes were a *Positive Attitude* of the team members (n = 32, 26.6%) with the subcategory *Surgeons Taking the Lead* (n = 9, 7.4%). Furthermore, good *Teamwork* emerged as a facilitating factor (n = 27, 22.3%), getting *More Time* to carry out the checklist (n = 13, 10.7%) and *Modifications to the checklists content* (n = 12, 9.9%).

Perception of patient safety

A detailed overview of respondents' perception of patient safety is provided in table 6. In general, most respondents would feel safe when undergoing surgery in their hospital. There was no significant difference in the perception of patient safety between the participating hospitals, nor between nurses, surgeons, and anaesthetists.

Table 6 Perception of patient safety (N=135); n(%)

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly
I would feel safe if I should undergo surgery at this hospital.	0(0.0)	0(0.0)	15(11.1)	91(67.4)	29(21.5)
I have made mistakes that potentially could harm patients.	21(15.6)	62(45.9)	31(23.0)	21(15.6)	0(0.0)
I have seen others make mistakes that potentially could harm patients.	6(4.4)	43(31.9)	45(33.3)	37(27.4)	4(3.0)

Perception of checklist usage

A detailed overview of respondents' perception of checklist usage is provided in table 7. In general, half (51.1%) of respondents, slightly or strongly, agreed that briefings are a habit in their operating theatre. A quarter (25.9%) responded neutral and the remaining (22.9%) disagreed. More respondents agreed that the checklist is used during each surgical procedure in which they are involved, compared to all surgical procedures in the hospital (57% vs 42.2%). Answers to the statement '*The high work pressure in the operating theatre means that I can not perform the checklist*' were equally distributed, with 38.5 per cent of respondents disagreeing versus 41 per cent agreeing. Further, 68.8 per cent of respondents agreed with the statement that sometimes parts of the checklist are not checked. Last, 77 per cent of respondents disagreed with the statement '*When the checklist is run, everyone will stop his activities in the operating theatre and listens until it is completed*'.

When comparing hospitals, scores for two statements significantly differed. There was a difference in scoring for the question '*When the checklist is run, everyone will stop his activities in the operating theatre and listens until it is completed*' ($F(3, 131) = 4.71$, $P = .004$), with respective scores varying across hospitals: hospital 1 $M = 2.53$, SD = 1.05; hospital 2 $M = 1.86$, SD = 0.68; hospital 3 $M = 1.83$, SD = 0.91; hospital 4 $M = 2.00$, SD = 0.94. Second, there was a marked

difference in scoring for the question '*The high work pressure in the operating theatre means that I can not perform the checklist'*, wherein especially hospital 1 scored lower compared to other hospitals (hospital 1 *M* = 2.53, SD = 1.11; hospital 2 *M* = 3.14, SD = 1.02; hospital 3 *M* = 3.31, SD = 1.22; hospital 4 *M* = 3.00, SD = 1.06).

Likewise, when comparing the perception of checklist usage across professional groups, the same questions differed significantly. Nurses gave on average lower scores on the question if all activity is stopped until the checklist is completed (*M* = 1.86, SD = 0.84) compared to surgeons (*M* = 2.61, SD = 0.99) and anaesthesiologists (*M* = 2.36, SD = 1.08) (*F*(2, 132) = 7.64, *P* = .001). The effect of work pressure on checklist performance was, on average, perceived more prevalent by nurses (*M* = 3.28, SD = 1.13) compared to surgeons (*M* = 2.52, SD = 1.12) and anaesthesiologists (*M* = 2.14, SD = 0.54) (*F*(2, 132) = 9.74, *P* = .000).

Table 7 Perception of checklist usage (N=135); n(%)

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly
The complete checklist is used for each surgical procedure in this hospital.	8(5.9)	49(36.3)	21(15.6)	45(33.3)	12(8.9)
The complete checklist is used for each surgical procedure in which I am involved in this hospital.	3(2.2)	35(25.9)	20(14.8)	55(40.7)	22(16.3)
When the checklist is run, everyone will stop his activities in the operating theatre and listens until it is completed.	40(29.6)	64(47.4)	19(14.1)	10(7.4)	2(1.5)
Sometimes parts of the checklist are not checked.	0(0.0)	21(15.6)	21(15.6)	82(60.7)	11(8.1)
The high work pressure in the OT means that I can not perform the checklist.	11(8.1)	41(30.4)	29(21.5)	41(30.4)	13(9.6)
Briefings are a habit in the OT where I work.	3(2.2)	28(20.7)	35(25.9)	59(43.7)	10(7.4)

Beliefs regarding the checklist

A detailed overview of respondents' beliefs regarding the checklist is provided in table 8. In general, beliefs are positive. There was a small but significant difference in scoring between professional groups for the belief that using the checklist improves patient safety in the operating theatre (*F*(2, 132) = 3.39, *P* = .036). Anaesthesiologists (*M* = 4.29, SD = 0.82) and nurses (*M* = 4.33, SD = 0.65) were more positive compared to surgeons (*M* = 3.91, SD = 0.733). Nurses (*M* = 4.55, SD = 0.56) scored, on average, slightly higher to the statement '*If I have surgery, I want the checklist used'* compared to anaesthesiologists (*M* = 4.00, SD = 1.04) and surgeons (*M* = 4.00, SD = 0.90) (*F*(2, 132) = 8.65, *P* = .000). No significant difference between hospitals was found.

Table 8 Beliefs regarding the checklist (N=135); n(%)

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly
I believe that the not using the checklist is an unprofessional attitude.	4(3.0)	11(8.1)	19(14.1)	78(57.8)	23(17.0)
I believe that using the checklist reduces the chance of human error in the OR.	0(0.0)	3(2.2)	13(9.6)	79(58.5)	40(29.6)
I believe that using the checklist improves patient safety in the OR.	1(0.7)	2(1.5)	8(5.9)	75(55.6)	49(36.3)
I believe that using the checklist improves teamwork in the OR.	2(1.5)	17(12.6)	40(29.6)	64(47.4)	12(8.9)
I believe that using the checklist improves communication in the OR.	0(0.0)	22(16.3)	33(24.4)	64(47.4)	16(11.9)
The use of the checklist should be mandatory for any surgical procedure.	2(1.5)	8(5.9)	14(10.4)	67(49.6)	44(32.6)
If I have surgery, I want the checklist used.	0(0.0)	5(3.7)	4(3.0)	58(43.0)	68(50.4)
Using the checklist is subordinate to the efficient operation of the OR.	9(6.7)	60(44.4)	41(30.4)	21(15.6)	4(3.0)
Briefings before the start of a surgical procedure are important for patient safety.	0(0.0)	2(1.5)	1(0.7)	85(63.0)	47(34.8)

Implementation support

Respondents' perceptions of implementation support is provided in table 9. Perception of support by surgeons ($F(3, 131) = 4.31$, $P = .006$), anaesthesiologist ($F(3, 131) = 6.29$, $P = .001$), and nurses ($F(3, 131) = 2.71$, $P = .048$) differed significantly between hospitals. When comparing professional groups, only support by surgeons significantly differed ($F(2, 132) = 8.96$, $P = .000$); with surgeons ($M = 3.52$, SD = 0.73), giving higher scores compared to nurses ($M = 2.56$, SD = 0.98) and anaesthesiologists ($M = 2.71$, SD = 1.27). There was no significant difference between hospitals, nor professional groups for the perception of management support to checklist implementation.

Strategies suggested to improve checklist implementation

In total, 77 respondents (57%) suggested interventions to improve checklist implementation. Almost a quarter of the suggestions (n = 19, 24.7%) contained recommendations to *modify the content of the checklist*. Especially the use of a shorter checklist for smaller, ambulatory surgery was mentioned. A second theme concentrated around *management support* (n = 22, 28.6%). More *compliance monitoring and feedback* followed by appropriate consequences was suggested (n = 7). Suggested consequences included both *incentives* (n = 3) and *punitive action* (n = 4). The need for a *formal patient safety policy* and *concrete guidelines*

(n = 3) were also mentioned. A fourth theme dealt with *motivating team members* to use (n = 16, 20.8%) the checklist, although no tangible interventions were mentioned. Following this, more *education and training* (n = 13, 16.8%) was recommended; respondents suggested more awareness campaigns and practical team training. Last, a number of operational suggestions were provided (n = 12), which mainly focused around the need for more time to execution the checklist (n = 7) and simultaneous presence of all the team members during the execution of the checklist (n = 5).

Table 9 Perception regarding implementation support (N = 135); n(%)

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly
Surgeons support the use of the checklist.	13(9.6)	51(37.8)	33(24.4)	34(25.2)	4(3.0)
Anaesthetists support the use of the checklist.	4(3.0)	27(20.0)	30(22.2)	53(39.3)	21(15.6)
Nurses support the use of the checklist.	3(2.2)	11(8.1)	20(14.8)	79(58.5)	22(16.3)
OR management supports the use of the checklist.	1(0.7)	4(3.0)	13(9.6)	90(66.7)	27(20.0)
Hospital management supports the use of the checklist.	3(2.2)	2(1.5)	22(16.3)	78(57.8)	30(22.2)
I know the first and last name of all the staff I worked with during my last shift.	21(15.6)	62(45.9)	31(23.0)	21(15.6)	0(0.0)

Discussion

The results of this study reflect the perceptions and attitudes of clinicians towards the WHO surgical safety checklist, its usage, the barriers and facilitators to its implementation, and contextual factors linked to checklist usage.

Based on the SAQ, a significant difference in the perception of *Teamwork Climate*, *Perceptions of Management*, and *Working Conditions* was found between nurses, anaesthesiologists, and surgeons. For each of these three factors, nurses gave the lowest scores. When comparing SAQ factor scores between hospitals, it shows that *Job Satisfaction*, *Perceptions of Management*, and *Working Conditions* differed between sites. The fact that *Teamwork Climate* does not vary significantly between hospitals, but rather between nurses and physicians, suggests that teamwork problems are universal. This can also be found in the existing literature on the topic.[12,21]

In this study no difference was found in respondents' perception of patient safety. With the exception of the SAQ items on *Feedback*, *Reporting Safety Concerns*, and *Learning from Errors*, an overall positive perception of safety climate can be noticed. It is remarkable that safety climate does not vary significantly between professional groups nor between hospitals. However, differences in other aspects

of an organizational culture — such as *Teamwork Climate* — were notable. These findings question the importance of the concept of safety climate, compared with organizational culture in its broader context. If we look at the broader literature on safety culture, we can conclude that the concept of safety climate is not entirely clear.[22] Organizational climate is made up of shared perceptions among employees concerning the procedures, practices, and kinds of behaviours that get rewarded and supported with regard to a specific strategic focus.[22] Patient safety climate is a component of an "organisational culture" and reflects the shared beliefs, attitudes, values, norms, and behavioural characteristics of individuals. Moreover, it is assumed to influence staff member attitudes and behaviours in relation to their organisations' on-going patient safety performance. The relationship of climate with behaviour is partly dependent on the strength with which core assumptions are held.[23] However, our results suggest that safety climate plays a less important role compared to other aspects of an organisational culture.

The results of this study showed a noticeable variation amongst respondents' perception of checklist usage. About half of the respondents indicated that briefings are a habit in the operating theatre. Furthermore, there is a significant difference between hospitals and professional groups in the perception of collective stopping to carry out the checklist (timeout) and in the effect of work pressure on the performance of the checklist. Nurses reported a less positive view on checklist usage. This can probably be explained by the underlying expectations. In order to execute the checklist, nurses are dependent on the physicians' input. In the absence of sufficient cooperation checklist usage will be perceived as flawed. Surgeons on the other hand, have different expectations regarding checklist usage — often limited to the items that apply to them. This is presumably reflected in a different vision on its use.[24]

From the respondents' perception of the checklist and its effectiveness, we can conclude that there is a positive attitude towards the checklist. There was a small difference in the belief that checklist usage improves patient safety in the operating theatre between professional groups. Nurses have a more positive perception, which translates into a more positive attitude when it comes to wanting the checklist to be used when they themselves undergo surgery. Despite healthcare professionals confirming the importance of the checklist, compliance was perceived as moderate. Other research has revealed that individual perception of the usefulness of the surgical safety checklist stands in contrast to its actual application and compliance.[25] This calls for a deeper understanding between individual perception and actual application of the checklist. In seeking to understand stakeholders' experiences, it is appropriate to take a qualitative, inductive approach.[26] Specifically, grounded theory methodology would be appropriate as it is suitable for studying social processes in areas where little explanatory theory or knowledge currently exists.[27]

A positive agreement with the relevance of facilitating factors included in the the framework of Russ *et al*. was noticed. Regarding the barriers within this framework, more diverted answers are observed. There was a notable difference between the participating hospitals, the differences between professional groups are less explicit. If we contrast this with the data resulting from the SAQ, it is noticeable that there are more significant variations in factor scores between hospitals compared to professional groups. The fact that differences in perceptions are less pronounced between professional groups suggest that the local context is more important than differences in perception between professional groups. We must therefore try to measure the local status in a standardized way. Existing surveys, such as the SAQ, might be useful tools to identify important local factors. Unfortunately, our data set was too small to perform sophisticated statistical analysis linking the SAQ items with the perceptions and attitudes regarding barriers and facilitating factors.

There was a marked difference between sites in respondents' perception of implementation support by surgeons, anaesthesiologist, and nurses. In comparison between professional groups, only support by surgeons differed and was perceived more positive by surgeons themselves compared to nurses and anaesthetists. Respondents' perceptions of management support did not differ between sites and professional groups. These findings reinforce the importance of teamwork and the variation between hospitals. This shows that the local context certainly has its place in this story. These differences in the respondents' perceptions of barriers and facilitators and SAQ scores between study sites strengthen the proposition that the local context plays a key role in the implementation of surgical safety checklists and that generalisation across hospitals must be dealt with care.

Our findings must be viewed in light of the study design. Survey studies may be subject to bias. We used well established administration procedures by Sexton *et al.* to assure adequate response rates. Finally, our voluntary sample may have been biased in that these operating theatres have signed up to participate in previous studies. Whether this suggests better or worse ratings is not certain. In addition, any bias could be expected to affect ratings on survey instruments equally.

Conclusions

This study shows that, despite the positive perception and attitude of nurses, surgeons, and anaesthesiologist, the surgical safety checklist is not so easy to implement. The effective use of the checklist is affected by a plethora of factors. Throughout the results, it becomes clear that teamwork plays a crucial role. As our data shows, there's noticeable variation between hospitals compared to

differences between professional groups. Therefore, it is difficult to make universal recommendations. The implementation strategy must be tailored to the local context, in which the mechanisms linking these factors probably play a more important role that the factors themselves.

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Chapter 7

Disrupted routines and conflicting priorities: a grounded theory study of challenges in implementing a surgical safety checklist in the operating theatre

This chapter is submitted for review:

Bergs J, Lambrechts F, Hellings J, Vandijck D. Disrupted routines and conflicting priorities: a grounded theory study of challenges in implementing a surgical safety checklist in the operating theatre.

