A study on effects of safety checklists emphasizing quality of complication data

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Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
2020

UNIVERSITY OF BERGEN

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Date of defense: 16.01.2020

Year: 2020

Title: A study on effects of safety checklists emphasizing quality of complication data

Name: Anette Storesund

Print: Skipnes Kommunikasjon / University of Bergen

Scientific environment

The scientific environment of this doctoral thesis was the Surgical Safety Checklist Study Group at the Department of Anaesthesia and Intensive Care at Haukeland University Hospital. The project is also a part of the Research group on Quality, Safety and Outcome after Surgery and Critical illness (ROSC) at the Department of Clinical Medicine, Faculty of Medicine, University of Bergen. This regional research project has been a comprehensive interdisciplinary project with multiple collaborators from the Neurosurgical Department, Orthopaedic Department, the Gynaecology Department, and the section of Cardiothoracic Surgery at Haukeland University Hospital, Health Trust Fonna, Haugesund and Førde Central Hospital. Parts of the work were conducted in collaboration with the Patient Safety Unit, Department of Research and Development, Haukeland University Hospital; Department of Surgery, Academic Medical Center, Amsterdam, the Netherlands; and Centre for Implementation Science, Health Service and Population Research Department, King's College, London, United Kingdom. The doctoral training and courses were carried out at the Postgraduate School of Clinical Medicine at the University of Bergen, Bergen, Norway. In addition, I was connected to the Regional Western Health Authority – Strategic Research Programme on Health Sciences hosted by the Centre of Evidence-based Practice, Bergen University College.

Funding acknowledgement

The PhD study has received scholarships from the Western Norway Regional Health Authorities, Strategic Research Programme on Health Sciences (grant number 911755), from the Western Norway Regional Health Authorities, Patient Safety Program (grant number HV1085 and HV1173) and from the Norwegian Nurses Association (grant number 15/0023).

To

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Acknowledgements

Many people have contributed with valuable insights to make this PhD work a grand journey. Thanks to all of you who diligently make the surgical pathway safe – every day! And to all of you in the Department of Anaesthesia and Intensive Care, the Department of Neurosurgery, Department of Orthopaedic and the Department of Gynaecology who utilised the pre- and post-operative surgical safety checklists (SURPASS) in addition to the WHO SSC (Trygg kirurgi sjekkliste). You have done and are doing a tremendous effort – and now we know that patient safety have improved significantly. This would not have been possible without you.

My greatest thanks goes to my main supervisor, Eirik Søfteland, for having a strong commitment to safety in health care and to always believing that it is possible to improve further. You have inspired and encouraged me through all these years, kept your door open and provided close cooperation in the Safe Surgery Study Group through the weekly Monday-meetings. I will always be grateful for being included. I also want to thank my co-supervisor, Arvid Steinar Haugen who led the way with the WHO SSC. You are constant positive, encouraging, open-minded and provide fruitful discussions. I want to thank my co-supervisor Hans Flaatten who included me in the Research group on quality, safety and outcome after surgery and critical illness (ROSC) at the Department of Clinical Medicine at the University of Bergen and taught me to fight and never give up when you have a strong belief in something, and to my co-supervisor, Monica Wammen Nortvedt for standing up for systematically reviewing the literature and evidence based practice – for daring and sharing.

Thank you all for taking me along, engaging and caring.

With thorough insights in biostatistics, Geir Egil Eide has guided the statistics, double-checked my statistical tests, and with enthusiasm, asked the tricky questions, involved in inter-professional discussions and contributed with valuable reflections.

Also, I am grateful for advices, support and facilitation of the project from the director of Department of Anaesthesia and Intensive Care, Hanne Klausen.

Further, I would like to thank all the contributors to our large project. First, for positive engagement from the former CEO, Stener Kvinsland. And then, for the other leaders to engage openly and volunteer to implement the comprehensive checklists intervention in their departments at Haukeland University Hospital: Torhild Næss Vedeler and Rupavathana Mahasperan at the Department of Neurosurgery; Lars-Oddvar Arnestad, Ove Furnes, Kjell Matre and Jonas Meling Fevang at the Department of Orthopaedics; Ingrid Johanne Garnes, Line Bjørge, Heidi Frances Thornhill, Ingebjørg Bøe Engelsen and Linda Ertzeid at the Department of Gynaecology. Also, a thank goes to Nils Sletteskog, Dagny Strand Klausen and Rune Haaverstad who participated and facilitated data collection from the Health Trust Førde, Health Trust Fonna, Haugesund, and the Section of Cardiothoracic Surgery, Department of Heart Disease respectively Haukeland University Hospital.

Further, many-many thanks goes to all of you who committed to proper checklist-involvement and implementation for their specialty, some as leaders, secretaries, educators and/or care-givers:

Neurosurgery – ward - May-Brit Sæbø Gundersen, Åse Humberset, Eirik Johansen, Kristine Farestvedt Helland, Birthe Tvedt, Guro Vik Kvalsund, Magnhild Tunes and Aqueel Asghar Chaudhry; operative area - Lisbeth Viken Aasarmoen, Siri Johansen, Randi Mjøs Hordnes, Nina Viborg and Eirik Søfteland.

Post Anaesthetic Care Unit: Elsa Hesjedal Wallestad, Elisbeth Øksland, Kristin Vesterli Hundven.

Orthopaedics: ward for adults - Linda Hjortland, Turid Kjenes, Roy Sørensen, Anette Amandussen Nitter, Astrid Skei Bakketun, Marit Instebø, Linda Wold, Kirsten Hauge, Anette Meyer; ward for children - Åslaug Eide, Hilde Eikemo and Hege

Veronica Floen; operative area - Kate-Elin Hopland Solvi, Geir Morken Nilssen, Vibeke Johanne Olsen Rydland and Unni Håskjold Larsen and Bjarte Askeland.

Gynaecology: ward -, Inger Lise Sivertsen, Ingjerd Buestad, Kristin Sætre, Mari Helen Hvidsten; operative area - Margunn Toftevåg, Kari Synnøve Robøle, Frøydis Lygren, Synnøve Mathisen, Berit Gogstad, Britt Iren Skeide.

Special thanks goes to our international collaboration with Marja A. Boermeester from the Amsterdam Medical Centre for sharing their experiences on implementing the SURPASS checklists with us, and involving in our research projects with insights, pinpointed questions, and the unique combination of surgical expertise and top-level research capacity. Also, a special thanks goes to Nick Sevdalis from the Kings College of London for sharp thoughts, exquisite skills to highlight novelty and elaborate like an editor.

Others have also contributed with valuable expertise. From the Information Technology Support Unit of the Western Regional Norwegian Health Authority, Harry Waldeland has extracted and provided extensive quality checking of the data. Thanks also to Thor-Ludvig Thorsen (Webport) for thorough extraction and quality checking of data. In addition, Øystein Eeg designed the electronic pre- and postoperative SURPASS checklists in Orbit, and have contributed with extraction of data in collaboration with Nils Eivind Widnes Johansen. And thanks to Yngve Bjørkevoll Lande for magic Excel-skills.

I would also give my thanks to Regina Küfner Lein, librarian at the University of Bergen's Medical library for her sharing mentality and skills with building up search strategies and reference management. No problems too small or big.

I am also very grateful for the full support and thumbs up from Stig Harthug and colleagues in the Patient Safety Unit in the Department of Research and Development at Haukeland University Hospital.

Also, special thanks goes to the experts of the Global Trigger Tool method who did a profound job in classifying patient harm through record review: Many thanks to Janecke Veim, Jorunn Kleiva and Gerd Gran from the Health Trust Bergen, and Kari Furevik and Wenche Beathe Sjåstad from the Health Trust Førde.

I would like to thank the Dutch Anaesthesiologist, Geert de Pater, who back-translated our 11 checklists from Norwegian to Dutch to get it validated from the SURPASS group.

Thanks to all the co-authors in the PhD-projects: Øyvind Thomassen, Guttorm Brattebø, Magnus Hjortås, Øystein Tveiten, Bjørg Merete Hjallen, Catrine Hjelle Størksen, Heidi Frances Thornhill, Gunnar Helge Sjøen, Solveig Moss Kolseth, Oda Kristine Sandli, Hilde Valen Wæhle, Geir Egil Eide, Rupavathana Mahesparan, Jonas Meling Fevang, Rune Haaverstad, Nick Sevdalis, Marja A Boermeester and my super-supervisors. The collaboration has been most inspiring!

Others who should have a fair share of my gratitude are: my former nursing head, Elsa Hesjedal Wallestad for requesting advancement of clinicians, safe practice and for making your staff blossom; Hilde Valen Wæhle for actually introducing me to the Safe Surgery Group and never gave up on convincing me that this was a great project; and to Pål Ove Vadset in the Department of Research and Development for facilitating the final destination of this PhD Marathon.

I have also been fortunate to learn from other PhD-fellows through presentations and intellectual discussions through meetings led by Tone Merete Norekvål at Centre for Clinical Research at Haukeland University Hospital, in addition to all the staff at the Centre for Clinical Research led by Ernst Omenaas. Thanks to the Journal Club - Brita, Hilde, Jannicke, Ranveig, Kristin, Eli and Stig. In addition, I have also been fortunate to experience regional collaboration and inspiration through active member in the Western Regional Norwegian Health Authorities Network for Patient Safety Research.

And last, but not least, I want to thank my family; to the love of my life Geir and Liv – thank you for your patience and keeping me on the track; my parents Gunbjørg and Nils Johan – who have always encouraged me and for being great examples - showing that hard work matters; my brother and sister in law Cato and Dasha; father, brother and sister in law Steinar, Per and Kari, nieces and nephews. And warm thanks to the rest of my family and friends who have been cheering and supporting – it has been most appreciated ;)

Abstract

Introduction: Despite increased focus on patient safety, complication rates in hospitals have remained unchanged with reports ranging between one out of twenty patients and one out of four patients, often related to surgery. However, half of the complications may be prevented throughout the surgical pathway. To inform and study effects of targeted patient safety interventions requires patient outcome data of high accuracy. Introduction of the World Health Organization surgical safety checklists (WHO SSC) has been reported to increase safety, also in our hospital.

Aims: The overall objective for the study was to investigate effects of using safety checklists on patient outcomes in medicine. Further, to evaluate effects of adding a validated Norwegian version of the pre- and postoperative parts of the SURPASS checklists in combination with the established WHO SSC on emergency reoperations, 30-day unplanned readmissions, 30-day mortality and length of hospital stay, in addition to verified in-hospital complications using a reliable and validated method.

Methods: In the first study, we conducted a systematic literature search in Cochrane Library, MEDLINE, EMBASE and Web of Science on effects on patient outcomes of using safety checklists in medicine. Following the PRISMA guidelines ensured transparency of reporting. The studies were eligible if they quantitatively reported possible effects of using safety checklists.

In the second study, validation of a Norwegian version of the pre- and postoperative SURPASS checklists in combination with the established WHO SSC was performed in one neurosurgical department. Adaptation and validation of the new checklists were in accordance to guidelines from the WHO included forth- and back translation, testing the content in clinical practice, focus groups, expert panels, and final approval of the checklists.

The third study used a prospective observational design to investigate complications in surgical admissions using two different methods. Utilising the Global Trigger Tool

(GTT) and the International Classification of Diseases 10th version (ICD-10) identified and verified in-hospital complications in the same admissions with GTT appointed as the reference standard. Tests were performed to investigate strength of method agreement of estimating complications.