Healthcare is complex and prone to unwanted harm. The use of checklists is linked to strengthening compliance with guidelines, improving human factors, reducing the incidence of adverse events, and decreasing mortality and morbidity.[1] The use of checklists in healthcare gained momentum following the introduction of the WHO surgical safety checklist (SSC). The purpose of this checklist is to help operating theatre (OT) teams remember important details (e.g., antibiotic prophylaxis) that may be missed during an operation. In addition, it serves as a tool to encourage teamwork and communication.[2] Its use is associated with increased patient safety awareness, improved communication, reduction of surgical claims and reduction in the number of postoperative complications including mortality.[3-7] Despite these benefits, implementation of the surgical safety checklist in practice appears to be difficult.

The implementation of new guidelines and safety interventions has shown to be challenging in various healthcare settings, highlighting the importance of the implementation process.[8-11] The use of checklists makes eminent sense from a safety point of view. Nevertheless, research has shown that the perceptions of physicians and nurses working with the checklist show otherwise. This has resulted in various interpretations and ways of using of the original checklist.[12] Several studies have reported high levels of participation and checklist completion.[3,13] However, implementation requires more than installing individual verification of certain key issues followed by the physical act of ''checking the box''.[14] A growing body of literature points out that while the physical act of ''checking the box'' may not necessarily prevent all adverse events, the checklist is a scaffold on which attitudes toward teamwork and communication can be encouraged and improved. Recent evidence reinforces the fact that compliance with the checklist is crucial to realize its beneficial effects on patient safety.[10] Individual and collective willingness to use the checklist depends — at least partially — on physicians' and nurses' perceptions of the checklist, and by extent to their perception of patient safety in general.[10] As the checklist is essentially a tool to facilitate communication and teamwork, its implementation can be understood as a complex social intervention. Factors influencing the dissemination and uptake of evidence-based interventions or technological innovations may, therefore, not apply to this type of complex interventions.

Conceptual frameworks have been developed to incorporate factors influencing implementation, but frameworks specific to surgical safety checklists are limited.[10] From a more general perspective, Damschroder *et al.* reviewed existing theories and frameworks to develop an 'overarching typology' to guide theory development, incorporating five main constructs: outer setting, inner setting, characteristics of the intervention, characteristics of the people involved and the process of change.[15] A review of the empirical literature derived similar constructs.[16] Theories should have the ability to explain individual or group behaviour in terms of factors that are modifiable.[17] Numerous theories concerning

the implementation of evidence-based practice exist. However, there is a general lack of empirical evidence to support many of the theories and theory inductively developed from practice is scarce.[18] The available evidence does not lend itself to identifying the relative merits of particular theories.[19] Nonetheless, attempts have been made to establish a general theory of implementation.[20] Current understandings regarding the implementation of surgical safety checklists mainly consist of frameworks describing the barriers and facilitating factors. By example, Russ *et al.* summarised the barriers and facilitators toward implementation drawing from a large national (UK) study. To fully understand why attempts to replicate the impressive improvements of the checklist have sometimes failed dramatically we need to go beyond these frameworks. Eighteen qualitative studies, summarised in a recent qualitative systematic review, help explain why.[10] The operating theatre is a complex social space with established hierarchies and routines. Far from being a simple "technical" procedure, the checklist demands new forms of cooperation and communication between surgeons, anaesthetists, and nurses. Depending on a host of contextual factors, safety checks may substantially disrupt team routines and be resented rather than welcomed. When (and to the extent that) the checklist is treated as a tick-box exercise, it will fail to generate benefits and may even lead to harms. Further, Gillespie *et al*. used a realist synthesis methodology to explain when, why, and how surgical safety checklist implementation adherence interventions work.[21]

It was this perspective which largely drove the decision to take an inductive approach to the research, focusing on the perspectives of key players in a major process of change, rather than testing an existing theory. The ontological perspective formed the basis for the research question: what mechanisms influence the implementation of the WHO surgical safety checklist in operating theatres and what are the relationships between those mechanisms? A mechanism was defined as the structures, powers, and relations that are not directly observable but that can be identified through their effects. Mechanisms explain how things work.

Methods

In seeking to understand stakeholders' experiences, it was appropriate to take a qualitative, inductive approach.[22] Specifically, grounded theory methodology was chosen as it is suitable for studying social processes in areas where little explanatory theory or knowledge currently exists.[23] Grounded theory is a qualitative, systematic approach used to explore processes in the context of situated interaction, with an embedded focus on human action and interactions, and involves the concurrent collection and analysis of data to formulate theories that are grounded in the world of the participants.[23-25] The intent of this research

method is to move beyond description, and to generate or discover a theory that explains the situated actions and interactions as they experience, engage with, and manage the phenomenon of study. This is done by focusing on the main concern or problem that the individuals' behaviour is designed to resolve. The goal of grounded theory is thus to discover this main concern, and hence the social processes that explain how people continually resolve it. The main concern or problem must be discovered from the data. Charmaz' constructivist approach to grounded theory was followed because our view accords with hers that researchers are intrinsically part of a study and do not discover theory but construct it through interaction and interpretation with the participants.[23,24] Grounded theory utilises well-developed methods of purposeful sampling from relevant populations, concurrent data collection, and constant comparative analysis which are continued until data saturation is reached along with the development of theoretical concepts.[23] The application of these methods in this study are outlined below.

Participants and setting

This study was carried out at four hospitals in Belgium. Belgium, amongst other countries, is committed to implement the World Health Organisations' surgical safety checklist on a national level. Within Belgium's Flemish region this commitment is spurred by the Flemish coalition agreement. The Flemish Government has decided to revise the supervision of hospitals — and healthcare in general — by endorsing formal accreditation (e.g., Joint Commission International or NIAZ Qmentum International), its own Flemish Indicators Project (VIP^2), and by imposing a set of accreditation standards that are developed in consultation with the stakeholders involved. A first set of standards, implemented in 2013, encloses the treatment trajectory of surgical patients. One of the elements within this framework is the obligated use of the WHO Surgical Safety Checklist.

Sampling and data collection

Qualitative research elicits detailed information about beliefs and experiences, and the factors that shape them to create a thorough understanding of an issue. A grounded theory approach was used to collect and analyse data such that views, experiences, needs, and suggestions emerged freely during interviews and inductively during data analysis rather than being restricted to the components of established theory. In grounded theory, collecting data is not envisioned as a single, unidirectional line, but its process is guided by the developing grounded theory. Detailed information from representative, rather than a large number of cases is needed in qualitative research.

Sampling was controlled by the emerging theory as in theoretical sampling, according to Charmaz.[23] Sampling was concurrent with data collection and analysis, and proceeded until unique themes no longer emerged from successive interviews (theoretical saturation). This was determined by discussion of emerging themes between two independent reviewers, the principal investigator and a research assistant. In accordance to the grounded theory, each transcript was analysed before the next interview. Recruitment was facilitated by a local contact. All physicians and nurses were invited to participate by regular mail or email with an invitation letter and consent form.

Data collection was conducted using a combination of methods including individual interviews of surgeons and anaesthesiologists, and focus group interviews of operating theatre nurses and implementation teams. Qualitative interviews and focus groups were conducted to explore how adaptation, implementation, integration and monitoring or other process, and individual, team or other factors influenced surgical safety adherence. A total of 60 respondents from 4 hospitals were interviewed (11 focus group interviews were combined with 16 individual interviews). Interviews were conducted in Dutch language with all consenting participants by the principal investigator. Participants were asked about perceived adherence with the surgical safety checklist; how the surgical safety checklist was adapted, implemented, integrated, and monitored; factors influencing these processes; and suggestions for improving checklist adherence. Interviews of approximately 60 minutes were audio-recorded, then transcribed verbatim. Interviews were conducted over a time period of twelve months from November, 2014 to November, 2015.

Rigour was optimized by sampling participants with various characteristics that could influence their views and experiences; exploring responses inductively for emerging ideas; demonstrating responses from an array of participants by anonymously identifying exemplary quotes; comparison of independently-derived analysis across two individuals, and thorough, high-level interpretation of the findings. It was further ensured by complying with Relevance, Appropriateness, Transparency and Soundness (RATS) principles for reporting of qualitative research.

Data analysis

The transcripts were analysed using the constant comparative method: each interview was analysed and compared to the previous interview or focus group.[23,25] In accordance with grounded theory methodology, an open coding was performed manually line-by-line, by the first author, constantly focusing on the incidents: the meaning, action, and interaction of "what is actually going on in the area studied". Unique themes were identified in an inductive manner through iterative stages. First, interview transcripts were read to identify, define, and

organize themes in participant responses relevant to each of the main interview questions (first level coding). Second, a codebook was developed to organize codes reflecting emerging themes, their definition, sample quotes illustrating application of that code, and an account of decisions related to that code. Third, transcripts were reviewed (constant comparative technique) to assess whether and how to expand or merge themes (second level coding). The codes were subsequently grouped into broader, tractable categories, and further into more extensive, universal categories, thereby translating the descriptive concepts until theoretical saturation was obtained. Interview transcripts and the codebook were analysed independently by a research analyst and the principal investigator. The two met to compare findings and achieve consensus by discussion. Data (quotes labelled with an anonymous identifier reflecting profession, province, type of hospital and time using the surgical safety checklist) were tabulated for each main interview question by theme and profession to identify trends. During the whole process of analysis; memos, theoretical ideas about codes, categories and their relationships were written and used in the analysis. When the core category was identified, it was finally compared with the literature in the field according to Charmaz, 2014, to see if the findings were supported.[23]

Ethical concideration

This research was approved by the ethical advisory committee of Hasselt University and all participating hopsitals (ref. B117201421085). All participants signed a consent form prior to the interviews.

Results

Checklist adherence

When asked about adherence, most participants said that the surgical safety checklist was incompletely and inconsistently reviewed and documented for each patient. Participants described the use of the checklist as a kind of "grey area". The checklist is used, but not in a consistent manner and often not in accordance with institutional recommendations. Particularly, collective review of the checklist items is rare. Participants described how this lead to alternative ways of use (e.g., merely checking-off the checklist items, individual verification, or collective review within a smaller part of the team). Motives to use the checklist in an alternative way arose from several explanations, inter alia, personal conviction of the importance of checklist usage, the obligation to follow institutional norms, and fear of legal consequences if the checklist would not be used. Experiences or views were similar across participants from different hospitals, and different health profession groups.

Het gebruik van de checklist varieert, het is een gijze zone tussen het correct gebruik waarbij we in team de items overlopen en het gewoon afvinken.[Nurse]

More specifically, participants indicated that the sign-in part of the checklist is often used as an individual control instrument without collective team review. In order to complete the items, nurses tried to collect the necessary information by passively listening to the conversation between the anaesthetist and the patient, by actively seeking information from fellow nurses, or by reviewing the patient file. Most anaesthesiologists verified the patient related sign-in items (e.g., patient identification, allergies) during their conversation with the patient prior to induction. However, they did not always consider it necessary to discussed the items with the nurses. Hospital policy or checklist layout suggesting that certain items are specifically assigned to nurses or anaesthesiologists reinforced this way of working. This created a sense of individual responsibility, to the detriment of collective responsibility. Both nurses and anaesthetists indicate that communication prior to induction took place, however collective review of the sign-in items was not routinely utilised.

De sign-in word wel een stuk, op een of andere wijze, tijdens het operatie gebeuren toegepast, iedereen een beetje op zijn eigen manier.[Nurse]

Tijdens de voorbereiding (sign-in) heb ik de vragen gesteld, wel niet zoals het hoort: namelijk met het papier voor me en een verpleegkundigen langs me.[Anaesthesiologist]

Ook al zijt ge niet echt samen aan het babbelen, toch doe ik mijn ding en dan wordt er weer geluisterd. Ik hoor dikwijls, ofwel zij of ikzelf, zeggen "ja ik heb just gehoord dat ge tegen mijn collega al gezegd hebt dat ge nuchter zijt of niet niet allergisch zijt" dus da wordt eigenlijk wel gedaan. Niet zoals wij nu samen rond de tafel zitten, maar het wordt wel samen gedaan.[Anaesthesiologist]

All the participants agreed that the time-out part was most difficult to implement. Finding a suitable moment at which all team members (i.e., the nursing staff, the anaesthetist, and the surgeon) were able to briefly stop their activities to collectively review the time-out items was seen as the greatest challenge. The participants felt that the application of the time-out varied largely depending on the team composition. Notably, participants perceived that the surgeons' commitment plays a decisive role. Nurses felt that their commitment and efforts to utilise the checklist varied based on the surgical teams' climate. When nurses believed that this team climate was safe for interpersonal risk taking, they initiated the time-out. If not, nurses adjusted their team involvement depending on their perception of what felt safe — i.e. action that may be taken without social consequences. In order to meet institutional requirements, time-out items are often checked off even when they were not verified in team.

De checklist tot voor de time-out verloopt vrij goed. Maar de echte time-out loopt niet goed.[Anaesthesiologist implementation team]

Maar de effectieve time-out, wat onze betrachting was om dat verder te implementeren, daar zijn we tot vandaag niet in geslaagd.[Head nurse Implementation team]

Regarding the sign-out part, participants stated that the surgeon often left the operating theatre before the sign-out items could be reviewed in team. Hence, the sign-out was customarily conducted within in a smaller part of the team (e.g., nurses only or nurses and anaesthesiologist).

Barriers and facilitating factors

The participants experienced several barriers that hindered checklist implementation. Also several facilitating factors were expressed. All factors could be framed in a previously developed framework based on the existing literature.[10] No additional dimensions, categories, or subcategories were identified. This shows that the current evidence regarding barriers and facilitating factors appears to be a well-saturated body of knowledge.

Mechanism explaining why checklist implementation

More important than the individual barriers and facilitating factors, are the mechanism connecting them.

Mechanism 1: the literalism pitfall

The literalism pitfall describes the mechanism underlying the formation of physicians and nurses' perceptions regarding the checklists effectiveness and usability. This mechanism is situated at two levels: at the level of the individual user, and the the organisational level.

None of the participants — even the surgeons — was radically opposed against the use of a safety checklist. However, the way one perceived the instrument strongly defined the value they attributed to the effectiveness of the checklist. Which in turn influenced their willingness to use the checklist. It became clear that most participants applied a very rigid literal — almost verbatim — interpretation to the content and language of the checklist items. This literal interpretation often hindered practical application of the checklist and resulted in resistance amongst physicians and nurses. Participants reported that the checklist did not fit into their way of working. Some of the doubts stemmed from the fact that the checklist was perceived as irrelevant during smaller, ambulatory surgical procedures. A frequently used example was the verification of placement and operation of a pulse oximeter. Many participants perceived this unnecessary, because a pulse oximeter was always used in the operating theatre. However, one anaesthetist stated that this safety check contained a deeper meaning: "is all relevant monitoring equipment, needed to preform the procedure safely, connected and working?".