In the fourth study, the validated pre- and postoperative SURPASS checklists were implemented as an add-on to the established WHO SSC using a Stepped Wedge Cluster Controlled Trial (SWCCT) design in three surgical clusters, each serving as their own controls (neurosurgery, orthopaedics and gynaecology) in one hospital. One separate department in the intervention hospital and two external hospitals without new checklists constituted parallel controls. Effects on verified in-hospital complications, emergency reoperations, 30-day readmissions, 30-day mortality and length of hospital stay were investigated over 29 months from November 2012 through March 2015.

Results: Thirty-four studies met the inclusion criteria of the systematic review of the literature showing improvements in four groups of patient outcomes: morbidity and mortality; adherence to guidelines; human factors; and adverse events. None of the included studies reported on checklist use resulting in decreased patient safety (Study I).

Translation of the pre- and postoperative SURPASS checklists in combination with the WHO SSC was completed and reached face validity. Testing of the content was performed for 29 neurosurgical procedures with all checklist users (ward nurse and physicians, surgeons, anaesthesiologists, operating theatre nurses, post-anaesthetic care unit nurses, and discharging physicians and nurses). Focus groups revealed that wording needed to be adapted to clinical practice and that checklist items challenged existing workflow. The expert panels scored content validity to > 80 %. All the steps involved adjustments to the checklist content. The final back translated SURPASS checklist version was approved by the Dutch copyright holder (Study II).

In 700 random surgical admissions complications were identified in 30.3 % (298/700) using the GTT method. Extracted ICD-10 codes indicating a complication yielded a rate of 47.4 % (332/700) in the same admissions. However, when excluding ICD-10 codes representing conditions present on admission, in-hospital complications were verified for 20.1 % (141/700) of the admissions. After the verification procedure, agreement of complications between findings using both methods increased from 68.3 % to 83.3 % (Study III).

The fourth study compared 3,892 before and 5,117 procedures after the pre- and postoperative SURPASS checklists implementation in intervention clusters. In addition, investigations of 9,678 surgical procedures in parallel control hospitals were performed. Crude analysis of in-hospital complications showed an increase of complications from 14.7 % to 16.5 % (p=0.025). However, in-hospital complications decreased in adjusted intention to treat analyses (Odds Ratio (OR): 0.73; 95% Confidence Interval (CI): 0.54 to 0.98; p = 0.035). Logistic regression on effects of the SURPASS checklists, show a significant decrease in in-hospital complications (OR: 0.70; 95% CI: 0.50 to 0.98; p = 0.036) and emergency reoperations (OR: 0.42; 95% CI: 0.23 to 0.76; p = 0.004) with full compliance to the preoperative SURPASS checklist in adjusted analysis. With obtained full compliance to the postoperative SURPASS checklists 30-day readmissions were decreased (OR: 0.32; 95% CI: 0.16 to 0.64; p = 0.001) in adjusted analysis. Thirty-day mortality and length of hospital stay remained unchanged. For parallel control hospitals, the in-hospital complications increased, whereas emergency reoperations, 30-day readmissions and 30-day mortality were unchanged.

Conclusions The systematic review of the literature concluded that use of safety checklists may have positive impact on patient outcomes as more clinicians adhere to standardised guidelines and procedures; improve human factors; and reduce adverse events, morbidity and mortality. We need more studies with strong study designs investigating effects of checklists used throughout the surgical pathway. The first Norwegian version of the pre- and postoperative SURPASS checklists in combination with the already established WHO SSC was validated following guidelines on translation and adaptation from the WHO. Using ICD-10 codes to monitor complications increased accuracy significantly when codes indicating complications were verified to have emerged in-hospital. Full compliance with the pre- and postoperative SURPASS checklists were associated with reduced in-hospital complications, emergency reoperations and 30-day readmissions when added to the already established intraoperative WHO SSC.

List of Publications

Paper I

Thomassen Ø, **Storesund A**, Søfteland E, Brattebø G. The effects of safety checklists in medicine: a systematic review. Acta Anaesth Scan, 2014; 58: 5: 5-18.
http://www.ncbi.nlm.nih.gov/pubmed/24116973

Paper II

Storesund, A, Haugen, AS, Wæhle, HV, Mahesparan, R, Boermeester, MA, Nortvedt, MW, Søfteland, E. Validation of a Norwegian version of Surgical Patient Safety System (SURPASS) in combination with the World Health Organizations' Surgical Safety Checklist (WHO SSC). BMJ Open Quality, 2019; 8: e000488.
https://bmjopenquality.bmj.com/content/8/1/e000488.citation-tools

Paper III

Storesund, A, Haugen, A.S, Hjortås, M, Nortvedt, M.W, Flaatten, H, Eide, G.E, Boermeester, M.A, Sevdalis, N, Søfteland, E. Accuracy of surgical complication rate estimation using ICD-10 codes. Brit J Surgery, 2019; 106: 236-244.
https://onlinelibrary.wiley.com/doi/abs/10.1002/bjs.10985

Paper IV

Storesund, A, Haugen, A.S, Flaatten, H, Nortvedt, WN, Eide, G.E, Boermeester, M.A, Sevdalis, N, Tveiten, Ø, Mahesparan, R, Hjallen, B.M, Fevang, J.M, Størksen, C.H, Thornhill, H.F, Sjøen, G.H, Kolseth, S.M, Haaverstad, R, Sandli, O.K, Søfteland, E. Clinical efficacy of combined SURPASS and WHO checklists in surgical pathways. In manuscript

Abbreviations

AE = Adverse Event

GTT = Global Trigger Tool

HUH = Haukeland University Hospital

ICD-10 = International Classification of Diseases 10th version

LOS = Length of Stay in hospital

PACU = Post Anaesthetic Care Unit

PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses

SURPASS = SURgical PAtient Safety System

SWCCT = Stepped Wedge Cluster Controlled Trial

WHO = World Health Organization

WHO SSC = World Health Organization Surgical Safety Checklist

Contents

1. INTRODUCTION

1.1 Background

Surgical procedures may be lifesaving and hinder disabilities [1]. However, compared to general wards, surgery has been more prone to patient harm [2, 3]. Half of all surgical complications have been estimated to be preventable [2]. However, adverse events rates remain unchanged despite strong efforts [2, 4, 5]. Complications have been reported with a prevalence of 6-25 % [6-8]. Though, in order to rely on patient safety outcome measures, we need reliable and validated methods to ensure accurate estimates on large scale data. Whether the International Classification of Diseases, 10th version (ICD-10) codes reflect accurate measures on in-hospital complications, also when compared to record review methods, remains to be investigated.

A call for systematic changes in health care [4] has led to development of several instruments to increase patient safety. The World Health Organization (WHO) launched the “Safe Surgery Saves Lives” campaign [1], which was followed by the development of the WHO Surgical Safety Checklist (WHO SSC) for use in operating theatres [9]. Early single studies on checklists’ effects on patient outcomes show variable results [10-13], thus to perform a systematic review of the literature of safety checklists’ effects on patient outcomes would gain new knowledge.

Incidents that harm surgical patients may result from communication breakdowns leading to loss of critical information in care transitions throughout the surgical pathway [14, 15]. To date, only one systematic checklist approach to cover the total surgical patient pathway with evidence of effects on outcomes exists: the Dutch SURgical PAtient SAfety System (SURPASS) [16]. The original SURPASS reported a decrease in overall morbidity (from 27.3 % to 16.7%, $p<0.001$) and mortality (from 1.5% to 0.8, $p= 0.003$) [16]. Further, an Indian SURPASS study reported a reduction in complications from 66.6% to 51.1%, $p=0.024$ [17]. However, thousands of hospitals worldwide have implemented the perioperative WHO SSC [18] for use in the operating theatre (OT) including our health region, the Western Norway Regional Health Authority. Here patient outcomes improved significantly with WHO SSC usage, with a decrease in complications from 19.9 % to 11.5 %, $p<0.001$, and reduction of mean length of stay by 0.8 days [19].

A broader understanding of effects of using safety checklists on patient morbidity is needed, and in particular, to investigate if there is more to gain with implementation of validated pre- and postoperative SURPASS checklists in combination with the already established WHO SSC.

1.2 Definitions

1.2.1 Patient safety

The WHO defines patient safety as "*the prevention of errors and adverse effects to patients associated with health care*" [20]. The Norwegian Knowledge Centre for Health Services has defined patient safety as "*a process where no patients should experience preventable harm, or risk of being harmed, as a result of provided or omitted health care* [21]. Patient safety may also be defined as "*a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery"*[22]. Regardless of definitions it is also important to acknowledge that understanding of patient safety changes with increased knowledge on what is deemed preventable [23]. In 2004, the WHO launched a global initiative programme, called "World Alliance for Patient Safety" encouraging worldwide monitoring and studies investigating adverse events [24]. Improving patient safety systematically could imply identifying causes and risk factors to adverse events related to technology, equipment, procedures and human factors and build barriers (like safety checklists) to prevent errors from happening. This approach is often called a Safety I approach [25]. A model to analyse causes of accident was developed by Reason (The Swiss Cheese Model). The model visualised a trajectory of a latent risk factor through several layers leading to an adverse event [26]. The model has been widely adopted to analyse risk-factors and risk management in healthcare, also by using safety checklists as instruments to lower risk and improve patient safety [27].

The Safety I approach is also widely adopted in aviation and nuclear industry [25]. The concept of Safety I is used as an overriding framework throughout this thesis. In supplement to the traditional Safety I approach, a Safety II approach seeks to understand and learn from mechanisms of how things usually go right [28]. The Safety II approach studies variability, resilience and personnel behaviour. As such, this is not a subject in our studies reported here.

1.2.2 Medical error

Medical error is defined as *"an act of omission or commission in planning or execution that contributes or could contribute to an unintended result"* [29]. Medical errors are often divided in two: *"Errors of omission occur as a result of actions not taken, while errors of commission occur as a result of the wrong action taken"* [30]. However, not all errors are followed by patient complications. Still, learning from errors and near misses may increase patient safety.

1.2.3 Adverse events and patient harm

Not all medical errors result in patient harm [4]. The Institute for Healthcare Improvement defined adverse events (AEs) as extensions of harm from drug administration to cause "*unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death"* [31]. Traditionally, this definition is utilised when using the Global Trigger Tool (GTT) (see 1.3 and 3.6.1 below) to classify presence and severity of a complication resulting from delivery of active care [32]. In this thesis, adverse events is defined as "*any incident that leads to patient harm*" [33].

1.2.4 Medical complication

A medical complication is defined as an incident with adverse outcome: *"an unintended and undesired occurrence in the healthcare process, which causes harm to the patient"*[34]. A complication may also be defined as "*a disease or injury that develops during the treatment of a pre-existing disorder. The complication frequently alters the prognosis*" [35]. In this thesis, adverse events and complications are utilised interchangeably and refer to an incidence harming the patient.

1.2.5 Safety checklist

Historically, safety checklists were developed in aviation to increase safety, and to aid human memory in high-risk situations [36]. Following this, high-reliability organisations such as nuclear power stations, oil industries, engineering and military, and later, also medicine, have all established their own safety checklists. Checklists may have different functions and purposes. Whereas some are a list of to-do things, like following a protocol, others are used to verify that everything is prepared for or performed [37]. Two largely similar definitions are often used in medicine: *"A checklist is typically a list of action items or criteria arranged in a systematic manner, allowing the user to record the presence/absence of the individual items listed to ensure that all are considered or completed*" [37]. A safety checklist can also be defined *"as an additional tool designed to ensure that an operation, procedure, or task is performed as planned by checking that all of the important preparations have been completed beforehand"* [38].

1.3 Quality of data on complications

To make improvements when learning from errors in health care, we need data of high quality, also to ensure accurate recommendations to improve patient safety. Investigating accuracy and validity of the data sources requires sound methods to investigate large datasets [39]. There is no agreement as to methodological standards on how to measure complications [40], and both prospective and retrospective study designs may be used. Prospective methods may include observational [41] and ethnographic designs [42] or mandatory incident reporting systems [43]. The Clavien-Dindo tool classifying complications may be used both prospectively and in retrospect [44]. Retrospective review methods for medical records are well established and regarded as thorough, and present reliable results and high scores on validity [45]. The most frequently used medical record review methods are the Harvard medical practice method and the GTT [40]. The Norwegian Directorate for Health requires all hospitals to report on complications using the GTT method [46]. GTT has been recognised to disclose as much as ten times more complications and have high sensitivity and specificity compared to voluntary reporting systems [47]. The GTT method is regarded as comprehensive, and was developed for internal monitoring to improve patient safety [31]. Large-scale studies designed to compare in-hospital complications may benefit from using less labour-intensive methods, such as extracting system-level administrative data. The World Health Organisation (WHO) provides a disease classification system, the International Classification of Diseases 10^{th} version (ICD-10) [48]. In Norway it is mandatory to classify diseases in all specialist patient consultations by using the ICD-10 system and report to the National Patient Registry [49]. ICD-10 codes are also used to identify a wide range of complications, setting the ground for electronic extraction in large studies [19, 50]. In the Nordic countries, population based registries, with data based on personal identification numbers, open up possibilities of longitudinal investigations, linking data from different sources [51, 52].

1.4 Safety checklists in medicine and surgery

Safety checklists in medicine may increase standardisation, and promote health care personnel to follow established protocols and guidelines [53]. One early checklist intervention study showed that more health care providers followed established guidelines to reduce catheter related bloodstream infection when having used a checklist [54]. The study was based on results from one ICU, then replicated and confirmed in 108 ICUs [55]. Structured team briefings facilitated by a checklist were reported to increase teamwork and decrease misunderstandings due to suboptimal communication [56]. In 2008, the WHO initiated the WHO SSC by identifying a simple set of surgical safety standards summarised in a checklist for use in operating theatres globally [1]. At the same time, the SURPASS checklist system was developed and validated in the Netherlands, with standardised checklists covering safety risks at transition points throughout the surgical patient pathway, from admission to discharge [57]. Customised safety checklists have increased patient safety in other fields of medicine, such as interventional radiology [58], and emergency department medicine [59].

1.5 The WHO SSC

The WHO SSC was developed for global use to increase patient safety and avoid adverse events by improving teamwork and communication in the operating theatre [1]. The WHO SSC is divided in three parts, the first (sign in) performed before induction of anaesthesia, the second (time out), before skin incision, and the third (sign out), before the patient leaves the operating theatre [9] (Appendices 8.1). The sign in part involves confirmation on patient identity, marking the operative site, known allergies, any risk for high blood loss or difficult airways and necessary medication and equipment prepared for. The time-out part requires introduction of all team members, new confirmation of patient identity, surgical procedure and site, antibiotic prophylaxis, and individual patient, procedural and equipment information to share with the team, display of imaging results. The sign-out part involves naming the actual procedure performed, counting equipment used, labelling of specimens and key concerns for recovery. The first study to show effects of implementing the WHO SSC included eight hospitals in eight countries worldwide from both developing and industrialised countries [10]. The study reported a reduction of morbidity (11.0% to 7.0%, P<0.001) and mortality (1.5% to 0.8%, P=0.003) with use of the WHO SSC. As in several other nations, the WHO SSC is compulsory to use in all Norwegian operating theatres. Checklist compliance is monitored by the Norwegian Directorate of Health [60]. The WHO SSC has become the most frequently safety checklist reported on, and introduction of the WHO SSC has also been studied nation-wide with multiple hospitals included, or on national levels [61]. The WHO SSC was associated with reduced mortality in a 7-day prevalence study of 426 hospitals in 28 European countries [62]. Several systematic reviews on effects of complying with the WHO SSC suggest reduced complications [63, 64], or reductions in both complications and deaths [38, 61, 65-68]. Optimal use of the WHO SSC may increase teamwork and communication, but may impair teamwork if the team members do not use the checklist as intended [69]. Some question if any effects registered may result from a general increased standard of care, rather than the use of checklists per se [61]. Others raise concerns as to suboptimal study designs, lack of longitudinal reported effects and a risk of publication bias with emphasis on positive effects only [70, 71].

1.6 The SURPASS checklists

Development of the Dutch SURPASS checklists started with a systematic review of investigations on hospital adverse events and their frequencies, distributions and preventability [7]. The review pointed at surgery as the medical area with the most frequent rates of adverse events, with all surgical transfer-points in need of improvement to increase safety. A first edition of the SURPASS checklists was validated by comparing theoretical safety risk factors in the literature to observed clinical safety risk factors [57]. The checklists were introduced in gastrointestinal, vascular and orthopaedic surgical procedures, followed by comprehensive interviews of checklist users with content adjustments before final adaptation: The contents of the checklist should mirror established protocols to be completed before patient transfers to the next step in surgical care. The SURPASS checklist system follows the complete surgical patient pathway: pre- intra- and postoperatively. The individualised checklists customized for each profession should be completed by the personnel directly involved in planning, preparing and/or performing the specific surgical procedures. The check should be performed by the personnel in charge of the designated assignment as a last task in preparation for the next step in the patient's pathway.

Implementing the SURPASS checklists in 3760 patients from six Dutch hospitals reduced complications per 100 patients from 27.3 % to 16.7%, P<0.001. In-hospital mortality was reduced from 1.5% to 0.8%, P=0.003. In the study period, the complication and mortality rates remained unchanged in five control hospitals not having used the checklists [16]. The original SURPASS checklist content was published with the effect-results [16]. Further investigations on the preventive effects of using the SURPASS checklist were conducted [72]. The first 1000 completed checklists with added checklist-user information on procedures or tasks that had been solved as a consequence of using the SURPASS checklists were analysed: The intercepted incidents had occurred throughout the surgical pathway (54.8% preoperative, 14.2% intra-operative and 31.0% postoperative) [72]. In another sub-study, increased adherence to a protocol of antibiotic administration improved timeliness of appropriate antibiotic prophylaxis [73].

1.7 Updated systematic literature review of effects of using checklists in surgery

We first searched the literature (conducted 25th May, 2012) to systematically describe effects of implementing safety checklists in medicine (Study I). To gain updated knowledge for the present thesis, a new systematic search confined to the field of surgery only, with reports on possible effects of using safety checklists was conducted anew (15th November, 2018). Both searches were done in collaboration with a librarian from the University of Bergen. Databases included in the updated search were MEDLINE (PubMed), EMBASE and Cochrane (reviews and trials).

The reference software system EndNote X9 (Clarivate Analytics, https://endnote.com) facilitated management of the literature reviewed. A full search string is provided in Appendices 8.2.

Included in the updated search were full text articles, abstracts, letters, editorials, original articles, reviews and systematic reviews. Identified were 3,828 publications, and after exclusion of duplicates, 2,932 titles were screened. No extra hand search of literature was conducted.

From the screened titles 22 publications were identified as reviews, systematic reviews and/ or meta-analysis, one of these being our own previous review (Study I). Nine review studies reported on effects on teamwork, communication and handover [38, 64, 67, 69, 74-78], three reviews assessed adherence to protocols and guidelines [38, 67, 70], four reviews reported on effects on joint understandings of care goals, safety attitudes or culture [27, 38, 77, 79], 11 reviews studied effects on complications and mortality [38, 61, 63-67, 71, 76, 77, 80, 81], one review assessed effects on unplanned reoperations [63], whereas six reviews summarised effects of checklist on perspectives on implementation or complexity of implementation (including barriers and facilitations) [64, 76, 79, 82-84]. Three reviews included studies which reported effects of unplanned readmissions to hospital [67, 71, 84]. Very few of the systematic reviews investigated effects of checklists on length of hospital stay (LOS), [38, 71]. Since the reviews summarise findings from original studies, they were not further included in the present systematic review.

Thus, further inclusion provided studies to be original (excluding reviews, or systematic reviews), the checklist intervention should be described as the only new intervention, and reports should be on quantitative outcome effects. The majority of the titles did not fulfil the inclusion criteria. However, 249 abstracts from original studies were reviewed, and 117 publications met our inclusion criteria. These publications reported on a wide range of effects of using checklists in surgery, including both “softer” outcomes (human factors), such as communication, adherence to protocols and guidelines, team performance, joint understanding of care goals, safety attitudes and “hard” patient outcome measures, i.e. complications, mortality, unplanned reoperations, hospital readmissions, and LOS. However, for the objectives to be in line with our own present studies in Study III and IV, we narrowed studies to be included in this updated systematic review to those with “hard” outcomes only. Following thorough full text reviews of the 117 publications, 40 studies were included in the final analyses, with quantitative outcomes reported, i.e. complications, mortality, emergency reoperations, hospital readmissions and LOS.

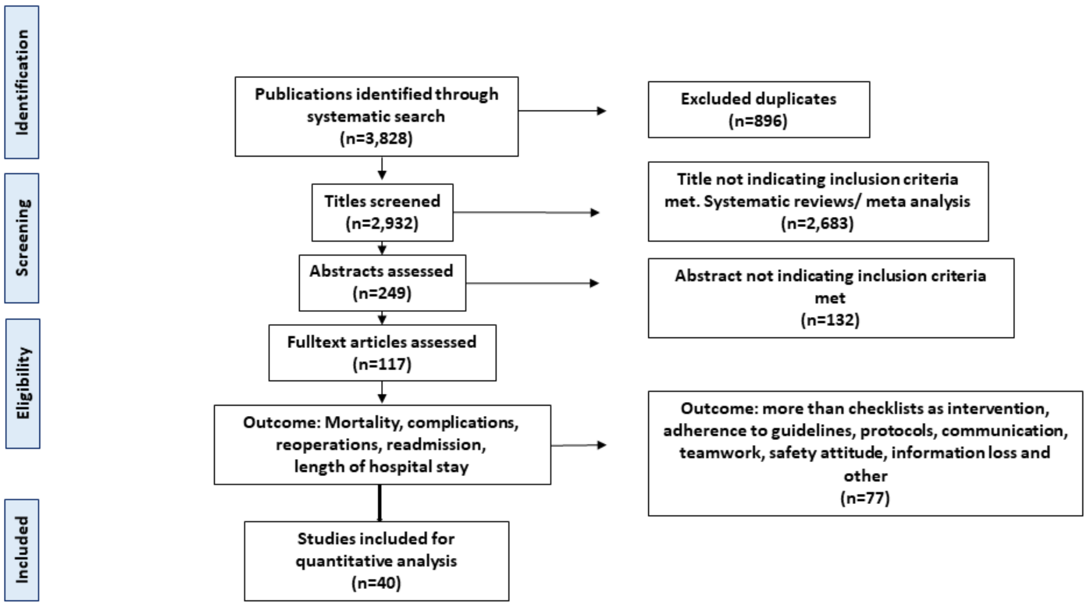


Figure 1: PRISMA flow chart of the search strategy to an updated systematic review on effects of using safety checklists in surgery [85].