Ik denk dat we ook minder letterlijk naar de items moeten kijken, de controle op de aanwezigheid van een saturatiemeter bijvoorbeeld. Dat is een heel relevante vraag in Afrika waar je in het beste geval niet meer dan dat hebt. Hier bij ons is dat standaard, ik doen niemand in slaap zonder dat ik een saturatie op het scherm zie. Je kan dan zeggen dat het item overbodig is maar er zit eigenlijk veel meer achter. Het gaat over de vraag of je de juiste monitoring hebt voorzien om tijdens de ingreep veilig te kunnen werken.[Anesthesist]

A second example emerged around the item relating to the assessment of expected blood loss. Several respondents indicated that it was difficult to estimate the expected blood loss. Again, the focus was on the literal indication of the item as listed on the checklist — which asks if more than 500 ml blood loss is expected. Others interpreted the question broader and framed it as a trigger to collectively reflect upon expected blood loss and if necessary to initiate the appropriate precautions. This shows that many clinicians applied a literal interpretation to the items, and thereby neglecting the deeper underlying pragmatic intention of the safety checks. The participants' paradigm determinant if they were able to distil the pragmatic intention of the items and translate them into a meaningful contribution.

The literal interpretation of items was also imposed by the institutional policy. Many participants indicated that they were required to hold themselves literally to the items. They received this feedback during audits. This was also confirmed during the interviews with the implementation teams. The team members indicated that there was little to no room to modify the items, as otherwise accreditation agencies would reject the checklist. From a management perspective the checklist was seen as an accreditation objective to be fulfilled literally. This strong institutional focus on the literal use of the checklist was transferred during information sessions. The deeper meaning of the items was rarely mentioned.

Mechanism 2: Conflicting priorities

The mechanism of conflicting priorities describes what determines whether the use of the checklist is prioritised within a surgical team. Every clinician — physicians and nurses alike — has a personal perception of what (patient) safety means in their context. The participants understanding of risks was found to influence their perception of the importance and necessity for adapting a specific safety intervention. Consequently, this determines the attitude one has towards patient safety and the specific safety intervention. The collective totality of perceptions and attitudes in a given team creates a certain safety climate.

Participants indicated that, in addition to ensuring safety, several other goals and objectives exist. To each of these priorities a certain degree of importance is allocated. Besides priorities on a personal and team level, participants also described the existence of institutional priorities. The latter are contained in the organizational culture are made explicit by the (safety) policy and the "act upon" by executive leaders. At certain stages in care process one — or more —

objectives collide with the patient safety priority. The participants indicated that they had the impression that an efficient functioning of the operating theatre was the key institutional priority. This often clashed with the personal belief that patient safety should be top priority.

Ik probeer de checklist te volgen maar vaak lukt dat niet, we krijgen de tijd niet om dat correct te doen. Het moet alleemaal snel vooruit.[Nurse]

The relative importance of the objectives is not fixed. Every individual — based on his own conviction and in interaction with team climate and organisational culture — will determine the priority given to the various objectives. From this collection of perceptions and attitudes priorities within the team will emerge. Hence, the priority attributed to checklist usage can vary according to the composition of the team. Striking was that nurses indicated that maintaining a professional identity and social acceptance strongly steered these priorities.

Ik wil die checklist echt gebruiken, maar als je steeds word uitgelachten of belachelijk wordt gemaakt stop je daar vanzelf mee hoor. Ik ben ook maar een mens en geen robot zonder gevoelens, niemand wordt graag belachelijk gemaakt.[Nurse]

The participants indicated that it is easier to prioritise patient safety if it stands high on the institutional priority list — explicitating the important role of executive management. The need for a formal patient safety policy, maintained en enforced by executive leadership, was expressed at several occasions. This will facilitate prioritising patient safety as the central objective, and creates a culture in which it is safer to take interpersonal risks when conflicting priorities emerge.

Het zou makkelijker zijn moest het gebruik van de checklist prioriteit zijn in het ziekenhuis. Vandaag voelt dat niet zo aan, we moeten snel doorwerken en in orde zijn met het papierwerk. Ik heb niet het gevoel dat directie echt wakker ligt wat hier gebeurt, als het maar klopt op papier.[Anaesthesiologist]

De directie moet dat formeel verplichten, heel duidelijk stellen dat dit de manier van werken is. Wie zich daar niet aan houdt moet daarop gewezen worden alleen dan kunnen we vooruit.[Nurse]

There was a clear link with the literalism pitfall. When physicians and nurses perceived some items as less relevant, this was often generalized to irrelevance of the entire checklist. Especialy those who gave a literal interpretation to checklist items were found tho quickly regarded as the checklist as irrelevant.

Artsen en verpleegkundigen kijken zeer letterlijk naar de checklist vragen zonder rekening te houden met de pragmatische betekenis ervan. Hierdoor gaat men bepaalde items snel als irrelevant beschouwen. Als men deze items niet goed kan kaderen zal men snel de irrelevante perceptie doortrekken tot de volledige checklijst.

As ge iedere keer dezelfde nutteloze vragen moet stellen gaat u dat irriteren. Dan steek ik liever mijn tijd in andere taken, zoals administratie.[Surgeon]

Mechanism 3: Disrupted routines

The mechanism disrupted routines describes the effect of checklist implementation on the surgical teams workflow. The introduction of a new way of working must find its place in the existing routines. Wherein the use of checklists will slowly be established as the new normal.

Het moet een routine worden, dat heeft tijd nodig. Iedereen moet zich kunnen aanpassen aan de nieuwe manier van werken.[Anaesthesiologist]

Participants reported that existing routines were disrupted due to the introduction of the checklist. The participants described how they, at an individual level, needed to alter their workflow in order to fit-in the new tasks or how they rearranged existing tasks — as some controls already existed before introduction of the checklist. Participants' personal perception regarding safety, risks, and the intervention plays an determining role. This perception leads to an attitude towards the checklist which translates to a certain willingness to incorporate the checklist in his or her way of working (i.e., agency). However, this compels more than a pure cause-effect relationship. The final behaviour will also be affected by the context in which the participant operates. Further, especially nurses, found that it should feel safe to apply the new way of working without being "punished" by other team members (e.g., being ridiculed). If it appears that if a social conflict emerged, nurses adjusted their behaviour according to the team climate. Here, the role of the surgeon was perceived as dominant.

An important aspect of the checklist is collective checking items to check. However, this form of practice is not a habit and requires breaking with existing routines. The required synchronisation between the different workflows of the surgeon, anaesthetist, and nurses appears not easy to achieve.

Discussion

This study shows that adherence with the checklist was poor though often documented as complete. These results are in line with previous publications on checklist adherence. Patel *et al*. showed differences in adherence between surgical specialties.[13] The current study adds that variation occurs depending on the personal commitment of physicians and nurses. With the commitment of the surgeon playing a decisive role. Yet on an individual basis, for various reasons, there was a positive attitude towards the checklist. This translated into alternative ways of checklist usage, ranging from the merely check off the checklist items, individual usage, or collective checks within a smaller part of the team. It was mainly nurses who tried to comply to institutional norms, looking for ways to verify the checklist items either individually or within a smaller part of the team.

The factors influencing checklist fidelity are diverse, and the mechanisms linking these factors likely even more complex. In the present study we could not detect

any additional barriers or facilitators that have not been described in the literature. However, we were able to identify three mechanisms that give meaning to these factors.

In a first mechanism, which takes place on two levels, the danger of a literal interpretation of the content and application of the checklist is described. The first level includes the sharpend users (i.e., clinicians working with the checklist). Some of the items are considered as less relevant — or even irrelevant — by physicians and nurses. The interviews revealed that most participants perceived the content and application of the checklist items in a literal way. It seems difficult, for both physicians and nurses, to restructure certain checklist items to their pragmatic intent. This created aversion, or the impression that the item is irrelevant in their practice. The checklist was mainly conceived as a procedural checklist (read — do), and the participants explained how they try to carry out the checks during their usual routine. As a consequence, the essences of the checklist — the act of collectively reviewing the items — was often lost. A checklist is a safety tool, a tool to check if a minimum number of safety related issues are considered just before a crucial step in the process. Although often the comparison with aviation is made, we believe that the use of a checklist during surgery has a different aim. In aviation a checklist is used to guide certain critical procedures (e.g., take-off). Where the entire team is working with a single procedure. In the operating theatre, physicians and nurses are engaged in various, often distinct, procedures and processes. The checklist is not intended to guide these processes, but rather as a facilitator for the synchronizing of information between team members at certain crucial points during the operation. Often many of the checks have already been preformed by individual team members, the checklist provides a way to synchronise this information just before crucial steps take place. This initiation of teamwork is probably one of the biggest challenges in the implementation of the surgical safety checklist. In summary, we conclude that the intent and objectives of the checklist are not well understood. This resulted in different interpretations, where the different team members are not always at the same level. The second level is located at the level of the hospital management. The checklist has been developed in order to be useful in different health care settings (i.e., hospitals, countries, ...). Modification of the checklists' content, in order to fit the local way of working is considered crucial for implementation success and has been encouraged by the WHO. However, it shows that hospital management gave little to no room for modification and rather retained as much as possible to the original checklist. They do this because the checklist implementation is often part of accreditation or quality intervention for which they are accountable. As a result, the checklist is implemented and perceived by clinicians in a very literally, verbatim, way. Where it is difficult for many to see the pragmatic intention underlying the safety check. An example of this is the monitoring of the presence and operation the pulse oximeter. This item is

frequently conceded irrelevant because in Belgium the pulse oximeter is applied to each patient. From a more pragmatic sense, this item is about the presence of adequate monitoring in order for the surgical procedure to be preformed as safe as possible. Wherein the use of a pulse oximeter is a minimum requirement, applicable in different countries and healthcare settings. The literal, almost verbatim, interpretation of the items results in losing this underlying intention.

The second mechanism describes how the use of the checklist is prioritized within a team. Through the care process one has to deal with several objectives, sometimes collide them with completing the checklist. Depending on the assigned priority, one will be chosen to use the checklist or serve the colliding objective. The interviews show that this priority is shaped by the interaction between personal perception and attitude, and the perception and attitude of other team members. Others have described a gap between individual perception and actual application of the surgical safety checklist.[26] In their study, Sandlhofer *et al.* showed that despite healthcare professionals confirming the importance of the checklist, compliance was moderate. Therefore, we believe that the resulting climate team eventually determines the priority given to the checklist by a group. If this collides with the personal beliefs, team members will often change their contribution and team involvement in order not to lose the professional status and social acceptance. This has been described as normative influence, where it becomes more important for the individual to gain the approval, or in its negative sense, to avoid disapproval of other people. Normative influence happens when one changes one`s behaviour to conform to group norms or standards in order to be accepted by others. This has also previously been described by Waehle *et al.*, they concluded that even though nurses seem to have a loyal attitude towards the WHO's checklist, they adjusted their team involvement according practical, social, and professional conditions in their work environment.[27]

The third mechanism describes how the implementation of the checklist disrupts existing routines. The introduction of the checklist seems to have a disruptive effect on the workflow of physicians and nurses. This effect has been previously described following the introduction of other interventions and organizational improvement projects.[28] It seems that this new way of working can be difficult to fit into the usual way of working. Interpretation problems in content and usage as described earlier could play a role. Other research shows that workflow adjustment is seen as one of the greatest challenges to systemic use checklists in surgery. Process changes in the way that surgical safety checklists are used need to Incorporate the temporal demands of the workflow. Any changes made must ensure the process is reliable, is easily embedded into existing work routines and is not disruptive.[29]

How can we mitigate the adverse effects of these mechanisms? We should probably pay more attention to the translation of such instruments. Research

shows that the cultural component of an intervention is important.[30] Because of this, classical translation methods such as "translate and back translate" will not always lead to the most accurate result. Some elements of an intervention or questionnaire indeed carry local, culturally loaded items that lead to various interpretations in different contexts. Therefore, we recommend to guide the translation by the pragmatic intention of the various items. In addition, we need appropriate training of physicians and nurses with sufficient attention to the underlying intent of the items. Finally, the strong managerial focus on the literal use of the checklist should be reviewed. These findings emphasized the importance of leadership from unit management and executive level. Having a formal safety policy might facilitate the choice for safety (i.e., using the checklist) when a conflict emerges.

Limitations and strengths

An important limitation of this study is the lack of participants who are explicitly opposed against the use of a surgical safety checklist. The input of participants against the use of checklist could have led to a deeper understanding of the resistance. As a second limitation, the study context should be taken into consideration. The participating hospitals were involved in the implementation of the checklist for at least four years. As a result, there is a chance that the mechanisms found also reflect this stage of implementation. It is not inconceivable that other mechanisms are at play in different stages of the implementation process.

On the other hand, this study has also a number of strengths. First, this study used participants from different professional groups, allowing to create a global image of the implementation issues. The inclusion of the implementation team enhanced the depth and allowed to compare the perception of those using the checklist (i.e., doctors and nurses) with the people who implemented the checklist in the hospital. This allowed to compare user and organisational. Furthermore, this study employs a large number of respondents from various hospitals.

Conclusions

In this study, three mechanisms influecing the implementation of surgical safety checklists have been described. First, the literal focus on the content and application of the checklist makes it difficult to apply the new way of working in existing routines. Second, the introduction of the checklist disrupted the existing routines in the operating theatre. Consequently, there should be more time and energy spend on the implementation of the checklist. From the literature we learn that the use of team learning shows encouraging results. Last, it was found that respondents perceived the expectation to preform the checklist often conflicts

with other organisational priorities (e.g., efficiency). Patient safety should therefore be set as an institutional priority by formulating and disseminating a formal safety policy. It is expected that such a formal policy — when supported by hospital management — will ease decision making in favour of the checklist when other priorities hamper it's execution.

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Chapter 8

Quality and safety seen through the patients' eyes: surgical safety and checklists

This chapter is submitted for review:

Bergs J, Lambrechts F, Hellings J, Marneffe W, Schrooten W, Desmedt M, Vandijck D. Quality and safety seen through the patients' eyes: surgical safety and checklists.

Belgium, amongst other countries, is committed to implement the World Health Organisations' surgical safety checklist on a national level. Within Belgium's Flemish region this commitment is spurred by the Flemish coalition agreement. The Flemish Government has decided to revise the supervision of hospitals — and healthcare in general — by endorsing formal accreditation (e.g., Joint Commission International or NIAZ Qmentum International), its own Flemish Indicators Project (VIP^2), and by imposing a set of accreditation standards that are developed in consultation with the stakeholders involved. A first set of standards, implemented in 2013, encloses the treatment trajectory of surgical patients. One of the elements within this framework is the obligated use of the WHO Surgical Safety Checklist. The potential for safety checklists to improve surgical outcomes is supported across the literature [1-5]; however its implementation appears to be difficult. The use of checklists makes eminent sense from a safety point of view. Nevertheless research has shown that the perceptions of physicians and nurses working with the checklist show otherwise. This has resulted in various interpretations and usage of the original checklist.[6] Individual and collective willingness to use the checklist depends, at least partially, on physicians' and nurses' perceptions of the checklist, and by extent patient safety in general.[7] One aspect forming this perception is the concern around patients' experiences and perceptions, often leading to the omission of items perceived as causing stress in patients (e.g., expected blood loss) or performing of the checks without verifying out loud.[7]

Research addressing the questions of how surgical patients perceive surgical safety and the implementation of the surgical safety checklist is limited. Contradicting the concerns expressed by physicians and nurses, patients seem supportive without any added anxiety. Parents of paediatric surgical patients, for example, considered their involvement in the sign-in part of the surgical safety checklist (i.e., confirming with staff the identity of their child, the procedure to be performed, the operating site, and the consent being adequately obtained and recorded) to be important for surgical safety without any added anxiety.[8] Kawano *et al.,* found that awake patients, undergoing Caesarean section, perceive the implementation of the surgical safety checklist to be a highly positive aspect of their surgical care.[9] Furthermore, Russ *et al.,* showed that surgical patients have positive attitudes towards the implementation of surgical safety checklists, and agree that it would have a positive impact on their safety and will benefit surgical team performance. Moreover, those worried about coming to harm in hospital were particularly supportive.[10] On the other hand, this research also showed that items discussing expected blood loss and potential difficulties during intubation created some worries amongst patients. Generally, patients' perspective on surgical safety practice is perceived positively. However, patients identified physician-patient interactions, relationships, and trust as the most positive factors influencing their perception of the safety environment.[11]

This study explores the attitude and perception of patients towards surgical safety in hospitals, with an emphasis on the usage of surgical safety checklists. As a secondary aim, we also explored if previous experience of error in hospital or other respondent characteristics influence these views.