The 40 studies included in this review were published from 2009 to 2019. An overview of the included studies' first authors, study country, year of publication, setting, study participants, type of checklist intervention, study design, outcome measures reported and main results are presented in table 1.

Table 1. Summary of an updated systematic literature on effects of safety checklists in surgery on complication, unplanned reoperation, readmission to hospital, length of hospital stay and mortality.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Anwer, Pakistan, 2016	Operating theatre, 1 hospital	Elective surgery, total 3638 procedures. 1st year 840, 2nd 857, 3rd 935, 4th 932	WHO SSC	Prospective Longitudinal (4 years)	x	3				x	Surgical site infection: 1st year 7.5%, 2nd 6.06%, 3rd 4.7%, 4th 2.12%. Chest complications, site/side error, mortality no change.
Askarian, Iran, 2011	Operating theatre, 1 hospital	Elective surgery 144 pre-intervention 150 post-intervention	WHO SSC	Prospective Pre/post		11					Any complications: 22.9% to 10%.
Bliss, USA, 2012	Operating theatre, 1 hospital	High-risk procedures. 246 without checklist 73 with checklist 2079 historical controls.	WHO SSC	Cohort, Historical controls		20				x	30-day morbidity from 23.6% without checklist, 15.9% historical cases, 8.2% with checklists, p<0.001.
Boaz, Israel, 2014	Operating theatre, 1 hospital	Orthopaedic patients. 380 pre-intervention, 380 post-intervention	WHO SSC	Cross sectional study		16	x				Postoperative fever: OR 0.53 (95% CI 0.29 to 0.96), p = 0.037. Other complications not significant. Mortality: 0.8% to 2.7%, p=0.049.
Bock, Italy, 2016	Operating theatre, 1 hospital	5444 pre-intervention, 5297 post-intervention	WHO SSC	Retrospective, Pre/post	x			x	x		30-day mortality: OR 0.79 (95% CI 0.56 to 1.11), p=0.79. 90-day mortality 0.73 (95% CI 0.56 to 0.96), p = 0.02). 30-day readmission: 0.90 (95% CI 0.81 to 1.01), p=0.79. LOS: 10.4 days (95% CI 10.3 to 10.6) to 9.6 days (95% CI 9.4 to 9.7), p<0.001.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Chaudhary, India, 2015	Operating theatre, 1 hospital	Gastro-intestinal + hepato-pancreatico patients. 350 pre-intervention, 350 post-intervention	WHO SSC	Prospective RCT, Parallel groups	x	8 groups			x		Wound-related complications: Intervention: 4.5% vs control 8.5%, p=0.04. Abdominal complications: Intervention 19.7% vs control 28%, p=0.01. Bleeding: Intervention 0.5% vs control 2.8%, p=0.03. Mortality: Intervention 5.7% vs control 10.0%, p=0.04. LOS, respiratory, septic, renal, cardiovascular complications not significant.
de Jager, Australia, 2019	Operating theatre, 1 hospital	8000 pre-intervention, 4,252, 0-1 year post-intervention, 4,494, 1-2 years post-intervention, 4,560, 2-3 years post-intervention	WHO SSC	Retrospective, longitudinal (5 years)	x	14			x		Mortality: 1.2% to 0.92%, OR 0.74 (95% CI 0.56 to 0.98), p=0.038. LOS: 5.2 to 4.7 days, p=0.014. One or more complications: Not significant.
de Vries, the Netherlands, 2010	Surgical pathway, 6 intervention, 5 control hospitals	3760 pre-intervention, 3820 post-intervention	SURPASS	Prospective, Pre/post	x	193	x				Total number of complications per 100 patients: 27.3% (95% CI 25.9 to 28.7) to 16.7% (95% CI 15.6 to 17.9), p<0.001. One or more complications: 15.4% to 10.6%, p<0.001. In-hospital mortality: 1.5% (95% Ci 1.2 to 2.0) to 0.8% (95%CI 0.6 to 1.1), p=0.003. Reoperation: 3.7% to 2.5%, p=0.005. Control hospitals: complications and mortality unchanged.
Hardiman, USA, 2016	Ward, 1 hospital	Ileostomy patients, 255 pre-intervention, 175 post-intervention	Checklist for patient to use, locally developed	Retrospective, Pre/post				x			Readmissions: 28% to 20%, p=0.04.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Haugen, Norway, 2015	Operating theatre, 2 hospitals	2212 pre-intervention, 3083 post-intervention	WHO SSC	Stepped Wedge Cluster RCT	x	87	x		x		One or more complications: 19.9% to 11.5%, p<0.001. Emergency reoperation: 1.7% to 0.6%, p<0.001. Overall in-hospital mortality: 1.6% to 1.0%, p=0.151. Mean LOS 7.8 days to 7.0 days, p=0.022.
Haugen, Norway, 2019	Operating theatre, 2 hospitals	1398 pre-intervention, 2304 post-intervention	WHO SSC	Stepped Wedge Cluster RCT		5				x	Surgical infections 7.4% to 3.6%, p<0.001, cardiac complications 8.0% to 5.0%, p<0.001, respiratory complications 8.3% to 4.0%, p<0.001, wound rupture 1.8% to 0.2%, p<0.001, bleeding 2.6% to 1.0%, p<0.001.
Hawranek, Poland, 2015	Interventional radiology, 1 cardiovascular department, 1 hospital	1011 pre-intervention, 1053 post-intervention	Local periprocedural checklist	Retrospective, Pre/post		6					Complications: 6.8% to 3.9%, p=0.004.
Haynes, USA, 2017	Operating theatre, 48 hospitals in South Carolina state	Intervention hospitals, 22514 pre-intervention, 18112 post-intervention, Control hospitals, 38876 pre-intervention, 30218 post-intervention	WHO SSC	Retrospective review, Pre/post	x		x	x			Intervention hospitals: Readmissions: 9.35% to 7.87%, p=0.08. Reoperations: 2.59% to 2.5%, p=0.26. 30-day mortality: 3.38% to 2.84, p<0.001. Control hospitals: 30-day mortality 3.5% to 3.71%, p=0.002. Readmission and reoperations unchanged.
Haynes, 8 countries, 2009	Operating theatre, 8 hospitals, 8 countries	3733 pre-intervention, 3955 post-intervention	WHO SSC	Prospective, Pre/post	x	17 major	x				Any complications: 11.0% to 7.0%, p<0.001. In-hospital mortality: 1.5% to 0.8%, p=0.003. Emergency reoperation: 2.4% to 1.8%, p=0.047.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Hazelton, USA, 2015	ICU, 1 hospital	Bronchoscopy-guided percutaneous tracheostomy, 63 pre-intervention, 184 post-intervention	Locally developed	Prospective, Pre/post		7					Complications: 14.1% to 3.2%, p=0.020.
Igaga, Uganda, 2018	Operating theatre, 5 hospitals	859 patients	WHO SSC	Prospective cohort study	x	21			x	x	No change in outcome. Low checklist compliance.
Jammer, Eropean countries 2015	Operating theatre, 426 hospitals, 28 countries	45,591 patients	WHO SSC	7 day prevalence cohort study	x						Crude mortality: OR 0.84, (95% CI 0-75-0.94), p=0.002. Adjusted mortality: OR: 0.71 (95% CI 0.58-0.85), p<0.001.
Kwok, Moldova, 2013	Operating theatre, 1 hospital	2,145 pre-intervention, 2,212 post-intervention	WHO SSC	Prospective, Pre/post	x	7	x			x	Overall complication rate: 21.5% to 8.8%, p<0.001. Unplanned return to OR and mortality: Not significant.
Lee, USA, 2018	Operating theatre, 1 hospital	Paediatric surgery, 924 pre-intervention, 889 post-intervention	Locally developed	Prospective, Pre/post		1 infection					Shunt infections: 3.03% to 1.01%, p=0.003.
Lepänluoma, Finland, 2014	Operating theatre, 1 hospital	89 pre-intervention, 73 post-intervention	WHO SSC	Retrospective, Pre/post	x	27	x	x	x	x	Readmissions: 25.3% to 10.4%, p=0.02. Wound complications: 19.3% to 7.5%, p=0.04. Unplanned reoperation: Not significant. Mortality, LOS: unchanged.
Lepänluoma, Finland, 2015	Operating theatre, 1 hospital	Neurosurgical patients, 2665 pre-intervention, 2753 post-intervention	WHO SSC	Retrospective, Pre/post			x				Overall preventable reoperations: 3.3% (95% CI 2.7% to 4.0%) to 2.0% (95% CI 1.5% to 2.6%).
Lübbeke, Switzerland, 2013	Operating theatre, 1 hospital	609 pre-intervention, 1818 post-intervention	WHO SSC	Prospective, Pre/post	x	4 infections	x			x	Reoperations for surgical site infections: 3.0% to 1.7%, RR 0.56 (95% CI 0.32 to 1.00). Unplanned return to OR, unplanned admission to ICU or in-hospital mortality: Not significant.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Mayer, England, Wales, 2016	Operating theatre, 5 hospitals	6,714 patients	WHO SSC	Retrospective, Longitudinal (16 months)	x	18					Likelihood of complication: OR 0.79, (95% CI 0.70 to 0.89), p<0.01. All three parts of checklist used, complications: OR 0.57 (95% CI 0.37 to 0.87), p<0.01. Mortality: Not significant.
McCaroll, USA, 2015	Operating theatre, 1 hospital	Robot-assisted hysterectomy, 89 pre-intervention, 121 post-intervention	WHO SSC	Prospective, Pre/post				x		x	30 day- readmission to hospital: 12 days to 5 days, p=0.02. Duration of surgery: Not significant.
Mehta, India, 2018	Surgical pathway, 1 hospital	200 pre-intervention, 172 post-intervention	SURPASS	Prospective, Pre/post	x	23	x				Complications elective procedures: 164 to 96, p=0.008. Complications emergency procedures: 239 to 135, p= 0.024. Reoperations, mortality: Not significant.
Morgan, Canada, Toronto, 2013	Operating theatre, 1 ambulatory setting	180 pre-intervention, 195 post-intervention	WHO SSC	Prospective, Pre/post		2			x	x	Postoperative pain and postoperative nausea and vomiting and LOS: Not significant.
O'Leary, Canada, Ontario, 2016	Operating theatre, 116 hospitals	Children, 14,458 pre-intervention, 14,314 post-intervention	WHO SSC	Retrospective, Pre/post	x	18	x		x	x	LOS: 10 days to 9 days, p<0.001. Complications, return to operating theatre, mortality: Not significant.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Reames USA, Michigan, 2015	General and vascular surgery, 29 hospitals	14,005 pre-intervention, 14,801 post-intervention, 36,085 controls	Keystone Surgery Program checklist tool, Locally developed checklist	Longitudinal (6 years), Pre/post	x	22					Superficial surgical site infection, wound complication, any complication, 30-day mortality: Not significant. Controls: No change.
Rodella, Italy, 2018	Operating theatre, 48 hospitals	225,687 pre-intervention (>75% compliance to SSC), 434,070 pre-intervention (<75% compliance to SSC), 160,480 post-intervention (<75% compliance SSC), 346,187 post-intervention (>75% compliance SSC)	WHO SSC	Retrospective longitudinal (9 years), Pre/post	x			x		x	Patients with LOS≥8 days, >75% compliance to SSC: OR 0.873 (95% CI 0.858 to 0.888), p<0.001. 30-day readmission, >75% compliance to SSC: OR 0.947 (95% CI 0.926 to 0.968), p<0.001. Entire study cohort: Patients with LOS≥8 days: 0.867 (95% CI 0.789 to 0.806), p<0.001. Entire study cohort: 30-day readmission: OR 0.946 (95% CI 0.925 to 0.968), p<0.001. Mortality: Not significant.
Rodrigo-Rincon, Spain, 2015	Operating theatre, 1 hospital	801 pre-intervention, 801 post-intervention	WHO SSC	Retrospective, Pre/post	x	16					Complications per 100 patients: 31.5% to 26.5%, p=0.39. 30-day mortality: Not significant.
Rose, USA, 2018	Surgery, 1 hospital	54,003 procedures, distribution of procedures per year not reported	Locally developed, debriefing checklist	Longitudinal (5 years)	x					x	Unadjusted analyses: 30-day mortality: 0.82% to 0.51%, p=<0.05.
Rosenberg, USA, 2012	Operating theatre, 1 hospital	Plastic surgery, 212 pre-intervention, 180 post-intervention	WHO SSC	Retrospective, Pre/post	x	10	x				Complications per 100 patients: 15.1% to 2.71%, p<0.001. Mortality and reoperations: Not significant.
Sewell, England, 2011	Operating theatre, 1 hospital	Orthopaedic patients, 480 pre-intervention, 485 post-intervention	WHO SSC	Prospective, Pre/post	x	17	x			x	Complications, unplanned reoperations and mortality: Not significant.