Methods

Design and recruitment

An observational, cross-sectional, study design was applied by using an online questionnaire. Participants were recruited from the Flemish Patients' Platform network. The Flemish Patients' Platform is an independent organisation founded in 1999, which unites approximately 100 patient associations. The main goal of this platform is to defend patients' rights and strive for more quality care and an active role for patients in health policy. Sampling was opportunistic, based on opting-in, and within the constraints of the following inclusion criteria: all patients were over 18 years of age, were able and willing to provide informed consent to participate, and could fully understand and express themselves in Dutch. To mitigate potential selection bias (e.g., patients active in a patient organization, in general, represent a population with serious, long-term diseases potentially altering their point of view) we additionally distributed the questionnaire using social media (Twitter and Facebook) with the aim of including a case mix of patients who had and had not underwent a surgical procedure. In contrast to other studies, clinicians (i.e., nurses and physicians) were not excluded from the sample; as they as a patient might have different views on the use of surgical safety checklists.

Materials

A questionnaire was developed based on the questions used in other research in this area.[8-10] To safeguard the relevance of the questions and maintain understandable language, the questionnaire was developed in conjunction with two staff members of the Flemish Patients' Platform network.

The final questionnaire comprised three sections. The first section contained items exploring the demographic characteristics of the participants (Table 1). The second section contained 11 items which describe the following three dimensions: (1) respondents' perception of patient safety (two items, see table 2), (2) attitudes towards the WHO surgical safety checklist (five items, see table 3), and (3) attitudes regarding how the checklist is used in practice (four items, see table 4). Each item, except for the questions regarding the respondents' perception of patient safety, was phrased as a statement, for example, 'I would feel safer if the checklist is used' or 'Repetitive verification of my identity before my operation

would make me anxious'. Participants respond by using a five-point Likert scale ranging from strongly disagree to strongly agree, with a neutral mid-point. Data were coded from one to five (1 = 'strongly disagree', 5 = 'strongly agree'), and negatively worded items were reverse scored so that, for all items, higher scores reflected more positive perceptions. To measure perception of patient safety respondents were asked to rate the risk of adverse events during a hospital stay and during surgery (0% - 100%). The final section contained seven items eliciting information on what patients, who underwent surgery, remembered about the usage of a surgical safety checklist (e.g., 'Was a checklist used').

To communicate the concept and usage of the surgical safety checklist, the questionnaire was preceded by a section containing an example of the surgical safety checklist and an explanation of its use. The explanation of how the checklist is used, was written in the most neutral language possible. As with the content of the questionnaire, this description was developed in conjunction with two staff members of the Flemish Patients' Platform network. Proof of the checklists effectiveness was not provided in order not to influence the respondents' views.

Data collection and ethical consideration

Between June and October 2015, questionnaires were distributed through an online platform using the mailing list of the Flemish Patients' Platform network and social media. Participants were informed that the collected information would be kept confidential and that the questionnaire was anonymous. There were no incentives provided for completing the questionnaire. This study was reviewed and approved by the institutional review board at the University of Hasselt.

Statistical analyses

The univariate analyses were conducted to describe baseline demographic characteristics for each study population. We calculated the median score of patient perceptions due to the ordinal nature of the outcome variables (strongly disagree = 1, disagree = 2, neither disagree neither agree = 3, agree = 4, and strongly agree = 5). Bivariate correlations of covariates with the attitude towards the WHO surgical safety checklist and its use in practice were tested using the chi-squared test. The nonparametric Wilcoxon-Mann–Whitney U test was used for assessing differences in continuous variables (age and number of previous operations). To assess the predictive factors for respondents' perception, an ordinal logistic regression model was utilized as the dependent variable to determine unadjusted or crude odds ratios (ORs) and adjusted ORs with 95% confidence intervals (c.i.). An adjusted odds ratio strips away the effects of other factors, theoretically leaving only the relationship between the two studied factors standing. The covariates included age, gender, level of education, clinical background, previous experience of complications, total number of previous

surgeries, and education level. All analyses were performed using R: A Language and Environment for Statistical Computing version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria). The significance level α was set at .05. The analysis and the description in this paper follow the STROBE guidelines for cross-sectional studies.

Results

In total, the questionnaire was answered by 525 people; 81 of the responses were not fully completed and were therefore not further included in the analysis. The final data set consisted of the replies from 444 respondents.

Respondents' characteristics

A wide age range was represented in the sample (median = 50 years, range = 18–91 years). The sample included more females than males (70.5% n = 313 vs. 29.5% n = 131). More than half of the respondents hold a college or university degree (57.5%). Some were active clinicians — physician or nurse (13.1%). Finally, 36.3 per cent of the respondents (n = 161) reported that they had experienced a previous adverse event following surgery in hospital (e.g., medication error, surgical site infection, or wrong site surgery). A detailed overview of the respondents' characteristics is presented in table 1.

Table 1 Respondents' characteristics (N=444)

Characteristic	n(%)
Sex: male	131(29.5)
Education level	
Less than high school	63(14.2)
High school	126(28.4)
College	197(44.4)
University	58(13.1)
Number of past surgical operations	
0	52(11.7)
1	64(14.4)
2	71(16.0)
3	58(13.1)
4	32(7.2)
5	36(8.1)
6	31(7.0)
7	21(4.7)
8	14(3.2)
9	5(1.1)
10	8(1.8)
>10	52(11.7)
Previous errors in care: yes	161(36.3)
Active as a clinician: physician or nurse	58(13.1)

View on patient safety

Table 2 Respondents' view on adverse event risk versus previous surgical experience

	All median(range)	No surgery median(range)	Surgery median(range)	Surgery with complication median(range)
Chance of an adverse event during surgery	25(1-83)	22(2-80)	22(1-81)	30(1-83)
Chance of an adverse event in hospital	30(1-90)	22(5-79)	25(1-90)	33(5-90)

The results of respondents' view on the risk of an adverse event are shown in table 2. Notwithstanding the wide scoring range, multivariable regression analysis showed that respondents who previously experienced a surgery related adverse event rated the chance of an adverse event during surgery higher compared to others (β = 8.104, SE = 2.30, *P* = 0.00). In addition, the education level influenced respondents risk perception for an adverse event during surgery, with higher educated respondents giving lower risk scores (β = -3.25, SE = 1.25, *P* = 0.01). The respondents age, gender, the number of previous operations, and being active as a clinician had no significant effect on the risk perception for an adverse event during surgery. Respondents' view on the risk of an adverse event during a hospital stay was influenced by the respondents' education level, with higher educated respondents giving lowers risk scores (β = -3.52, SE = 1.21, *P* = 0.004) and the respondents' gender, with females giving higher risk scores (β = 4.517, SE = 2.225, *P* = 0.037). The respondents' age, the number of previous operations, and being active as a clinician had no significant effect on the risk perception for an adverse event during hospital stay.

Attitudes towards the WHO surgical safety checklist

The majority of respondents (n = 376, 84.7%) reported to either 'strongly agree' (46.6%) or 'agree' (38.1%) that errors during a surgical procedure would be reduced when a surgical safety checklist is used. In line with this positive perception of checklist effectiveness, 93.2 per cent reported to either 'strongly agree' (62.6%) or 'agree' (30.6%) that use of the checklist would make them feel safer. Consequently, most respondents want the checklist to be used when they undergo a surgical procedure (n = 406, 91.4%). However, asking the surgeon or anaesthesiologist if the checklist will be used seems less obvious for the respondents as 65.1 per cent reported to either 'strongly agree' (35.6%) or 'agree' (29.5%) with the question 'I will ask the surgeon or anaesthesiologist if the checklist will be used if I have an operation'. Even fewer would refuse surgery if the checklist is not used (n = 150, 33.8%). The results are provided in detail in table 3.

Bivariate analysis showed that respondents with a clinical background (physician or nurse) were more likely to agree that the checklist would reduce errors (96.6% vs 82.9%) (χ^2 = 7.33, df = 2, *P* = .026). Respondents' previous experience with surgery influenced their response to the question '*I want the checklist to be used if I have an operation*': respondents without previous surgery (82.7%) were less likely to agree with this statement compared to those who underwent surgery (91.3%) and those who experienced complications during surgery (94.4%) (χ^2 = 13.70, df = 4, *P* = .008). Respondents who experienced a complication were more likely to agree that they would ask the surgeon or anaesthesiologist if the checklist will be used (72.0% vs 62.3% vs 55.8%) (χ^2 = 23.30, df = 4, *P* = .000). Respondents over 50 years of age were slightly more committed to be actively engaged: they were more likely to agree that they would ask the the surgeon or anaesthesiologist if the checklist will be used (78.3% vs 52.0%) (χ^2 = 35.59, df = 2, *P* = .000) and more willing to refuse an operation if the checklist is not used (44.8% vs 22.9%) (χ^2 = 25.204, df = 2, *P* = .000). A detailed overview of the results is provided in table 4.

Multivariate ordinal logistic regression was performed, with respondents' characteristics as covariates, predicting attitude towards the WHO surgical safety checklist. The first series of models specified the response variable that measured the respondents' perception and attitude towards the surgical safety checklist. Our findings showed that respondents' perception on the effectiveness of the surgical safety checklist (i.e., 'Errors during an operation would be reduced if the checklist were used') tend to be more positive with older age (adjusted OR 1.03; 95% c.i. 1.02–1.04; *P* < 0.05); and being active as a clinician (adjusted OR 2.18; 95% c.i. 1.21–3.98; *P* < 0.05). Older age (adjusted OR 1.03; 95% c.i. 1.02–1.05; *P*<0.05), female respondents (adjusted OR 1.60; 95% c.i. 1.02–2.52; *P* < 0.05), and being active as a clinician (adjusted OR 5.21; 95% c.i. 2.54–11.51; *P* < 0.05) made respondents more likely to agree with the statement that the use of a checklist would make them feel safer. The same covariates made them more likely to agree with the statement 'I want the checklist to be used if I have an operation' (Age: adjusted OR 1.04; 95% CI 1.02–1.05; *P* < 0.05, Female: adjusted OR 1.65; 95% c.i. 1.04–2.62; *P* < 0.05, Clinician: adjusted OR 4.10; 95% c.i. 2.04–8.73; *P* < 0.05). The Likelihood for respondents to ask the surgeon or anaesthesiologist if the checklist will be used during an operation increased with age (adjusted OR 1.05; 95% c.i. 1.04–1.07; *P* < 0.05), being female (adjusted OR 1.11; 95% c.i. 1.04–1.07; *P* < 0.05) or having a clinical background (adjusted OR 1.97; 95% c.i. 1.13–3.45; *P* < 0.05). On the contrary, higher educational levels decreased the likelihood. The likelihood for refusing an operation if the checklist is not used increased with age (adjusted OR 1.04; 95% c.i. 1.03–1.05; *P* < 0.05) and decreased for respondents holding a college degree (adjusted OR 0.48; 95% c.i. 0.28–0.84; *P*<0.05). The results are provided in detail in table 5.

Table 3 Attitudes towards the WHO surgical safety checklist

	Strongly disagree n(%)	Disagree n(%)	Neither agree or disagree n(%)	Agree n(%)	Strongly agree n(%)
I would feel safer if the checklist is used	4(0.9)	5(1.1)	21(4.7)	136(30.6)	278(62.6)
I want the checklist to be used if I have an operation	4(0.9)	4(0.9)	30(6.8)	108(24.3)	298(67.1)
I will ask the surgeon or anaesthesiologist if the checklist will be used if I have an operation	15(3.4)	47(10.6)	93(20.9)	131(29.5)	158(35.6)
I will refuse an operation if the checklist is not used	39(8.8)	91(20.5)	164(36.9)	92(20.7)	58(13.1)
Errors during an operation would be reduced if the checklist were used	4(0.9)	6(1.4)	58(13.1)	169(38.1)	207(46.6)

Table 4 Bivariate analysis

	Gender	Clinician	Group	Education
I would feel safer if the checklist is used	χ^2=10.208, df=4, P=0.037**	χ^2=11.088, df=4, P=0.026**	χ^2=5.786, df=8, P=0.671	χ^2=8.207, df=12, P=0.769
I want the checklist to be used if I have an operation	χ^2=1.093, df=4, P=0.895	χ^2=5.155, df=4, P=0.272	χ^2=21.556, df=8, P=0.006**	χ^2=22.351, df=12, P=0.034**
I will ask the surgeon or anaesthesiologist if the checklist will be used if I have an operation	χ^2=3.137, df=4, P=0.535	χ^2=8.072, df=4, P=0.089*	χ^2=24.985, df=8, P=0.002**	χ^2=50.155, df=12, P=0.000**
I will refuse an operation if the checklist is not used	χ^2=5.563, df=4, P=0.234	χ^2=7.248, df=4, P=0.123*	χ^2=32.690, df=8, P=0.00**	χ^2=24.981, df=12, P=0.015**
Errors during an operation would be reduced if the checklist were used	χ^2=3.169, df=4, P=0.530	χ^2=7.336, df=4, P=0.119*	χ^2=15.742, df=8, P=0.046**	χ^2=16.747, df=12, P=0.159
Repetitive verification of my identity before my operation would make me anxious	χ^2=0.566, df=4, P=0.967	χ^2=10.971, df=4, P=0.027**	χ^2=17.220, df=8, P=0.028**	χ^2=12.818, df=12, P=0.382
Repetitive verification of the procedure and operation site before my operation would make me anxious	χ^2=0.806, df=4, P=0.938	χ^2=11.135, df=4, P=0.025**	χ^2=20.697, df=8, P=0.008	χ^2=10.411, df=12, P=0.58
Hearing staff discussing potential airway problems before my operation would make me anxious	χ^2=7.944, df=4, P=0.094	χ^2=6.583, df=4, P=0.160*	χ^2=19.250, df=8, P=0.014*	χ^2=12.494, df=12, P=0.407
Hearing staff discussing blood loss before my operation would make me anxious	χ^2=9.152, df=4, P=0.057*	χ^2=7.364, df=4, P=0.118*	χ^2=18.217, df=8, P=0.020**	χ^2=9.24, df=12, P=0.682

* Significant at the 0.2 level (2-tailed) ** Significant at the 0.05 level (2-tailed)

Table 5 Unadjusted and Adjusted Odds Ratios and 95% Confidence Interval from Ordinal Logistic Regression on participant attitude and perception.

	Participant characteristics		Unadjusted OR (95% CI)	Adjusted OR (95% CI)
I would feel safer if the checklist is used	Age	years	1.02 (1.01-1.04)*	1.03 (1.02-1.05)*
	Surgery	#surgery	0.99 (0.95-1.06)	0.95 (0.88-1.02)
	Gender	male	reference	reference
		female	1.11 (0.73-1.68)	1.60 (1.02-2.52)*
	Clinician	no clinician	reference	reference
		clinician	2.98 (1.56-6.20)*	5.21(2.54-11.51)*
	Group	no surgery	reference	reference
		surgery	0.94 (0.51-1.70)	0.85 (0.42-1.67)
		complication	1.17 (0.61-2.18)	1.20 (0.53-2.70)
	Education	Less then high school	reference	reference
		High school	0.75 (0.39-1.39)	0.79 (0.41-1.52)
		College	0.81 (0.44-1.46)	0.68 (0.35-1.30)
		University	0.62 (0.29-1.29)	0.77 (0.34-1.75)
I want the checklist to be used if I have an operation	Age	years	1.03 (1.02-1.04)*	1.04 (1.02-1.05)*
	Surgery	#surgery	1.03 (0.97-1.09)	0.97 (0.90-1.05)
	Gender	male	reference	reference
		female	1.11 (0.73-1.69)	1.65 (1.04-2.62)*
	Clinician	no clinician	reference	reference
		clinician	1.92 (1.03-3.80)*	4.10 (2.04-8.73)*
	Group	no surgery	reference	reference
		surgery	0.87 (0.45-1.64)	0.75 (0.36-1.52)
		complication	1.36 (0.67-2.66)	1.21 (0.51-2.83)
	Education	Less then high school	reference	reference
		High school	0.66 (0.33-1.29)	0.73 (0.35-1.47)
		College	0.56 (0.29-1.05)	0.51 (0.25-1.01)
		University	0.52 (0.23-1.12)	0.74 (0.31-1.77)
I will ask the surgeon or anaesthesiologist if the checklist will be used if I have an operation	Age	years	1.05 (1.04-1.06)*	1.05 (1.04-1.07)*
	Surgery	#surgery	1.05 (1.00-1.1)	0.95 (0.89-1.01)
	Gender	male	reference	reference
		female	1.14 (0.79-1.64)	1.77 (1.19-2.64)*
	Clinician	no clinician	reference	reference
		clinician	0.8 (0.50-1.29)	1.97 (1.13-3.45)*
	Group	no surgery	reference	reference
		surgery	1.78 (1.01-3.14)*	1.41 (0.76-2.61)
		complication	2.39 (1.32-4.32)*	1.96 (0.94-4.07)
	Education	Less then high school	reference	reference
		High school	0.49 (0.28-0.86)*	0.52 (0.29-0.94)*
		College	0.38 (0.22-0.64)*	0.40 (0.22-0.72)*
		University	0.15 (0.07-0.30)*	0.23 (0.11-0.48)*
I will refuse an operation if the checklist is not used	Age	years	1.04 (1.03-1.05)*	1.04 (1.03-1.05)*
	Surgery	#surgery	1.07 (1.02-1.12)*	1.00 (0.94-1.07)
	Gender	male	reference	reference
		female	0.93 (0.64-1.35)	1.26 (0.85-1.86)

	Clinician	no clinician	reference	reference
		clinician	0.84 (0.52-1.35)	1.73 (1.00-2.99)
	Group	no surgery	reference	reference
		surgery	1.25 (0.70-2.23)	0.94 (0.50-1.75)
		complication	1.96 (1.07-3.59)*	1.36 (0.65-2.82)
	Education	Less then high school	reference	reference
		High school	0.54 (0.31-0.92)*	0.61 (0.35-1.06)
		College	0.41 (0.24-0.68)*	0.48 (0.28-0.84)*
		University	0.33 (0.17-0.64)*	0.54 (0.27-1.09)
Errors during an operation would be reduced if the checklist were used	Age	years	1.02 (1.01-1.03)*	1.03 (1.02-1.04)*
	Surgery	#surgery	1.01 (0.96-1.06)	0.97 (0.90-1.03)
	Gender	male	reference	reference
		female	0.78 (0.53-1.14)	1.01 (0.67-1.53)
	Clinician	no clinician	reference	reference
		clinician	1.62 (0.97-2.76)	2.18 (1.21-3.98)*
	Group	no surgery	reference	reference
		surgery	0.76 (0.43-1.33)	0.70 (0.37-1.30)
		complication	1.21 (0.66-2.19)	1.23 (0.58-2.60)
	Education	Less then high school	reference	reference
		High school	0.73 (0.40-1.31)	0.82 (0.45-1.50)
		College	1.04 (0.59-1.81)	1.15 (0.62-2.10)
		University	1.03 (0.52-2.03)	1.46 (0.69-3.07)

* Significant at the 0.05 level (2-tailed); OR = odds ratio

Attitudes towards use of the WHO surgical safety checklist in practice

Most respondents (n = 320, 72.1%) reported to either 'strongly disagree' (43.5%) or 'disagree' (28.6%) that repetitive verification of their identity before an operation would make them anxious. Likewise, 71.6 per cent did not bother the repetitive verification of the procedure, and the operation site. Respondents with a clinical background were less anxious as a result form repetitive identity checks (adjusted OR 0.38; 95% c.i. 0.21–0.68; $P < 0.05$) and repetitive site and procedure checks (adjusted OR 0.33; 95% c.i. 0.18–0.60; $P < 0.05$). Respondents who previously experienced a surgery related complication were also less anxious as a result from repetitive site and procedure checks (adjusted OR 0.49; 95% c.i. 0.24–0.99; $P < 0.05$). Overall, respondents were divided with regards to whether they felt that hearing discussions around potential airway problems or blood loss prior to their surgery (part of the 'sign-in' portion of the checklist) would make them feel anxious. When detailing on the discussion around blood loss, 53.6 per cent reported to either 'strongly agree' (16.4%) or 'agree' (37.2%) that it would make them anxious, 32.6 per cent reported to either 'strongly disagree' (14.4%) or 'disagree' (18.2%), and 13.7 per cent were impartial. The same held for the discussion around potential airway problems, were 52.7 per cent agreed that it would make them anxious, 32.6 per cent said that it would not, and 13.1 per cent

were impartial. Only the number of past surgical operations slightly decreased the likelihood for being anxious when hearing staff discussing blood loss (adjusted OR 0.93; 95% c.i. 0.87–0.99; $P < 0.05$). The results are provided in detail in table 6 and 7.

Table 6 Attitudes towards use of the WHO surgical safety checklist in practice

	Strongly disagree n(%)	Disagree n(%)	Neither agree or disagree n(%)	Agree n(%)	Strongly agree n(%)
Repetitive verification of my identity before my operation would make me anxious	193(43.5)	127(28.6)	53(11.9)	39(8.8)	32(7.2)
Repetitive verification of the procedure and operation site before my operation would make me anxious	180(40.5)	138(31.1)	50(11.3)	43(9.7)	33(7.4)
Hearing staff discussing potential airway problems before my operation would make me anxious	60(13.5)	92(20.7)	58(13.1)	160(36.0)	74(16.7)
Hearing staff discussing blood loss before my operation would make me anxious	64(14.4)	81(18.2)	61(13.7)	165(37.2)	73(16.4)

Table 7 Unadjusted and Adjusted Odds Ratios and 95% Confidence Interval from Ordinal Logistic Regression on participant attitude and perception.

	Participant characteristics		Unadjusted odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Repetitive verification of my identity before my operation would make me anxious	Age	years	1.00 (0.99-1.01)	1.00 (0.98-1.01)
	Surgery	#surgery	0.95 (0.9-1.0)*	0.95 (0.89-1.02)
	Gender	male	reference	reference
		female	1.06 (0.73-1.55)	1.04 (0.70-1.55)
	Clinician	no clinician	reference	reference
		clinician	0.47 (0.27-0.78)*	0.38 (0.21-0.68)*
	Group	no surgery	reference	reference
		surgery	0.75 (0.44-1.29)	0.79 (0.44-1.43)
		complication	0.53 (0.30-0.95)*	0.60 (0.30-1.22)
	Education	Less then high school	reference	reference
		High school	0.86 (0.50-1.49)	0.80 (0.46-1.40)
		College	0.76 (0.46-1.28)	0.85 (0.49-1.49)
		University	0.57 (0.30-1.07)	0.46 (0.23-0.92)*
Repetitive verification of the procedure and operation site before my operation would make me anxious	Age	years	1.00(0.99-1.01)	1.00 (0.98-1.01)
	Surgery	#surgery	0.95 (0.90-0.99)*	0.97(0.90-1.03)
	Gender	male	reference	reference
		female	1.14 (0.78-1.66)	1.13 (0.76-1.67)
	Clinician	no clinician	reference	reference
		clinician	0.42 (0.24-0.71)*	0.33 (0.18-0.60)*
	Group	no surgery	reference	reference
		surgery	0.71 (0.41-1.23)	0.72 (0.40-1.30)

		complication	0.48 (0.27-0.85)*	0.49 (0.24-0.99)*
	Education	Less then high school	reference	reference
		High school	1.03 (0.60-1.78)	0.97 (0.56-1.71)
		College	0.90 (0.54-1.50)	1.04 (0.59-1.82)
		University	0.74 (0.39-1.41)	0.63 (0.31-1.25)
Hearing staff discussing potential airway problems before my operation would make me anxious	Age	years	0.99(0.98-1.00)	0.99 (0.98-1.01)
	Surgery	#surgery	0.93(0.88-0.98)*	0.95 (0.90-1.02)
	Gender	male	reference	reference
		female	1.25 (0.87-1.80)	1.24 (0.85-1.81)
	Clinician	no clinician	reference	reference
		clinician	0.80 (0.50-1.29-)	0.75 (0.44-1.29)
	Group	no surgery	reference	reference
		surgery	0.66 (0.38-1.14)	0.78 (0.43-1.41)
		complication	0.44 (0.25-0.78)	0.59 (0.29-1.17)
	Education	Less then high school	reference	reference
		High school	1.15 (0.66-2.02)	1.05 (0.59-1.86)
		College	0.98 (0.58-1.65)	0.86 (0.49-1.52)
		University	1.15 (0.60-2.21)	0.87 (0.43-1.74)
Hearing staff discussing blood loss before my operation would make me anxious	Age	years	0.99 (0.98-1.00)*	0.99 (0.98-1.00)
	Surgery	#surgery	0.92 (0.88-0.97)*	0.93 (0.87-0.99)*
	Gender	male	reference	reference
		female	1.37 (0.95-1.97)	1.33 (0.91-1.94)
	Clinician	no clinician	reference	reference
		clinician	0.82 (0.51-1.33)	0.75 (0.44-1.29)
	Group	no surgery	reference	reference
		surgery	0.85 (0.49-1.45)	1.12 (0.62-2.02)
		complication	0.58 (0.33-1.02)	0.94 (0.47-1.87)
	Education	Less then high school	reference	reference
		High school	1.16 (0.66-2.03)	1.00 (0.56-1.76)
		College	1.08 (0.65-1.81)	0.87 (0.49-1.53)
		University	1.33 (0.66-2.03)	0.89 (0.44-1.80)

Experience during surgery

The respondents who underwent surgery in the past (n = 392), were asked what they remembered about the use of the surgical safety checklist. In total 390 respondents answered the questions regarding their remembrance of checklist usage. While we should certainly take into account the existence of recall bias, we discuss in what follows, some noteworthy findings. Although most respondents denied, or could not recall, that a checklist was used during their last surgery. Trrough the years we more respondents confirmed the performance of specific items such as checking the identity, procedure, site, and allergy. It is noticeable that most respondents indicate that checks for potential blood loss and respiratory problems were not executed. Conclusions about the underlying reason for this can

not be drawn from the existing results. A detailed overview of these results can be found in table 8.

Table 8 Overview of respondents' remembrance of checklist usage based on last surgery

	Response	Bef.-2000	2001-2005	2006-2010	2011-2015	Total
Was the checklist used?	Yes	1(2.1)	1(3.0)	2(3.1)	36(14.7)	40(10.3)
	No	17(35.4)	15(45.5)	17(26.6)	55(22.4)	104(26.7)
	Don't know	30(62.5)	17(51.5)	45(70.3)	154(62.9)	246(63.1)
Identity check	Yes	13(27.1)	14(42.4)	32(50)	186(75.9)	245(62.8)
	No	9(18.8)	9(27.3)	12(18.8)	25(10.2)	55(14.1)
	Don't know	26(54.2)	10(30.2)	20(31.3)	25(13.9)	90(23.1)
Procedure check	Yes	9(18.8)	8(24.2)	11(17.2)	112(45.7)	140(35.9)
	No	4(8.3)	6(18.2)	8(12.5)	21(8.6)	39(10.0)
	Don't know	35(72.9)	19(57.6)	45(70.3)	112(45.7)	211(54.1)
Site check	Yes	12(25.0)	11(33.3)	28(43.8)	137(55.9)	188(48.2)
	No	7(14.6)	9(27.3)	7(10.9)	28(11.4)	51(13.1)
	Don't know	29(60.4)	13(39.4)	29(45.3)	80(32.7)	151(38.7)
Allergy check	Yes	17(35.4)	16(48.5)	26(40.6)	133(54.3)	192(49.2)
	No	7(14.6)	10(30.3)	14(21.9)	59(24.1)	90(23.1)
	Don't know	24(50.0)	7(21.2)	24(37.5)	53(21.6)	108(27.7)
Bleeding check	Yes	2(4.2)	3(9.1)	4(6.3)	11(4.5)	20(5.1)
	No	36(75.0)	26(78.8)	48(75.0)	196(80.0)	306(78.5)
	Don't know	10(20.8)	4(12.1)	12(18.8)	38(15.5)	64(16.4)
Airway check	Yes	1(2.1)	2(6.1)	1(1.6)	14(5.7)	18(4.6)
	No	37(77.1)	29(87.9)	53(82.8)	198(80.8)	317(81.3)
	Don't know	10(20.8)	2(6.1)	10(15.6)	33(13.5)	55(14.1)

Discussion

Clinicians' individual and collective willingness to the use of safety interventions depends on several factors, including the perception of effectiveness, ease of use, etc. A specific factor in the use of surgical safety checklists is the perception and experience of patients. Several studies show that physicians, and especially nurses, find repeated and aloud checking of items (e.g., identity, type and location of the surgery) difficult and even avoid this in order not to unnecessarily frighten the patient. Studies describing the patients' perspective, however, display a different picture. These studies show that patients feel safer when they know that a checklist will be used. The present study explored the perceptions of Belgian patients. Besides a general view, we also focused on the impact of previous experiences with surgery and adverse events. In addition, we explored the possible effect of being active as a physician or nurse on the perception and experience of patients.

First, we have described how patients assess the incidence of adverse events during a hospital stay and during surgery. The respondents in this study estimate

the probability of an adverse event, both in-hospital and during surgery, higher than the incidence described in the literature.[12,13] Respondents who reported that they had experienced an adverse event during surgery had the most negative perception about the incidence of adverse events. It is remarkable that being actively working as a clinician had no influence on this perception. Overall, the probability of an adverse event was double or even triple assessed in comparison with published numbers. It shows that hospitals should not be afraid to make their quality and safety indicators publicly available.