First Author, country, year	Setting	Participants	Checklist	Design	Outcome measures						Results
					Mortality	Number of complications	Re-operation	Re-admission	LOS	Others	
Tillman, USA, 2013	Operating theatre, 1 hospital	3,319 pre-intervention, 3,616 post-intervention	WHO SSC	Prospective, Pre/post	x	1 Surgical site infection				x	Mortality, Surgical site infections: Not significant.
Urbach, Canada, Ontario, 2014	Operating theatre, 101 hospitals	109,341 patients pre-intervention, 106,370 patients post-intervention	1)WHO SSC, 2)the Canadian Patient Safety Institute checklist, 3)Locally developed	Retrospective, Pre/post	x	15	x	x	x	x	Unplanned return to theatre: 1.94% (95% CI 1.87 to 2.00) to 1.78% (95% CI 1.72 to 1.85), p= 0.001. LOS: 5.11 days (95% CI 5.08 to 5.14) to 5.07 days (95% CI 5.04 to 5.10), p= 0.003. 30-day mortality, complications, risk off emergency department, and readmission to hospital: not significant.
van Klei, the Netherlands, 2012	Operating theatre, 1 hospital	14,362 pre-intervention, 11.151 post-intervention	WHO SSC	Cohort, historical control	x						30-day mortality, fully completion of SSC: OR 0.44 (95% CI 0.28 to 0.70).
Weiser, 8 countries, 2010	Operating theatre, 8 hospitals	Emergency patients, 842 pre-intervention, 908 post-intervention	WHO SSC	Prospective, Pre/post	x	17				x	Complications: 18.4% to 11.7%, p=0.0001. 30-day mortality: 3.7% to 1.4%, p=0.0067.
Westman, Finland, 2018	Operating theatre, 1 hospital	Neurosurgery, 4,678 pre-intervention, 2,342 post-intervention	WHO SSC	Retrospective, Pre/post		5 infections					Total percentage of postsurgical infections: 4.1 % to 4.5 %, not significant.
Williams, USA, 2017	Ward, 1 hospital	Paediatric supracondylar humerus fractures, 394 pre-intervention, 537 post-intervention	Locally developed, preop, postop, discharge	Prospective, Pre/post		4				x	Loss of fixation: 5 to 1, p=0.08, loss of alignment: 22 to 21, p=0.23, infection: 6 to 2, p=0.07 and nerve injury: 40 to 44, p=0.35
Zingiryan, USA, 2017	Operating theatre, 1 hospital	1,792 patients pre-intervention, 1,843 patients post-intervention	WHO SSC	Retrospective, Pre/post		9				x	Sepsis, respiratory failure, wound dehiscence, postoperative VTE, postoperative haemorrhage, transfusion reaction, retained foreign body, mortality, death among surgical in-patients with serious treatable complications: Not significant.

One study presented effects of checklists for patients to use themselves [86], while 39 studies assessed effects of implementing checklists conducted by health care personnel. The WHO SSC, which is to be completed by the operating theatre personnel, was the object for 31 of the studies. SURPASS is the only system of checklists on all transfer points throughout the surgical pathway having been investigated, with two studies having reported effects on patient outcomes [16, 17]. On-site developed checklists were studied in seven studies, and in a large Canadian study Urbach and colleagues measured effects of three different checklists [87].

Thirty-two of the studies were conducted in high-income countries. However, studies have also been performed in developing countries such as Pakistan, Iran, India, Uganda and Moldova and two studies included mixed high-income and resource limited hospitals. Whereas 27 studies were carried out in a single hospital, seven studies were conducted in settings with two to eight hospitals, and six studies involved multi-centres (11 to 116 hospitals) [62, 87-91].

One study used a cross sectional design [92], but most commonly prospective or retrospective pre/post study designs were used. Two studies were designed as cohort studies [11, 93]. Six studies collected data over longer time periods, from 16 months to nine years, both retrospectively and prospectively. One study on effects of the WHO SSC used a Stepped wedge cluster controlled Randomised Controlled Trial study design [19]. One study used a parallel group design with randomisation to either checklist intervention or a control group without checklists [94].

Favourable patient outcomes were associated with the use of WHO SSC in several studies with reductions in complications [10, 19, 92, 94-104], mortality [10, 11, 62, 88, 94, 102, 105, 106], unplanned reoperations [10, 19, 99, 107], and unplanned readmissions [91, 98, 108], LOS [19, 89, 105, 106], while other studies reported no significant changes after introduction of the WHO SSC as to complications [89, 93, 106, 109-114], mortality [19, 89, 91, 93, 95, 97-101, 110-112], reoperations [88, 89, 92, 97, 98, 101, 111], readmission [88, 105], or LOS [93, 94, 98, 109].

Use of on-site developed checklists were reported to reduce complications [115-117], mortality [118] and unplanned readmissions [86]. Nevertheless, there were also such studies reporting no change in complications [90, 119] or mortality [90].

Compliance to the SURPASS checklists was associated with reduced complications [16, 17], mortality and reoperations [16] in Dutch hospital settings. However, use of SURPASS did not result in change number of reoperations or mortality [17] in the Indian setting.

Complication data was reported in different ways. In total, four studies, one from Australia, one from Canada and two from Norway, extracted data using ICD codes [19, 89, 104, 106]. Some studies reported to use high quality extracted data on complications from registries [90, 112, 113] or a national database [16]. Majority of the studies provided information on how the complication data reached high quality. Others have reported to extract complication data revealing information on how the data was quality checked [99, 100, 117], whereas there was also a report of data extraction without information on quality checking of complication data [110]. There were also other studies without reporting of how the quality of complication data was ensured [92, 95, 96].

In conclusion, more studies on patient safety effects of validated checklists throughout the surgical pathway using strong study designs is warranted, with emphasis on thorough descriptions of complication data.

2. OBJECTIVES

The overall objective for the thesis was to investigate effects of using safety checklists on patient outcomes in medicine, and to evaluate effects of adding a validated Norwegian version of the pre- and postoperative parts of the SURPASS checklists to be used together with the established WHO SSC, as to emergency reoperations, 30-day unplanned readmissions, 30-day mortality, LOS, when also having verified in-hospital complications using a reliable and validated method.

More specifically, the aims of the study were
Paper I – To review the medical literature on any effects of safety checklists in medicine.

Paper II – To translate and validate the SURPASS' five preoperative and three postoperative checklists in combination with the already established Sign In, Time Out and Sign Out parts of the WHO SSC for use in Norwegian surgical care.

Paper III – To investigate the accuracy of verifying ICD-10-coded complications compared to the GTT as a reference standard, by conducting a concurrent validation of ICD-10-coded complications in surgical admissions.

Paper IV – To investigate clinical efficacy of combined SURPASS and WHO checklist use in surgical patient pathways on emergency reoperations, 30-day unplanned readmissions, 30-day mortality, LOS, and verified in-hospital complications using a Stepped Wedge Cluster Controlled Trial design.

3. Material and methods

3.1 Study design

Study I was designed as a systematic review of the literature to investigate publications reporting any effects of using safety checklists in medicine. The systematic review was an evaluation of an intervention in healthcare and transparency of reporting was based on the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines [85].

Study II was a validation study of the pre- and post-operative SURPASS checklists in combination with the already established WHO SSC performed in one department. Both quantitative and qualitative methods were used to test the feasibility of tailoring the content and implementing the checklists in the full-scale study (Study IV).

Study III used a prospective observational study design to investigate validity and reliability of using ICD-10 codes to identify and verify in-hospital complications compared to the GTT as a reference standard.

Study IV, is a study using the Stepped Wedge Cluster Controlled Trial (SWCCT) design when implementing the checklists in predefined surgical clusters/ departments. The study assessed effects of adding the pre- and postoperative SURPASS checklists to the already established team-based WHO SSC on emergency reoperations, 30-day unplanned readmissions, 30-day mortality, LOS, and verified in-hospital complications.

3.2 Ethics

The Study followed recommendations from the Helsinki declaration [120]. Prior to study start, ethical approval was obtained from the Western Norway Regional Ethical Research Committee (2012/560/REK West) and the data privacy unit at Health Trust Førde (Ephorte: 2012/3060) and Health Trust Fonna, Haugesund (Ephorte:

2015/2384-1). The studies presented in this thesis were considered to potentially bring benefit to all kind of surgical patients. Thus, patients of all ages and also any without the capability to actively give an informed consent were included. The ethical approval considering the society's interests and the participants' integrity were deemed fulfilled (Section *18 and 35* in the Norwegian Law on Health Research - "Helseforskningsloven").

Following ethical approval, the patients (or a legally authorised patient representative) in the intervention clusters received written information on the study. The information was in lay Norwegian language and explained the kind of data to be collected, the aim, voluntary participation, confidentiality, data-handling, and that the participant could refrain from data sharing with the research projects without any consequences for provided healthcare. For patients constituting controls, with no new checklists, data were routinely collected from the hospitals administrative electronic systems.

The protocol for the studies was registered in ClinicalTrials.com, NCT01872195 prior to study start.

Descriptions of rationale for modification of the original protocol are provided in Appendices 8.3.

3.3 Settings, sample and participants

Study I was an electronic search of healthcare databases MEDLINE; Cochrane Library, Web of Science and EMBASE, and included all medical settings.

In Study II, the first Norwegian version of the pre- and postoperative SURPASS checklists was validated in 29 neurosurgical procedures at Haukeland University Hospital (HUH) in Western Norway. Included were neurosurgical personnel using the checklists, involving ward doctors and nurses, neurosurgeons, anaesthesiologists, operating theatre nurses and Post Anaesthetic Care Unit (PACU) nurses covering eight individual SURPASS checklists.