Further, respondents' perception regarding the effectiveness of the WHO surgical safety checklist was positive. The results suggest that use of the checklist would also lead to increased sense of security for the majority of the respondents. Consequently, most of the respondents want a checklist to be used in future surgery. However, this positive perception did not translate into an attitude whereat patients will actively inform themselves by asking whether the checklist will be used. Also, refusal of surgery if no checklist will be used seems less evident. Being active as a clinician reinforced this perception and attitude. In contrast, prior experience with surgical procedures and adverse events had no significant effect. These findings can be explained by the concept of psychological safety. Patients experience around an operation is characterized by anxiety and stress. Additionally, the patient-physician relationship is considered as a relationship of dependence, in which the patient attributes status to the physicians. This makes it very difficult for patients to ask a physician if a safety checklist will be used, as patients don't want to question the professional capabilities of the surgeon or anaesthesiologist.

Thirdly, we explored patients' experience with checklist usage in the operating theatre. The results clearly demonstrated that the majority of respondents have no difficulty in the repetitive verification of items such as identity, type and location of the surgery. Respondents with a clinical background were the least anxious, which can probably be explained by their knowledge and experience with this routine procedure. The same is true for respondents who have already experienced an adverse event. Probably, this repetitive control creates a sense of security, so it does not come across as frightening. If we look at the items regarding specific risks (i.e., potential blood loss and airway problems) the answers are less constant. It is striking that there exists only a significant relationship with the number of previous surgeries. The relationship between working as a clinician and become anxious when they hear specific risks could not be established in this study.

Concurrent findings are reported in previous research.[8-10] Together, these results contribute to the argument that physicians and nurses are unduly concerned about the perception of patients. We see no reason to omit repetitive inspection for identity and procedure. This should be nuanced when it comes to hearing

specific risks such as expected blood loss. Here we must note that hearing these specific risks may induce a certain anxiety in patients. This dual experience, where some think that the checklist will reassure them that all eventualities have been taken into account, while others find that it would make them feel anxious and worried, is also described in another study.[10] Further this study showed that patients did not feel they had a strong role to play in safety improvement more broadly.[10] As a result, some have suggested that possibly some adjustments how the checklist is being used are needed.[10] However, we rather believe that the active involvement of the patient in the sign-in phase can reduce these fears and increases patient empowerment significantly. Another study showed that strong involvement of parents of paediatric patients while checking the sign-in items did not result in added anxiety from this involvement and 97% felt reassured that the correct procedure was to be performed.[8] Parents consider their involvement in the safety checks as worthwhile and they consider that it should be mandatory. Added to this, a patient's capacity to become involved will likely be influenced by their underlying intellectual, moral and behavioural profile.[14] Patients can be involved at most stages of healthcare, and this can have a number of benefits.[15] However, uncertainty persists about why and how to do involvement well and evaluate its impact, how to involve and support a diversity of individuals, and in ways that allow them to work in partnership to genuinely influence decision-making.[15] Greater attention is needed to enable power and decision-making to be shared more equitably with patients and the public in designing, planning and co-producing healthcare.

Knowing that a checklist is used makes a patient feel more secure. Hence, we need to find ways to facilitate the conversation between patients and clinicians on this subject. To this end, we can explore different ways:

1) Behaviour of one who reads aloud the checklist. By letting the patient know that he or she may ask clarifying questions on hearing anything unusual, does not only take the fear away but will also raise patient involvement and will empower them to contribute in creating a safe environment. It is not inconceivable that some patients are better informed about their allergies than those described in the patient record.

2) Communication among team members in the operating theatre, with a strong focus on patient involvement. Again, it is important to create the conditions in which patients are encouraged to ask questions at any ambiguities. Furthermore, it is important not to speak about the patient as being he or she is not present and to keep in touch with his or her concerns.

3) A third option is that, during the preliminary consultation, the surgeon would spontaneously confirm and explain the use of the checklist.

The results of this study must be appreciated while keeping some limitations in mind. Respondents consist largely of members of patients' organizations;

consisting of dedicated and committed individuals with a strong involvement in their care. This could possibly result in a more critical attitude towards quality and safety of care. Further, a large group of respondents (36.3%) reported to be confronted with surgical complications. This could skew the results and call for cautiousness when generalising the findings. We also included clinicians in this sample. Their perception of quality and safety is undoubtedly influenced by their professional experience. However, we feel that it is important to include this group, as physicians and nurses can enter a patient role.

Conclusion

In conclusion, the data shows that respondents perceive the surgical safety checklist as a reliable safety tool. They don't mind the repetitive questions to verify their identity and procedure. However, hearing physicians and nurses discussing specific, explicit, risks could cause anxiousness in some patients. It is therefore the task of the hospital and its staff to create a supportive environment where patients can ask questions without hesitation. Only then we can create more involvement and empower patients to actively contribute in the creation of a safe hospital environment.

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Chapter 9

General discussion

“I do not pretend to teach you how, I ask you to teach yourself and for this I venture you some hints”

— Florence Nightingale —

An innovation is an idea, practice, or object that is perceived as new by an individual or other unit of adoption. It matters little, so far as human behaviour is concerned, whether or not an idea is 'objectively' new as measured by the lapse of time since its first use or discovery.[1] Introducing innovations is an essential part of quality improvement. In the context of patient safety, innovations are necessary to deprive care processes of avoidable risks. The purpose of this dissertation is to advance the understanding about the implementation of innovations to improve patient safety in hospitals.

Resulting from a thorough problem analysis — discussed in the introduction — we decided to focus on the implementation of surgical safety checklists in the operating theatre. These checklists can be considered an innovation because they introduce a new way of thinking and practice in the operating theatre. By means of seven separate studies, this dissertation aims at filling several gaps in the literature. In this closing chapter the empirical findings of each study are summarized and the main implications will be discussed. First, the research results — in response to the research questions — will be reviewed. Following, derived from these findings and the broader literature, possible implications for healthcare providers and hospital management are discussed. Finally, recommendations and suggestions for future research are provided.

Overview of empirical findings

RQ1: To what extent are surgical safety checklists effective tools to improve patient safety outcomes?

The first part of this dissertation aimed to assess the effectiveness of surgical safety checklists in improving patient safety. Safety checklists appear to be effective tools to improve patient safety in various clinical settings by strengthening compliance with guidelines, improving human factors, reducing the incidence of adverse events, and decreasing mortality and morbidity.[2] At the start of this dissertation several studies demonstrating the beneficial effects of surgical safety checklists were already published. However, a systematic review was lacking. The findings of systematic reviews — synthesis of published results while taking the methodological quality into account — are important in the context of evidence-based practice and policy recommendations. To address this gap, a systematic review and meta-analysis on the effectiveness of the WHO surgical safety checklists was preformed.

In **chapter 2** a systematic review and meta-analysis, evaluating the evidence regarding the effectiveness of the WHO surgical safety checklist in reducing postoperative complications, was reported. The Cochrane Library, MEDLINE, Embase and CINAHL databases were searched using predefined inclusion criteria.

The systematic review included all original articles reporting a quantitative measure of the effect of the WHO surgical safety checklist on postoperative complications. Data were extracted for complications reported in at least two studies. Seven of 723 studies identified met the inclusion criteria. There was marked methodological heterogeneity among studies. The impact on six clinical outcomes was reported in at least two studies. A meta-analysis was performed for three main outcomes: any complication, mortality, and surgical site infections. The results showed a significant risk ratios for all main outcomes: any complication (RR 0.59; 95% c.i. 0.47 to 0.74), mortality (RR 0.77; 95% c.i. 0.60 to 0.98), and surgical-site infection (RR 0.57; 95% c.i. 0.41 to 0.79). Yule's Q contingency coefficient was used as a measure of the association between checklist effectiveness (i.e., significant risk ratio) and adherence with the checklist. There was a strong correlation between a significant decrease in any postoperative complications and adherence to aspects of care embedded in the checklist (Q = 0.82; *P* = .042). Based on the results of the meta-analysis and quality appraisal of the included studies we concluded that the existing evidence is highly suggestive of a reduction in postoperative complications and mortality following implementation of the WHO surgical safety checklist, but cannot be regarded as definitive in the absence of higher-quality studies.

Following our systematic review, several other reviews were published. The results from these studies were always in line with our findings.[3-9] Although the totality of evidence is highly suggestive that standardization of care improves patient safety, it cannot be assumed that implementation of a checklist will automatically lead to improved safety. A recent large before-after study showed this concern to be relevant.[10] This study, published in the *New England Journal of Medicine,* concluded that obliged checklist implementation was not followed by a significant effect on postoperative mortality or complication rates. This study included a total of 101 Canadian hospitals with over 100,000 patients; and showed no reduction in mortality or postoperative complications. During 3-month periods before and after implementation of a surgical safety checklist a total of 109,341 and 106,370 procedures respectively were analysed. The adjusted risk of death during a hospital stay or within 30 days after surgery was 0.71 per cent (95% c.i. 0.66 to 0.76) before implementation of a surgical checklist and 0.65 per cent (95% c.i. 0.60 to 0.70) afterward (OR 0.91; 95% c.i. 0.80 to 1.03; *P* = .13). The adjusted risk of surgical complications was 3.86 per cent (95% c.i. 3.76 to 3.96) before implementation and 3.82 per cent (95% c.i. 3.71 to 3.92) afterward (OR 0.97; 95% c.i. 0.90 to 1.03; *P* = .29). The authors concluded that implementation of surgical safety checklists in Ontario, Canada, was not associated with significant reductions in operative mortality or complications. Soon after, a second large study from the USA questioned the effectiveness of surgical safety checklists.[11] This study showed that implementation of checklist-based quality improvement intervention in 14 participating centers was not

associated with improvements in surgical outcomes. Adjusted rates of superficial surgical site infection (3.2% vs 3.2%, *P* = .91), wound complication (5.9% vs 6.5%, *P* = .30), any complication (12.4% vs 13.2%, *P* = .26), and 30-day mortality (2.1% vs 1.9%, *P* = .32) at participating hospitals were similar before and after implementation. Difference-in-differences analysis accounting for trends in 15 nonparticipating centers and sensitivity analysis excluding patients receiving surgery in the first 6 or 12 months after program implementation yielded similar results. The authors concluded that the implementation of a checklist-based quality improvement intervention did not affect rates of adverse surgical outcomes among patients undergoing general surgery in participating hospitals. Subsequently, a debate whether or not the surgical safety checklist should be used followed. In the Flemish hospital community, the evidence supporting the use of the checklist was also questioned. This led to anxious questions from hospitals, and dark edged "fan letters" reached our mailbox. The reactions in response to these publications demonstrate how vividly a discussion about patient safety can become. Anyway, these reactions show the strong involvement of stakeholders in this discussion. This is probably also a reflection of the social importance of the broader issue of patient safety. From our expertise in this field, but also from our strong commitment to improve patient safety, we felt obliged to contribute to this discussion and to discard the results of the "*New England syndrome*" (i.e., seeing results published in high impact journals as the only truth, without consideration of context and study limitations) by reframing these studies and their results in the right context. This took shape as an opinion paper published in the respective journals of the Flemish professional association of surgeons (*Acta Chirurgica Belgica*)[12] and anaesthesiologists (*Acta Anesthesiologica Belgica*)[13]. In brief, an important limitation of these studies is a lack of detail regarding implementation and program compliance at participating hospitals. Multiple prior studies have reported associations between these details and checklist effectiveness. Without these details, in our view, these study cannot be seen as evidence that the checklist is not effective, but merely proof that the implementation is difficult and related to different contextual elements. So various reasons for not finding a significant effect can be attributed to multiple factors. Additional research is needed to understand why checklist implementation was not successful prior to further dissemination and implementation of this model to other populations.

Due to the rapid succession of literature on the effectiveness, compliance, and implementation of surgical safety checklist, an updated overview of the available literature is provided in **chapter 3**. Based on the current literature, corroborated by systematic reviews and meta-analysis, we concluded that surgical safety checklists have a positive impact on team communication and reduce postoperative complications — including mortality. Despite proven effectiveness, the implementation of surgical safety checklists is not straightforward. As surgical

safety checklists are in essence complex sociological interventions, they must be implemented using a team perspective. Key factors for the implementation of these checklists have been suggested in the literature, although, the most profound way of implementation remained unclear.

RQ2: To what extent is the WHO surgical safety checklist disseminated, adopted, and implemented in Flemish hospitals?

As mentioned earlier, the mere availability of evidence-based interventions is no guarantee for improvement. To be effective, surgical safety checklists must be used as intended. The literature shows a vast variation in the dissemination, adoption, and implementation of surgical safety checklist between hospitals.[3,4,14,15] Therefore, the objective of part II of this dissertation was to describe the dissemination, adoption, and implementation of surgical safety checklists in Flemish hospitals.

In contrast to usual practice, first the constraints and limitations of part II will be discussed. This section is limited to a single chapter describing the the adoption rate of surgical safety checklists amongst Flemish hospitals and the modifications made to the surgical safety checklist. The absence of other chapters is not the result of laziness nor intentional neglect. Actually, a thorough analysis of checklist implementation and program fidelity were been included in the initial research proposal. Ironically for a PhD on implementation issues, this plan was not implemented as intended. The reason why will become clear in the following sentences, but first I want to reflect on some methodological considerations when measuring checklist fidelity. Correct use of the checklist is achieved through an interactive collaboration between physicians and nurses. Hence, evaluation of checklist implementation cannot be limited to verifying whether checklists are ticked off. In the absence of direct monitoring by observation the true compliance is unknown. From a methodological point of view, this observation is done best without prior knowledge of the physicians and nurses who are subject of observation. The so-called Hawthorne effect will indeed lead to different behaviour whereby positive observation bias arises. A study of hand hygiene clearly shows that this concern is real.[16] In order to minimize bias, we opted for clandestine observations. A new method to observe checklist usage in the operating theatre was developed. In brief, the intended observation method would be preformed by nursing students guided by an observation form. Unfortunately, the necessity an appropriateness of this approach was not recognized by the ethical advisory boards. The members of the advisory board opted for a written informed consent of all the physicians and nurses prior to observation. This suggestion introduced an important practical issue. Because checklist fidelity should be observed in the context of communication and teamwork it would be impossible to observe the checklist usage if one of the physicians or nurses did not wish to participate in the study. Based on this practical issue and the knowledge that the alternative would

result in data biased by the Hawthorne effect, it was decided not to proceed with this methodology. Research needs to be conducted in order to expand current knowledge. If you — from the start of a research project — know that your results will not reflect the reality your are trying to describe in a reliable way, it seems irresponsible to invest time and resources.