Study III used information from surgical admissions at HUH (neurosurgery, orthopaedics, gynaecology and thoracic surgery) and Health Trust Førde (general surgery, vascular surgery, gastroenterology, urology). The study sample contained 700 surgical admissions, which were randomly selected from 12,966 surgical procedures.

Study IV involved 18,687 surgical procedures and was carried out in surgical departments in three hospitals: HUH (neurosurgery, orthopaedics, gynaecology and thoracic surgery), Health Trust Førde (general surgery, vascular surgery, gastroenterology, and urology) and Health Trust Fonna, Haugesund (general surgery, vascular surgery, orthopaedics, ear/nose/throat surgery, and urology). The surgical procedures representing the study samples were collected before and after the checklist intervention, and completed after 29 months, with surgical procedures included in three trial clusters (neurosurgery, orthopaedics, and gynaecology at HUH). In order to compare study outcome changes over the same period, data from thoracic surgery (HUH), and surgical procedures at Health Trust Førde and Health Trust Fonna with care as usual, were collected to serve as a parallel control group.

HUH is a tertiary university hospital serving 1.1 million inhabitants, Health Trust Førde and Health Trust Fonna, Haugesund are central community hospitals serving

110.000 and 180.000 inhabitants, respectively. Geographically, all three hospitals are in the Western part of Norway and included in the Western Regional Norwegian Health Authorities.

3.4 Inclusion and exclusion criteria

Whereas Study I was confined to effects of checklists in all fields of medicine, Study II involved surgical personnel, Study III investigated surgical admissions, and Study IV encompassed surgical procedures. For Study I, II and IV, safety checklists developed to increase patient outcomes were the instruments being investigated. The different studies have distinct inclusion and exclusion criteria:

Study I: The inclusion criteria were studies investigating any effects of utilising safety checklists, handover protocols and daily goals sheets, perceptions of using checklists, reporting on quantitative effect outcomes, without restrictions to study design, time or language.

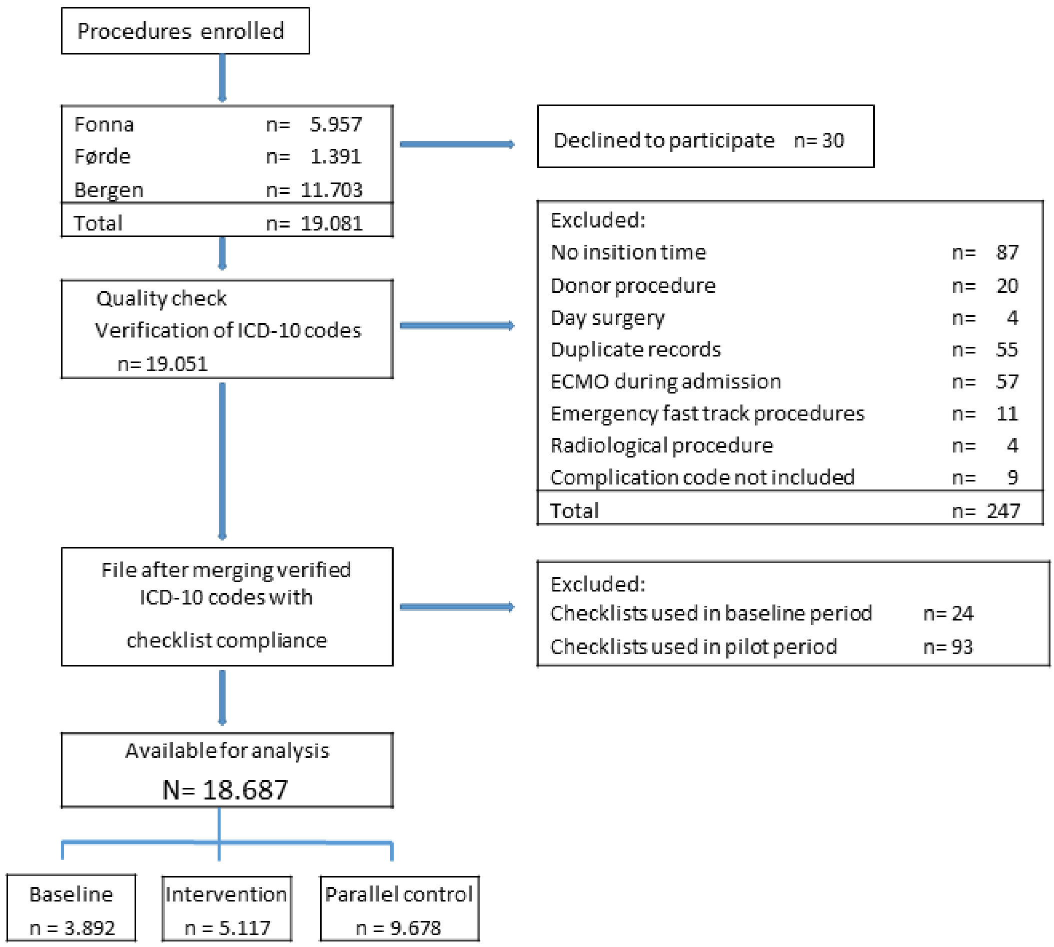
Study II: Eligible elective neurosurgical procedures performed during three weeks in June/July 2012 at the neurosurgical department at HUH were included. All the included personnel used the new SURPASS checklists during the pilot-period.

Study III: Patients from 18 years of age with performed surgery implying a hospital admission lasting 24 hours or longer were eligible for inclusion. The admissions were randomly selected from Study IV's population from HUH and Health Trust Førde.

Study IV: Emergency and planned operative in-hospital procedures performed within the predefined departments at HUH, Health Trust Førde and Health Trust Fonna, Haugesund were included from November 2012 through March 2015. There were no restrictions to age, duration of surgery or length of hospital admission.

Generally in Study II-IV, patients as donors, radiological procedures, gamma-knife surgery, extracorporeal membrane oxygenation (ECMO) procedures, day case surgery, and patients declining participation were excluded.

Figure 2. Flowchart for procedures included in Study IV



3.5 Methods

3.5.1 Outcome measures

Study I: All kind of outcomes measures reported as effects of using safety checklists using quantitative methods.

Study II: The tailored checklist items were outcome measures reflecting local safety risk factors.

Study III: The outcome measures were in-hospital complications using two established detection methods to identify and verify intra-hospital complications.

Study IV: The primary outcome measures were in-hospital complications, emergency reoperations, unplanned 30-day readmissions, 30-day mortality. A secondary outcome measure was length of hospital stay.

3.5.2 Ensuring transparency

Study I used the PRISMA statement following its 27-item checklist to ensure transparency of reporting the findings systematically [85]. This checklist guided the systematic search, quality assessment and structured targets to report on, e.g. participants, interventions, comparison, outcomes and study design (PICOS), follow-up period, study size and sites.

Study II followed recommended WHO guidelines with six recommended steps when translating and adapting the pre- and postoperative SURPASS checklists in combination with the WHO SSC to enhance and ensure the validation process [121]. The process (see Figure 3) contained forward language translation by an external professional translation-company, followed by the study group ensuring correct clinical terminology of the translated version. The next steps involved testing the contents in clinical practice, followed by focus group interviews. Eight focus study groups involving all the groups of checklist users (surgeons, anaesthesiologists, ward physicians, ward nurses, operating theatre nurses, PACU nurses, discharging physicians and discharging nurses). The focus groups captured the participants' reflections regarding checklist items, fidelity and compliance. The checklist items guided the interviews. Qualitative content analysis [122] was utilised to condense meaning units, and to identify codes and categories to reflect the checklist users perspective of content and using the checklist in clinical practice. Further, eight expert panels with health care providers evaluated appropriateness and relevance of the checklist content using a four-point content validity index (CVI) [123]. All the steps, until the last step, resulted in text modifications. Finally, the checklists were translated back to Dutch for approval by the SURPASS developer at Amsterdam Medical Centre, Amsterdam, the Netherlands.

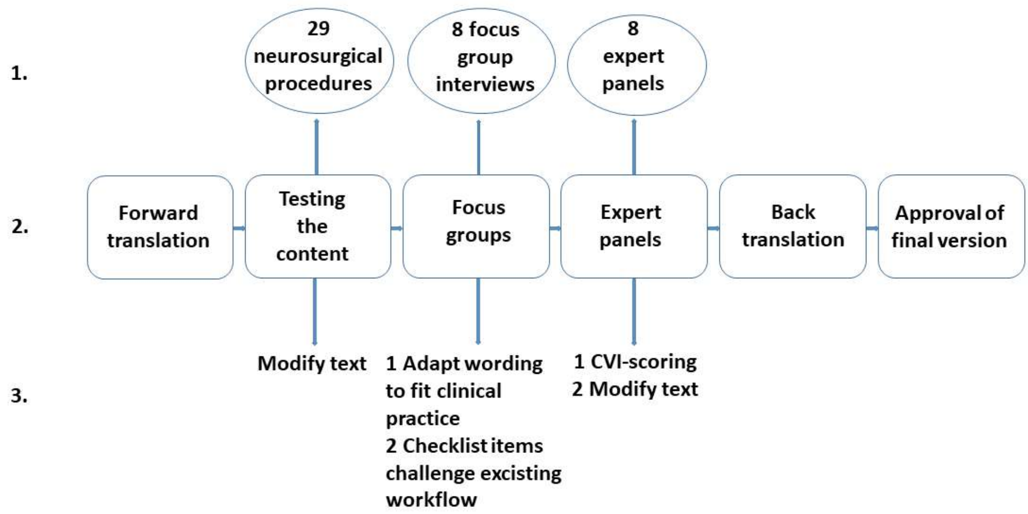


Figure 3. Validation steps of the Norwegian version of SURPASS.

1. Participants 2. The six validation steps 3. Findings.

3.6 Assessment of Complications

Imperative when investigating accuracy of in-hospital patient complications is the possibility to differentiate between complications already present on admission and those having emerged during hospital stay. For instance, a pulmonary embolism can both be an admission diagnosis and a complication during hospital stay.

In Study III, two nationally and internationally established methods to identify and verify complications were utilised to test agreement and investigate accuracy of the estimation of verified complications in the same surgical admissions. The GTT record review method was used as a reference standard and compared to verified in-hospital complications from electronically extracted ICD-10 complication codes for the same hospital admissions. In Study IV, ten experts (5 surgeons, 3 anaesthesiologists, 1 nurse anaesthetist and 1 intensive care nurse) in the research team were involved in verifying the ICD-10 codes. One group-educational lesson on how to use the verification method including discussions on how to classify and reach consensus.

3.6.1 Global Trigger Tool - GTT

The GTT method is a retrospective medical record review instrument that uses 55 trigger words or clues that could indicate the occurrence of an adverse event (AE) [31]. Using the GTT method has demonstrated valid and reliable identification of AEs compared to voluntary reporting systems or safety indicator reports [47, 50]. Since 2011, it has been mandatory to use the GTT method in all Norwegian hospitals with GTT teams reviewing a small sample of randomly selected patient records biweekly [60]. Two nurses perform the review individually before consensus are carried out in cooperation with a physician. The method allow a maximum of 20 minutes per record review. With identification of a trigger word, the reviewer extends to verify if one or more complications have occurred. When verified, the complication is classified according to 23 complication categories [31]. The method includes findings of AEs as a result of delivered care, while excluding omission of care. Severity of any verified complications is scored on a five-point scale, from temporary, to prolonged hospitalisation, permanent disability, life-supporting treatment and death.

3.6.2 ICD-10 codes indicating complications

The ICD-10 complication codes included in study III and IV were based on major complications as classified by the American College of Surgeons in the "National Surgical Quality Program" [124]. In addition, a broader range including minor complications, as described in previous checklist studies were included [10, 16, 19]. Altogether 154 and 155 (D62 Acute posthemorrhagic anaemia in addition) selected ICD-10 codes were used to identify potential complications in Study III and IV respectively. The electronic searches to identify ICD-10 codes indicating a complication as registered in the discharge letters in patient records were constructed to identify a three digit code (e.g. I50), without excluding any digits beyond three (e.g. I50.1). Any code may represent a condition present at hospital admission. However, any same code may indicate an in-hospital complication. To exemplify, I48 (Atrial fibrillation or atrial flutter) may have been present on admission or have emerged during hospitalisation. Following a patient record review, the ICD-10 codes verified to have emerged during hospitalisation, will in this thesis be referred to as ICD-10 complication codes (Appendices 8.4). The validating methodology used in Study III, was also applied to verify all complications in Study IV.

3.7 Intervention: The pre- and postoperative SURPASS checklists in combination with WHO SSC

Since the WHO SSC, covering the intraoperative phase, was already established and mandatory to use in Norway on a national basis [60], it was deemed appropriate to add the pre- and postoperative SURPASS checklists to evaluate any (additional) effects of having checkpoints throughout the surgical patient pathway: A majority of adverse events origin in the pre- and postoperative phases of surgical care [125]. Such checkpoints could potentially reduce such AEs even more than just the intraoperative WHO SSC alone.

The validation of the first Norwegian version of the pre-and postoperative SURPASS checklists in combination with the WHO SSC was conducted in the neurosurgical cluster. Experience from the validation process guided adaptation of the checklist content to the next intervention clusters: orthopaedics and gynaecology.

The five single SURPASS checklists in the preoperative phase are each performed individually by the ward physician, anaesthesiologist, surgeon, ward nurse and the operating theatre nurse as a last individual check-up before transfer of information to another care provider. The intraoperative phase has the team-based checklists, covered by the WHO SSC, with verbal team-based performance, involving surgeon, anaesthesiologist, nurse anaesthetist, and operating theatre nurse. The three single postoperative SURPASS checklists are each performed individually: by a PACU nurse before discharge from the PACU section; and then by the discharging physician and nurse each before the patient leaves the hospital. Through this some procedures are checked by more than one care provider (e.g. operation site marked by surgeon, checked by ward nurse before transition to operating theatre, and then again checked when using the intraoperative team-based checklists), others by only one person (e.g. the urine bladder emptied before entering the operating theatre by the ward nurse). Other checks to be completed are preoperative presence of instruments, laboratory tests examined, cessation of anticoagulants, allergies registered, classification of physical status – American Society of Anaesthesiologists (ASA) performed, cross typing performed, preoperative nutritional screening, instructions on pre- and postoperative medications, and information on normal recovery after discharge. The Norwegian version of the SURPASS checklist contents were adapted to orthopaedic and gynaecology procedures before being tested in all the involved personnel groups (ward physician, surgeon, anaesthesiologist, ward nurse, operating theatre nurse, PACU nurse and discharging doctors and nurses).

3.8 Implementation of the SURPASS checklists

Four clinical heads of surgery were invited to participate. Out of these, three consented to engage in the present study. The clinical heads made decisions to participate in close agreement with their respective clinical managers of daily care. The implementation strategy was thoroughly planned involving and educating both clinical managers, and dedicated key personnel appointed by their managers for all professions in each surgical specialty, using profession specific clinical teachers throughout.

Before piloting the content in clinical practice, all the personnel groups in the three intervention clusters (neurosurgery, orthopaedic and gynaecology) received lessons in groups, at least once per profession. In addition, all ward physicians, junior physicians and ward nurses were trained individually and comprehensively on how to use their individual SURPASS checklist electronically (in our standard operation planning program), since they were not familiar with electronic checklist usage. Additionally, informative e-mails were distributed and posters were displayed at visible places in the departments. When piloting the checklist contents, the surgical personnel critically discussed concerns on contents and potential disruption of existing workflow with the implementation team. Compliance rates were followed closely and feedback was regularly displayed and discussed with managers and checklist users. Personnel were requested to write down comments on contents, practical obstacles and other barriers to high fidelity use in an assigned notebook. Throughout the pilot-periods in all the three intervention clusters, study personnel were visibly available and invited checklist users to discuss openly issues to be adjusted. Some of the most enthusiastic checklist users were local champions, acting as supervisors, facilitating the implementation process.

When the intervention clusters switched from control to intervention clusters, the compliance rates were followed in close collaboration with the respective clinical managers. The managers received compliance reports for all the personnel groups for their specialty, which for some contributed to friendly competitions. All managers were asked to declare their compliance goals, with these being transparent for the other managers in the intervention clusters (departments). Different strategies of involving their staff involved distributing the checklist compliance rates to their staff by e-mails, wall posters, and discussed in monthly personnel meetings.

3.9 Data management and quality

Comprehensive extractions and quality checking of patient data from the hospitals electronic patient record system (DIPS) were performed in close collaboration with the Information Technology Support Unit of the Western Regional Norwegian Health Authority.
Compliances to the WHO SSC were entered routinely in the electronic operating planning systems (ORBIT/DIPS) by operating theatre nurses or anaesthetic care nurses. In a transition period of 12 months, the new Norwegian SURPASS checklists were available in both electronic and paper version in neurosurgery. For personnel performing orthopaedics and gynaecological procedures, compliance with the checklists was registered electronically, overall. The paper checklists used in the intervention period were entered manually by a research assistant twice and merged by a statistician to enable identification of mismatch of the two entering procedures. Twenty-one mismatches were detected and corrected by the principle researcher.

The ICD-10 codes in Study III and IV had been routinely documented in electronic patient records, usually at discharge, by physicians in charge of each patient. Trained secretarial and clinical staff provided quality checks of discharged patients' records as per routine to complete coding at department levels.

The outcome measures were coded as bivariate variables with verified in-hospital complications, emergency reoperation, 30-day hospital readmission or 30-day mortality entered as 1, whereas procedures verified without in-hospital complications, emergency reoperation, 30-day hospital readmission or 30-day mortal outcome were coded as zero.

Some hospital admissions required multiple surgical procedures. However, the ICD-10 codes are classified per admission, and one code may only be present once per admission. All patient outcomes and checklist compliances were linked to specific surgical procedures (Study III and IV).

If an emergency reoperation was confirmed related to one of these procedures, the procedure ahead of the reoperation was marked with the value 1 since the reoperation was regarded as a complication resulting from the procedure ahead. If more than one emergency reoperation was required per admission, only one (the first) was counted per admission. Planned reoperations, such as second procedures after external fixation of a fracture, surgical wound treatments due to primary infections or decubitus as indications to first surgery, Vacuum Assisted Closure-treatments or secondary closures of wounds were not considered to be unplanned, and coded as zero.

Information on mortality was retrieved from the National Registry which is maintained by the Norwegian Taxation Administration [126]. For patients with several hospital admissions during the study period, 30-day-mortality (in-hospital or after discharge) was counted from the first surgical procedure during the last hospital admission.

3.10 Statistical data analysis

Continuous variables in all studies were presented as means with standard deviations (SD) for normal distributed variables or medians with intra quartile range (IQR) (Study III & IV) for non-normal distributed variables. To test the strength of agreement between detection and verification of complications using two different methods we utilised Cohen's Kappa (*k)* and weighted *k* statistics (Study III and IV). The Kappa statistics were used to determine standard values for agreement: <0.20 (poor), 0.21-0.40 (fair), 0.41-0.60 (moderate), 0.61-0.80 (good) and 0.81-1.00 (very good) [127]. Group comparisons (control clusters/intervention clusters) were performed with Pearson's exact test with Bonferroni corrections for binary variables or Gosset's t-test for continuous variables (Study IV). When determining the association between the two methods to confirm complications in the same hospital admissions, we used binary logistic regression (Study III). Sensitivity and specificity was calculated to measure the ability to detect complications using both methods (GTT and ICD-10) and reported with 95% confidence intervals (CI) (Study III). In Study IV, binary and multivariate logistic regression was performed to study the effects on morbidity and mortality of adding the pre- and postoperative SURPASS checklists to the WHO SSC. Cox regression was used to evaluate effects of adding SURPASS checklists to the WHO SSC on length of hospital stay (Study IV). Both binary- and multivariate regression analysis are reported as odds ratios (ORs) and Cox regression as hazard ratios (HRs) with 95% confidence intervals (95% CIs).

The statistical analyses were performed using the software SPSS version 24 for Windows (IBM, Armonk, New York, USA) (Study III & IV). A Venn diagram was drawn and weighted *k* statistics were performed using Stata version 14.0 (StataCorp, College Station, Texas, USA) (Study III). Power analyses were calculated utilising the Sample Power 2 in SPSS version 24 (Study III & IV). A two-tailed p-value of ≤ 0.05 was regarded to be statistical significant.

4. Summary of results

4.1 Study I

The search strategy identified 7408 studies using the predefined words. After thorough review, the study group finally reached consensus of 34 studies being included in the systematic review. Of the included studies, 11 were published before 2010, while 23 were from 2010 to 19th October 2012. The majority were from the USA and countries in Europe (15 and 16, respectively), two from Canada and only one from the Middle East; Iran. We identified four different categories of effects: patient outcome (morbidity and mortality) as reported in seven studies, adherence to guidelines reported in six studies, human factors (daily goals, communication, information loss in transfer, safety awareness) as reported in 16 studies, and reductions of adverse events related to instruments or equipment as reported in five studies.. LOS was reported to decrease significantly in two studies and remained unchanged in one study. However, some studies reported outcome measures without any significant changes at all. The included studies were diverse as to study designs: three randomised control trials; 20 prospective pre-post designs; three retrospective pre-post designs; three prospective cohort studies; three post intervention studies; and two longitudinal studies. None of the included studies reported on effects of using checklists for longer than a year. The review disclosed a need for stronger study designs like RCTs, Stepped Wedge Cluster RCTs, and longitudinal designs, to establish robust evidence when investigating effects. There was only one concept of safety checklists developed to follow surgical patients throughout the surgical pathway having been validated and tested for effectiveness on patient outcomes; the SURPASS checklists.

4.2 Study II

The translation of the checklist content involved both worded translation and allocation of list items to different health care providers in accordance with Norwegian standards, local work flow and task distributions. When testing the content in clinical practice, the compliance rates ranged from 31% to 97%, with a mean of 78% (180/232) for the different checklist users during the test-period. The test revealed that some texts needed revision and some checkpoints needed reallocation to other health care providers in order to follow established local routines. Focus groups were conducted with groups representing each profession with their own checklists. Findings were summarized in the categories: “Adapt the wording to fit clinical practice” and “The checklist items challenge existing workflow”. The expert panels suggested modifications and rewording of some items. Relevance of the checklist items content using the Content Validity Item (CVI)-scores ranged from 0.83-1.00 for the different checklists. The last step in the validation process, after final modifications, was to back-translate the Norwegian version of combined SURPASS and WHO SSC into Dutch. The back-translated version was then approved for use in Norwegian surgical care by the SURPASS copyright holder. The first Norwegian SURPASS checklists were validated to be used in combination with the already established Norwegian version of WHO SSC. For checklist content, see Appendices 8.5.