Based on the literature, it is know that a growing number of organisations — worldwide — are endorsing the use and implementation of the WHO surgical safety checklist. The current guidelines allow — even encourage — modifications to the checklist in order to fit local workflow. However, this might have lead to a variety of checklists in terms of their content. Some of these modified checklists will be used under the pretend of the WHO label while bearing little or no resemblance to the original checklist. This highlights the importance of knowing what modifications are made by hospitals. As the literature does not provide any data on this, **chapter 4** aimed to describe the adoption rate and modifications made by hospitals by conducting a content-driven evaluation of the surgical safety checklists used in Flemish hospitals. An online survey was used to find out which checklists are used. An expert panel conducted a content-driven evaluation of the retrieved checklists by verifying the presence of the WHO items and evaluating any modifications made. All 36 hospitals participating in the survey reported the use of a surgical safety checklist. Based on self-report, 69.4 per cent (n = 25) of hospitals reported to use all WHO items. The expert panel determined that 17.1 per cent (n = 6) of checklists included all WHO items. Inclusion ranged from 7 to 22 items (*M* = 16.6, SD = 4.48). Detailing on the functional parts of the checklist, 48.6 per cent (n = 17) of checklists contained all sign-in items, 25.7 per cent (n = 9) contained all time-out items and 37.1 per cent (n = 13) enclosed all sign-out items. Sixty per cent (n = 21) of checklists added items not mentioned in the original WHO checklist. In conclusion, the modifications made to the WHO checklist vary between hospitals. Only a small number of hospitals included all 22 WHO items. It is unknown whether these modified checklists will be equally effective in decreasing mortality and the number of postoperative complications. More detailed recommendations and guidance regarding the modification of the WHO surgical checklist is required. It is unclear which items of the WHO surgical safety checklist are most crucial for producing its associated benefits. Thoughtless modification, especially removing items, can potentially lead to reduced effectiveness of the surgical safety checklist.

RQ3: What factors and underlying mechanisms influence the implementation process of a surgical safety checklist in the operating theatre?

In the third — and last — part of this dissertation, we try to contribute to the unravelling of the implementation problem. Both quantitative and qualitative

approaches were applied to answer the question why the implementation of the surgical safety checklist appears to be so difficult.

In **chapter 5** we aimed to obtain a better understanding of the user-related barriers against, and facilitators for, the implementation of surgical safety checklists by conducting a qualitative systematic review of the qualitative literature. We searched MEDLINE for articles describing stakeholders' perspectives regarding, and experiences with, the implementation of surgical safety checklists. The quality of the papers was assessed by means of the Qualitative Assessment and Review Instrument. Thematic synthesis was used to integrate the emergent descriptive themes into overall analytical themes. The synthesis of 18 qualitative studies indicated that implementation requires change in the workflow of healthcare professionals as well as in their perception of the checklist and the perception of patient safety in general. The factors impeding or advancing the required change concentrated around the checklist, the implementation process and the local context. We found that the required safety checks disrupt operating theatre staffs' routines. Furthermore, conflicting priorities and different perspectives and motives of stakeholders complicate checklist implementation. When approaching the checklist as a simple technical intervention, the expectation of cooperation between surgeons, anaesthetists and nurses is often not addressed, reducing the checklist to a tick-off exercise. The complex reality in which the checklist needs to be implemented requires an approach that includes more than eliminating barriers and supporting facilitating factors. The science and practice of implementation need to be connected with hospital leadership and implementation leaders must facilitate team learning to foster the mutual understanding of perspectives and motivations, and the realignment of routines. This chapter provides a pragmatic overview of the user-related barriers and facilitators upon which theories, hypothesising potential change strategies and interactions, can be developed and tested empirically.

The objective of **chapter 6** was to understand and compare clinicians' perceptions and attitudes towards the surgical safety checklist and patient safety in general. We applied a cross-sectional survey design among a voluntary sample of clinicians (including surgeons, operating room nurses, anaesthetists, and nurse anaesthetists) actively working in operating theatres of four Flemish hospitals. We designed the survey to investigate surgical team members' perceptions and attitudes towards patient safety and surgical safety checklists. The results of this chapter show that, despite the positive a perception and attitude, the surgical safety checklist is not so easy to implement. If and how the checklist will be used is affected by a plethora of factors. As our data shows, variation is more pronounced between hospitals compared to professional groups. This means that the overall hospital context (i.e., structure and culture) plays an important role in the specific barriers and facilitators for implementing. Therefore, it is difficult to make universal recommendations. The implementation strategy must be tailored

to the local hospital context, in which the mechanisms linking these factors probably play a more important role that the factors themselves. Throughout the results, it becomes clear that teamwork plays a crucial role. Further, the results demonstrate that despite positive individual perceptions, translation into a collective behaviour seems to be an ongoing challenge. The role of leadership — both formal and informal — can play a determining role in the promotion of use and usefulness towards the goal of gaining acceptance amongst healthcare professionals and raising compliance in order to create a safe environment for patients and employees.

In **chapter 7** we sought to explorer and understand stakeholders' experiences. To achieve this, it was appropriate to take a qualitative, inductive approach.[17] Specifically, grounded theory methodology was chosen as it is suitable for studying social processes in areas where little explanatory theory or knowledge currently exists.[18] Individual interviews and focus groups were conducted — using a semi-structured question guide — to explore nurses, anaesthesiologists, surgeons, and implementation team members' views. A total of 60 clinicians were interviewed. We found three mechanisms that play a role in the implementation of the surgical safety checklist. First, the literal focus on the content and application of the checklist makes it difficult to apply the new way of working in existing routines. Second, the introduction of the checklist disrupted the existing routines in the operating theatre. Consequently, there should be more time and energy spend on the implementation of the checklist. From the literature we learn that the use of team learning shows encouraging results. Last, it was found that respondents perceived the expectation to preform the checklist would conflict with other organisational priorities (e.g., efficiency). Patient safety should therefore be set as an institutional priority by formulating and disseminating a formal safety policy. It is expected that such a formal policy — when supported by hospital management — will ease decision making in favour of the checklist when other priorities hamper it's execution.

In **chapter 8** we sought to explore the views patients have towards surgical safety in hospitals — with an emphasis on surgical safety checklists. As described in previous chapters, individual and collective willingness to use the checklist depends — at least partially — on physicians' and nurses' perceptions of the checklist. One aspect forming this perception are the concerns around the patients experience and perception. The fear of causing additional anxiety for the patient lead to the omission of the items perceived as causing stress in patients or performing of the checks without verifying out loud. As a secondary aim, we explored if previous experience of error in hospital or other experiential/patient characteristics influence these views. An observational, cross-sectional, study design was applied by using an online questionnaire. Participants were recruited from the Flemish Patients' Platform network and social media between June and October 2015. An 11-item online questionnaire was designed to assess the

following constructs: perception of surgical safety (two items), attitudes towards the WHO surgical safety checklist (five items), and attitudes regarding how the checklist is used in practice (four items). A total of 444 patients participated. The respondents' view on the risk of an adverse event showed considerable variation. Perceived risk of an adverse event during surgery was influenced by the previous experience of an adverse event and the respondents' education level. Risk perception of an adverse event during a hospital stay was influenced by the respondents' education level and gender. Respondents were positive towards the checklist, strongly agreeing that it would impact positively on their safety. However, this positive perception did was not reflected in an attitude where patients actively inform themselves by asking whether the checklist will be used. Being active as a clinician reinforced this perception and attitude. The majority of respondents have no difficulty in the repetitive verification of items such as identity, type and location of the surgery. Respondents with a clinical background showed to be least anxious. Views were divided regarding hearing discussions around blood loss or airway problems. In general, respondents perceived the surgical safety checklist as a reliable safety tool. They don't mind the repetitive questions to verify their identity and procedure. However, hearing physicians and nurses discussing specific, explicit, risks could cause additional anxiousness for some patients. It is therefore the task of the hospital and its staff to create a supportive environment (e.g., a pre-operative pathway) where patients can ask questions without hesitation. Only then we can create more involvement and empower patients to actively contribute in the creation of a safe hospital environment.

Practical implications

Reading this dissertation can be useful for practitioners and hospital executives as it underlines the importance of contextual elements and includes several suggestions on how the WHO surgical safety checklist can be applied to improve patient safety. Apart from that, our findings also have policy implications for regulators and employers' organizations.

Our findings show that the WHO surgical safety checklist has an added value in patient safety management. By reviewing — together as a team — a minimum set of safety issues before performing critical steps in a process, the probability of error can be significantly reduced. Consequently, this will result in a reduced number of preventable adverse events. Checklists provide an answer to unintentional errors caused by human factors. If used properly this way of working allows to recognize irregularities in a timely manner without disturbing usual workflow. It strengthens the resilience of a team. The use of safety checklists in clinical practice should be encouraged and strongly supported by hospital

leadership. Preferably, this way of working should be introduced during basic training of physicians and nurses. **Educational institutions should introduce the use of checklists during training and simulation exercises**. One of the fundamental cornerstones for more safety is the educational and training system. However, training is largely focused on their discipline-specific field. During a large part of their internship trainees in health professions often work as individuals in an unsupervised environment. Despite the risks of that approach for the patients there is also limited attention to interprofessional education and learning, although the care of individuals with complex and/or chronic problems is most appropriately accomplished through interprofessional models of healthcare delivery. One of the recommendations of the "To Err Is Human" report was therefore: "*Restructuring clinical education to be consistent with the principles of the 21st-century health system throughout the continuum of undergraduate, graduate and continuing education for medical, nursing and other professional training programs and the assessing the implications of these changes for provider credentialing programs, funding and sponsorship of education programs for health professionals*".[19] New ideas and input for the education and training model for healthcare professionals are needed as the traditional way is not successful enough to bridge the gap with the safety challenges in healthcare. New ideas have already been initiated in the second report of the Institute of Medicine (Institute of Medicine, 2001). But important aspects of the US diagnosis are applicable to our education and training models:

- Lack of funding to review curriculum and teaching methods and of resources to make changes in them.
- Emphasis on research and patient care, with little reward for teaching. Need for faculty development to ensure that faculty are available at training sites and able to teach students effectively.
- Decentralized structure in medical schools, with powerful department chairs
- No coordinated oversight across the continuum of education and fragmented responsibilities for undergraduate and graduate education, licensing, certification, etc.
- Difficulty in assessing the impact of changes in teaching methods or curriculum.

Traditional methods of continuing education and training for health professionals — such as formal conferences and dissemination of educational materials — have been shown to have to little effect by themselves on changing clinician behaviour of health outcomes (Institute of Medicine, 2001). Furthermore there is too little focus on certification. Given the expansiveness and dynamic nature of the science base in healthcare, the education and training models should be expanded to

teach how to manage knowledge and use effective tools that can support clinical decision making on evidence based knowledge, multidisciplinary and teamwork, new skills and communication techniques to support patients in their self-management, etc. New technologies for training and certification became available.

Further, our research shows that — despite the available evidence — the concept of safety checklists has not yet been penetrated and embedded in the DNA of hospitals. All participating hospitals make use of a surgical safety checklist. Although, some of the modifications could be questioned. To data, we only have scientific proof that the checklist, with its 22 items, has a beneficial effect. We realize that the precise contribution of individual checklist items to the patient safety challenge is still unclear; and we also recognize the importance of modifications to fit the checklist into the local way of working. But what we do not advise is the unsubstantiated freedom with which some items have been deleted. The omission of checklist items based on poorly substantiated consensus is not a good guide. Modification of the checklist should be evidence based. Following our grounded theory study, we found that certain items are to be seen literally. Because of this they lose meaning in the context in which they are applied. The most prominent example is the monitoring of the presence and operation of a pulse oximeter. In our Western context, it is almost unthinkable that surgery starts without the presence of a pulse oximeter. But the underlying intent of this item is to interpret according to our broader: the necessary monitoring is available to perform the surgery as safe as possible. **We therefore propose to modify the content of the checklist.** Whereby we can not simply omit items, we need to reframe them. We should adhere to the underlying intention of the safety checks and translating the underlying intention in accordance with the local context — without losing connection with the local way of working.

When implementing the checklist in practice, we expect that all team members briefly stop their own work and — together as a team — synchronise the available information. This process is controlled by a list of items of which we know that they contribute significantly to the occurrence of errors in the perioperative context. Despite how simple this team activity seems, the actual realization in practice is a major challenge. As mentioned earlier, the checklist is essentially a complex social and team intervention. The difficulties in the implementation of a surgical safety checklist are diverse and context-dependent. This takes place in a complex adaptive system in which small changes in the context may change the relationship between the barriers and facilitators. This complex adaptive process makes it difficult to isolate specific factors for implementation teams to focus on. In addition to the existing literature, the empirical findings in this dissertation provide additional insights. Throughout the chapters of this dissertation is becomes clear that full implementation of the surgical safety checklist is dependent on leadership support. Managers need to develop a context — in

alignment with the clinicians — where the effective integration of the checklist is encouraged and barriers are removed systematically. Hospital management must **institute a formal patient safety policy**. This policy must be fully supported and maintained throughout all levels of the organization. Patient safety needs to be an explicit part of the organizational culture of the hospital and it needs to be clear to everyone that patient safety is a priority within the hospital. This will create a context in which it is safe for individuals to express their concerns when confronted with patient safety issues. A second leadership level is from the clinical perspective. The exemplary behaviour of the leading stakeholders in the operating theatre will further perpetuate the formal patient safety policy in practice. This has also been recognised in the literature.[20-22]

But there will be no simple solution available. Therefore, we cannot conclude with broadly applicable recommendations. Instead, we want to stimulate the search for solution by proposing assumptions arising from the above-mentioned theories and ideas: "*People don't change; they evolve while adapting to changing circumstances.*" This assumption implies that implementation programs must not aim to changing individuals; instead they must create a context supportive to individual and team evolution during adaptation to the changes needed for the innovation to become part of daily routine. This requires constant evaluation of program fidelity and resilient implementation strategies. Achieving this, requires an integrated approach including the perspective of the individual, the team, the organization. Success will be largely be determined by integration of these different dimensions. Realising and facilitating this integration is an important expectation of the leadership — both the operating room and throughout the organization.

Another suggestion is to make use of the experiences and insights from checklist development and implementation in non-medical, high reliability organisations. Inspiring examples can be found in aviation-style training for surgical teams [23] or the use of Formula 1 pit-stop and aviation models to improve safety and quality for patient handover from surgery to intensive care [24]. Studies in these contexts show that to achieve checklist acceptance and compliance, there must be a predefined need for which a checklist is considered a well suited solution. The end-users ("sharp-end") are the key stakeholders throughout the development and implementation process. Proximity and ownership must be assured through a thorough and wise process. All informants underlined the importance of short, self-developed, and operationally-suited checklists. Simulation is a valuable and widely used method for training, revision, and validation.[25] This fits perfectly with the promising use of team training in healthcare.[26-30] Both simulation and classroom-based team-training interventions can improve teamwork processes (e.g., communication, coordination, and cooperation), and implementation has been associated with improvements in patient safety outcomes. Larger effect sizes were reported for bundled team-training interventions that included tools and

organisational changes to support sustainment and transfer of teamwork competencies into daily practice.[31] Some have argued that team training (e.g., CRM) does not change behaviour or patient outcomes by itself, yet changes how participants think about errors and risks. This indicates that CRM requires a combination with other initiatives in order to improve clinical outcomes.[32] In recent years, research using diverse methodological approaches has led to significant progress in team research in healthcare. The challenge for future research is to further develop and validate instruments for team performance assessment and to develop sound theoretical models of team performance in dynamic medical domains integrating evidence from all three areas of team research identified in this review. This will help to improve team training efforts and facilitates the design of clinical work systems supporting effective teamwork and safe patient care.[33]

Limitations

Methodological limitations of the individual studies are addressed in the respective chapters. Here we provide some general considerations of the limitations and restrictions of this dissertation. First, we discuss some remarks regarding the samples of the included studies. To obtain relevant input, we were depending on the commitment of physicians and nurses willing to share their story with us. It was — as expected — difficult to motivate clinical staff to participate in the various parts of this research. Which inevitably translated into relatively small sample sizes. The low motivation to participate in research on the checklist probably reflects the underlying perception in the population. Second, the biggest shortcoming in the grounded theory study was the lacking of input from surgeons with a pronounced negative attitude towards the checklist. Many of the participating surgeons had their reservations about checklists and its use, but were to some extent still positive towards the initiative in its broader context. The absence of such negative voices could have influenced our findings. As a result, other factors and mechanisms relevant for this group of clinicians may remain underexposed in our analysis. The factors and mechanisms underlying the formation of perception by surgeons could certainly be further explored. However, the contribution of physicians both pro and contra the use of the checklist are required. It is difficult to motivate clinicians to participate in a study on something they regard as not important. Third, this dissertation lacks insight into the effective usage of the surgical safety checklist in Flemish hospitals. The reason for this has already been described in detail.

Concluding note and suggestions for further research

A first and important step to reduce the number of preventable adverse events is to standardize work processes. The probability that crucial steps are omitted or performed at the wrong time during a certain procedure has to be reduced. The easiest way to support healthcare professionals in remembering these crucial steps is by using checklists. Checklists help to identify preventable errors before things go wrong. Checklists, however, have to be tailored to the local context. On the one hand, they have to be as comprehensive as possible, on the other hand they should be short and clear. The WHO allows and promotes modification of the surgical safety checklist — to suit to the local needs of the hospital or specific discipline related issues — as long as the original items are included. Participation of all team members in this process is of key importance to ensure a sense of urgency and ownership. In the light of a new model for hospital inspection, the Flemish government advocated the mandatory use of the WHO surgical safety checklist (enforced since March 2013). The latter is — in mutual communication, and lasting acceptance among the professionals — appropriate to obtain an overall implementation. Above, implementation of the surgical safety checklist is also an accreditation standard for hospitals. Here, the need to structurally embed 'quality & safety' as an strategic issue into the hospital governance DNA. Most hospitals currently employ some form of checks in their operating theatre as part of a safety protocol and there appears to be some general conservative resistance among staff to adapt a new system. Frequently, surgical teams report that the checklist is merely an administrative exercise to meet accreditation standards. Although all Flemish hospitals currently mention to use a surgical safety checklist, personal communication with surgical teams learns us that while most healthcare professionals are aware of the surgical safety checklist, it is not being used systematically and often performed inadequate. The latter demonstrates that the overall introduction of the surgical safety checklist involves many challenges, as it requires changes in daily practice and in the organisational culture.

Therefore, the question today is not whether checklists are effective, but how we can ensure that physicians and nurses use these instruments accordingly. Although the general tendency seems quite simple, the vast majority of hospitals are struggling with effective checklist implementation. Part 3 of this dissertation elucidates that there are several barriers and facilitators influencing the implementation of checklists. Further, the individual importance of these factors varies depending on the context. Even more important than an overview of influencing factors, are the complex mechanisms and interactions in the context wherein the checklist is implemented. From complex adaptive systems theory we learn that these relationships are not unwavering, but rather sensitive to small changes in the context in which they occur. Therefore, future investigation will have to deal with this complex reality. This requires the application of research method that go beyond the capture of a static story. The complex reality is often described using cross-sectional surveys, making important nuances remain

underexposed. In addition to these static vision we need methods (e.g., action research) that take into account the complex iteration between agents, factors, etc.

There are several solid reasons suggesting that the safety of surgical care is improved following the implementation of a surgical safety checklist. Nevertheless, some essential considerations should be kept in mind. In order to be effective, the checklist needs to be implemented and used according its intentions. In the beginning of the checklist movement, it was suggested that treating this tool as tick-box exercises may lead the field astray. Logically, it is not the act of ticking of boxes that reduces the risk for adverse events, but the performance of the actions it calls for. Checklists contain not only technical elements, but important socio-adaptive ones as well. Technical elements, such as administration of antibiotics before incision, are discrete and easy to implemented. Socio-adaptive elements, such as the time-out procedure to discuss critical steps, involve more than simple actions. They require strong engagement of all team members. As most items of the surgical safety checklist act as a trigger to engage teamwork and communication, implementation efforts must consequently address the social interaction between humans. Checklist items like the introduction between team members, or reviewing critical steps such as assumed blood loss, etc., will achieve no benefit if done merely as tick-box exercises.[34] From this perspective, the Ontario study demonstrates how we not only need studies evaluating checklist effectiveness, but also studies that identify the underlying factors and mechanisms to effective implementation. A study from the Netherlands demonstrated the association between completion of the surgical safety checklist and post-operative death.[35] Full checklist completion resulted in statistically significant mortality reduction compared to partial or non-compliance with the checklist. As such, it is postulated that improvements obtained after implementation of the checklist might have arisen from enhanced teamwork, communication, as well as attitudes related to patient safety culture in the complex entity that is the operating theatre environment.[35,36] So, the benefits of the surgical safety checklist will be realized only if everyone is supportive to the change and if implementation is strict and robust. Sometimes it is argued that the use of a simple checklist might conflict with the perception of a healthcare professionals' own performance. Indeed, the surgical safety checklist will not improve individual performance. It will not make you a better surgeon, anaesthesiologist, or nurse. What it mainly does is improving team performance by anticipating potential risks in the surgical process. The idea to take a one minute break, rethinking previous actions and reflect on some forthcoming steps is essential in a complex environment.

Often it is argued that the use of the surgical safety checklist might be superfluous in low-tech and less complex surgical procedures (e.g., cataract surgery) as it is unlikely to see immediate large benefits due to the predominance of low mortality

and low morbidity procedures. However, checklists need to be seen as more than another obliged form or paperwork, and viewed instead as a element of a systems approach towards improved patient safety. Adoption of technology (e.g., surgical safety checklist) and principles (e.g., crew resource management) to enhance patient safety has also much to offer to minor risk surgery. Whilst, for instance, no significant reduction in overall postoperative mortality or complications can be reached, noticeable improvements in the safety processes (e.g., timely use of prophylactic antibiotics) can be obtained. Next, inefficient hospital resources, a lack of expertise in change management, in gathering data, in coaching, and in providing teamwork training and the appropriate use of the surgical safety checklist may hamper implementation. Here, learning from colleagues or from best practices might be inspiring. Communication concepts taught in a single lesson or as an isolated message in an attempt to resolve the existing compliance problem will be insufficiently. The way our hospitals are organized demands for new ways to learn and understanding. New ways of educating clinicians, as individual professionals and as multidisciplinary teams require innovative ways of teaching. The use of e-learning, simulation, and realistic team-based communication trainings could be valuable in this context and have already shown to effectively improve communication skills in the operating theatre.[27,29] Last, one should keep in mind that improving patient safety requires long-term efforts and continuous investments, so it is not surprising that promising innovations such as the surgical safety checklist will only be adopted stepwise.

In conclusion, working according to proven standards of care will help surgeons, anaesthesiologists, nurses, and other surgical team members to cope with the increasing complexity. The use of a safety checklist —such as the surgical safety checklist — in a rapidly changing environment will consolidate all team members aims and enhance both patient safety and clinical professionalism. Hence, there is a need for the development of a supporting context — with an important role for the leadership, both in the operating theatre and in the broader context of the hospital management. Patients have a right to the safest care possible, anticipating avoidable risks is an obvious expectation in this context. The WHO surgical safety checklist provides a relatively simple instrument to improve the safety of the perioperative surgical process. Despite the obvious expectations regarding the use of a checklist, implementation in practice is more complex than imagined. The fact that implementation in practice, for many reasons, is more difficult than expected can not and should not, be an excuse to lower safety standards. On the contrary, this fact should encourage all concerned — both in the operating theatre and in the broader context — to embrace patient safety as a priority. Only when all stakeholders, together, organise a system to systematically measure, monitor, and improve the care processes patient safety can be structurally ensured. Only in such a context will patient safety interventions, like the checklist, be able to effectively realize true added value.

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Nederlandstalige samenvatting

"Naar schatting één op vijf patiënten die een operatie ondergaat, loopt het risico op een complicatie. Een groot deel van die complicaties valt te vermijden door het gebruik van onder meer zo'n checklist. Sterker nog: een checklist redt mensenlevens", zegt prof. dr. Dominique Vandijck, verbonden aan de onderzoeksgroep Patiëntveiligheid, & gezondheidseconomie & zorginnovatie van de UHasselt.

De Wereldgezondheidsorganisatie (WHO) lanceerde in 2007 haar safe surgery-programma, waarvan de zogenaamde surgical safety checklist een onderdeel vormt. De lijst bestaat uit 22 items (onder meer: 'Is het nodige beeldmateriaal aanwezig?', 'Heeft de patiënt een gekende allergie?' …) die een operatieteam tijdens drie verschillende fases (voor de anesthesie, voor de incisie en bij afloop van de ingreep) zou moeten controleren. Dankzij de WHO-checklist krijgt elke zorgverlener binnen het operatieteam een duidelijk zicht op wie wat doet en voor wat verantwoordelijk is. "En dat is ontzettend belangrijk, want een operatie is een complexe gebeurtenis, met heel wat uiteenlopende handelingen. De identiteit van de patiënt moet gecontroleerd worden, het aantal kompressen geteld, de juiste operatiezijde gemarkeerd … Als je er als zorgverlener verkeerdelijk van uitgaat dat een collega een bepaalde handeling al gesteld heeft, dan kan dat de veiligheid van de patiënt in het gedrang brengen", zegt UHasselt-onderzoeker Jochen Bergs. "De oorzaak van complicaties tijdens of na een operatie is doorgaans niet te wijten aan gebrekkige kennis of kunde van het operatieteam."

8 op 100 patiënten

Maar de 'operatiechecklist' levert wereldwijd de nodige discussiestof op: zorgverleners zijn het er nog al te vaak niet over eens of het wel noodzakelijk is om die checklist te hanteren. UHasselt-onderzoekers focusten in hun studie dan ook op het effect van het gebruik van deze WHO-checklist op het aantal vermeden complicaties en overlijdens. Samen met de beroepsverenigingen voor chirurgen, anesthesisten en operatieverpleegkundigen analyseerden ze de resultaten van alle beschikbare studies rond dit onderwerp. "Ons onderzoek toont aan dat, vóór de WHO-checklist, gemiddeld 17 op 100 patiënten complicaties kregen die verband hielden met de chirurgische ingreep. Het gebruik van de checklist halveert dit aantal, naar 8 op 100 patiënten", aldus Jochen Bergs.

Onvolledige checklist

De checklist voor veilige heelkunde van de Wereldgezondheidsorganisatie (WHO) wordt slechts in een minderheid van de Vlaamse operatiezalen nauwgezet opgevolgd. Dat blijkt uit een studie van de onderzoeksgroep Patiëntveiligheid, Gezondheidseconomie en Zorginnovatie van de Universiteit Hasselt. "Hoewel 70 procent van de ziekenhuizen aangeven dat ze de checklist gebruiken, bleek na

analyse dat slechts 17 procent van de ziekenhuizen alle WHO items in hun checklist opnemen", aldus Jochen Bergs.

Van de 36 deelnemende ziekenhuizen gaf 70 procent aan de volledige checklist te gebruiken. Maar na analyse van de checklists door een groep van experts, bleek dat slechts zeventien procent van alle ziekenhuizen alle WHO-items in hun checklist hadden opgenomen. "De checklist bestaat uit drie groepen van items, met betrekking tot een fase van de operatie", verduidelijkt Jochen Bergs. "Ziekenhuizen bleken slechts een gedeelte van de bijhorende items in hun checklist op te nemen: van de stappen voordat de patiënt in slaap wordt gedaan (50%), voor het insnijden (25,7%) en voordat de patiënt de operatiezaal verlaat (37,1%)." Het opnemen van alle items zou nochtans complicaties met grote gevolgen kunnen voorkomen. "Eén derde van de ziekenhuizen (37,1%) heeft het item 'vragen naar identiteit, toestemming, type van operatie en operatiezijde' niet volledig opgenomen en ook de verbale telling van het gebruikte materiaal voor het sluiten van de operatiewonde blijkt in de helft van de ziekenhuizen niet opgenomen in de checklist", zegt Jochen Bergs nog. "Het achterblijven van materiaal zoals een kompres of een naald in het lichaam is nochtans geen onbelangrijke complicatie."

Implementatie is moeilijk

"Het bewijs over het nut van de checklist veilige heelkunde is sterk, maar een sluitend gebruik ervan blijkt niet vanzelfsprekend", zegt prof. dr. Dominique Vandijck. "Maar ondanks de grote inzet van het ziekenhuispersoneel en de ontwikkelingen op vlak van behandelingen, moeten we blijven streven naar betere en veiligere zorg." Het implementeren van dit — op zich eenvoudige — instrument blijkt in de praktijk echter niet evident. Dit was dan ook de focus van het onderzoek.

De resultaten van het onderzoek geven inzicht in welke factoren en mechanismen een rol kunnen spelen bij het implementeren van een innovatie in het ziekenhuis — in dit geval de checklist. De onderzoekers deelde deze factoren op in twee groepen: de factoren die de perceptie ten aanzien van de checklist beïnvloeden, en factoren die bepalen hoe makkelijk de innovatie ingepast kan worden in bestaande routines en manieren van werken. "Het belang van deze factoren en de mechanismes die hen verbinden zijn context specifiek waardoor het moeilijk is om één manier van implementeren naar voor te schuiven." Besluit Jochen Bergs.

Uit het onderzoek blijkt dat professionals moeten leren omgaan met deze nieuwe manier van werken, en dat is niet altijd makkelijk omdat het gebruik ervan bestaande routines verstoort en de verwachting om de checklist te gebruiken niet door iedereen gedeeld wordt. Hierdoor ontstaan er conflicten die liever vermeden worden. Dit toont aan dat er behoefte is aan een ondersteunende context — met een belangrijke rol voor de leidinggevende, zowel in de operatiekamer en ziekehuismanagement. Er is nood aan een ziekenhuis specifiek implementatie

plan met aandacht voor de juiste vertaling en aangepaste training in het gebruik ervan.

Operaties kunnen nog steeds beter en veiliger

Mede onder impuls van deze inzichten, heeft de Vlaamse overheid het gebruik van de checklist in de operatiekamer opgenomen in haar nieuw 'toezichtsmodel voor de ziekenhuizen. "Daarmee verplicht de overheid het gebruik van de checklist – een goede zaak voor de kwaliteitsdynamiek die zich reeds fors heeft ingezet in de zorgsector", besluit prof. dr. Dominique Vandijck.

De resultaten van dit onderzoek, bestaande uit zeven afzonderlijke studies, werden gepubliceerd in diverse toonaangevende tijdschriften zoals *The British Journal of Surgery* en *BMJ Quality and Safety*.

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