4.3 Study III

Using the GTT method complications were found in 212/700 admissions, whereas the ICD-10 method identified complication codes having been used in 332/700 admissions. However, only 141/700 of the registered ICD-10 complications were verified as having emerged in-hospital. Agreement between the two methods of in-hospital complications then increased from 68.3 % to 83.3 % when using the verified ICD-10 complication codes. Further, when testing method sensitivity using the GTT method we found that there was also an identified complication when using extracted ICD-10 codes with a mean of 0.52 (95% CI: 0.47 to 0. 57). Specificity identifying discharges without GTT complications compared to admissions identified with no complication using the ICD-10 method found a mean of 0.85 (95% CI: 0.81 to 0.89). Having performed the verification process of excluding ICD-10 complication codes present at admission we tested sensitivity of confirmed GTT complication with verified in-hospital ICD-10 complications and found a mean sensitivity of 0.86 (95% CI: 0.80 to 0.92), and there was a mean specificity 0.81 (95% CI: 0.78 to 0.84) accordingly.

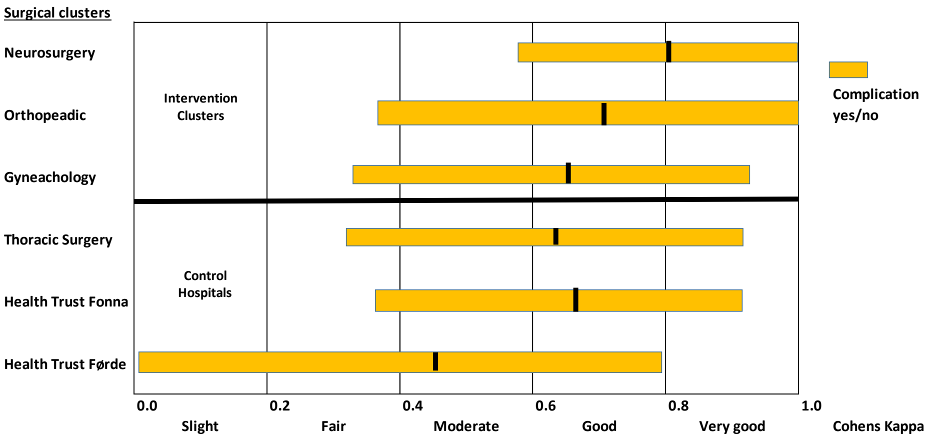
When comparing the methods (GTT and ICD-10), some complications were classified only by one or the other method. The GTT method identified 94 admissions as having a complication, without a corresponding verified ICD-10 complication code. On the other hand, 23 admissions with verified ICD-10 complication codes were not classified as having a complication using the GTT method.

4.4 Study IV

Surgical procedures constituted the main subject for investigation. In total, 18,687 surgical procedures were included as study samples, with 9,009 and 9,678 procedures in the intervention trial clusters and control hospitals respectively. A total of 7,772 and 8,121 unique patients in trial clusters and control hospitals were included respectively.

Ensuring the procedure of verifying in-hospital complications using the ICD-10 method (as validated in study III) Kappa agreement-tests in 30 surgical procedures for each surgical cluster was conducted. The inter-rater agreements between the methodological and surgical experts are shown in Figure 4.

Figure 4. Level of agreement between surgical- and ICD-10 method experts, 30 procedures (Kappa: 0.0 - 1.0, 95% Confidence Interval)



In total, 38% (7,094/18,687) of the surgical procedures were identified with an ICD-10 code indicating a possible in-hospital complication. After verification of complications to actually having emerged in-hospital, 15.7% (1418/9009) of the surgical procedures in intervention clusters were found to be associated with one or more in-hospital complications, compared to 20.6% (1993/9678) in control hospitals. Investigating the distribution of complications before and after introducing the SURPASS checklists in the intervention clusters revealed 14.7% (574/3892) before and 16.5 % after (844/5117), in unadjusted analyses. An intention to treat analysis showed a 14% increase in complications from baseline to intervention clusters in unadjusted analysis, p = 0.024. However, when having adjusted for age, sex, ASA classification, urgency of surgery, type of surgery, type of anaesthesia, time (month/year) of operation and WHO SSC usage, the in-hospital complications decreased (27% reduced odds; p = 0.035). When having used multiple regression to test effects on complications and emergency reoperations of actual full compliance to the five preoperative SURPASS checklists, a significant reduction was obtained for both outcomes (30% reduced odds; p = 0.036, and 58% reduced odds; p = 0.004, respectively) in adjusted analyses. In addition, there was a 68% reduced odds (p =

0.001) for unplanned 30-day readmissions to hospital when the three postoperative SURPASS checklists had all been fully completed. There were no changes in LOS or 30-day mortality.

In the same time-span, the control hospitals had a similar general increased rate of complications, whereas emergency reoperations, unplanned 30-day readmissions and 30-day mortality were unchanged.

5. Discussion

5.1 METHODOLOGICAL ISSUES

In order to rely on the findings of research, a study needs to be carefully designed and provide the correct statistical tests in order to reach valid and reliable conclusions [128]. Validity is the degree of whether a study measures what it is supposed to measure [129], differentiating between internal and external validity. Internal validity is seeking to establish a trustworthy connection between two variables and minimise other explanations for the results, whereas external validity refers to the ability of generalising findings to other settings [129]. Threats to validity could be both random errors caused by imprecision, such as small sample sizes, or systematic errors, related to bias and confounding factors [128]. Reliability implies consistency and stability, and refers to the likelihood of others to reach the same conclusions if the study is replicated [129].

5.1.1 Study design

Study I was a systematic review of literature, Study II was a validation of the Norwegian pre- and postoperative SURPASS checklists to be used together with the established WHO SSC using both quantitative and qualitative methods, Study III was performed with a prospective observational design, and Study IV was a Stepped Wedge Cluster Controlled Trial design.

The PRISMA statement [85] guided the transparency of reporting the reviewed literature systematically in Study I. This implies a study protocol with predefined research questions including criteria for inclusion and exclusion. The report disclosed search strategy, flowchart, evaluation of quality, and summary of results. Our intention was to produce a systematic review on effects of using safety checklists in all fields of medicine and reveal research gaps, if any, to prepare for our future studies (Study II, III, and IV).

Study II, implied translation and validation of the original Dutch pre- and postoperative SURPASS checklists into Norwegian [121]. The validation process was prospective, following recommended steps to ensure linguistic precision and consistency with the original instrument to avoid systematic measurement bias resulting from the translation process [130], in order to reflect safety issues throughout the neurosurgical care pathway properly.

Study III was conducted using a prospective observational research design. The surgical patient admissions investigated were randomly selected from two out of three hospitals in the Study IV population. The design is favourable, being inexpensive and simple, with all data collected following routines as reported by clinicians in the electronic patient records for all admissions [129]. Since we intended to investigate agreement between two methods used to identify patient complications during hospitalisation, without investigating causality, an observational study design seems appropriate [131].

Study IV included implementation of the new SURPASS checklists using a SWCCT design. This design was regarded as favourable for several reasons: Previous extensive checklist experience in the research team [19, 132] enabling t allocation of checklist instructor-resources to one cluster at a time when implementing eight different individual checklist users per surgical setting [133]; for ethical reasons, not having to withdraw the checklists after having implemented them, as in a parallel study design; and a possibility to adjust for secular time trends, which is not provided for in a simple pre-and post-study design [133]. Challenges using the design may be the complexity of data extractions from several documentation systems with different time-steps for each cluster and parallel cluster. However, apart from the new intervention, all data were routinely documented and systems for computer extractions were already established.

Due to time restrictions it was regarded unfeasible to randomise the different clusters, locking up the timing for a switch from control to intervention periods. Still, not using a RCT design would increase risk of bias, and should be regarded as a limitation [134].

However, inclusion of a parallel control group (control hospitals) following the same outcome measures during the same time-period as the checklist clusters, was deemed advantageous making it possible to evaluate concurrent secular trends affecting results [135].

5.1.2 Validity

In Study I, we did a comprehensive search for relevant studies in databases without limitations to language or time for publication, to avoid selection bias. To increase internal validity two independent researchers were blinded to each other's decisions when determining inclusion or exclusion of the 7408 studies. Quality of the individual studies was evaluated using a validated assessment instrument [75] to ensure both internal (i.e. rigor of method) and external validity (i.e. population included, checklist intervention and outcomes studied). Reporting on levels of evidence might have strengthened the study, determining effectiveness of the presented findings [134]. However, this was not included in the quality assessment tool used to facilitate our review [75], and is therefore not provided. Reporting bias was reduced by using the PRISMA guidelines throughout [85].

Study II followed recommended validation guidelines from the WHO to secure external validity, ensure transparency and increase the possibility of replication [121]. Face validity confirmed health care providers' subjective perception that the checklists covered the intended safety aspects in neurosurgery. The checklist content validity index scores between 0.83 and 1.00 were regarded satisfactory [123], again guiding adjustments to checklist items contents. In line with recommendations in the WHO implementation manual [136], we adjusted the content to fit each surgical discipline's work flow. Knowledge from the validation process performed in Study

II, guided adjustments in later checklist contents for orthopaedic and gynaecology procedures in Study IV.

In Study III, statistical power calculations were performed to avoid random errors caused by too few surgical admissions having been included, which would have hampered representativeness [129]. Using GTT method experts and clinical nurses and physicians to classify ICD-10 complications with standardised methods and tests of agreement were regarded a strength. Separating the ICD-10 complication codes reflecting complications present on admission from the overall complication codes registered decreased random error and increased accuracy of the remaining complication codes as representing complications having emerged during hospital stay. Sensitivity and specificity analyses are used to investigate concurrent validity by comparing a chosen method to an already validated method [128]. The sensitivity of identifying complications when having used both methods on the same admissions increased significantly from a mean of 0.52 to 0.86 after verifying the complications as new during admission. In addition, specificity showing agreement on no complications using both methods decreased slightly from 0.85 to 0.81. Thus, ICD-10 complication codes reach higher accuracy and validity when first having verified such codes truly representing complications to have emerged in-hospital.

In Study IV, the clusters each contributed with patient data both before and after the study intervention serving as their own controls, and thus minimising selection bias [133]. Since single surgical procedures were subjects of investigation, it was unlikely that any subject could have been in both control and intervention groups, hence within cluster contamination was avoided [135]. This strengthened the chance of comparing homogeneous procedures. Contamination of study clusters caused by information bias due to personnel working in several disciplines or sections/departments was largely avoided: The operating theatres and surgical teams were separately located with their own organizational units and specialised personnel (neurosurgery, orthopaedic surgery, gynaecology and the parallel control departments including thoracic surgery, general surgery, vascular surgery, gastroenterology, and urology, orthopaedics and ear/nose/throat surgery).

To strengthen internal validity and decrease information bias, healthcare providers using checklists and patients were not informed on outcome measures. Also, the physicians verifying ICD-10 complication codes were blinded to checklist-usage. Collection of routine data from the hospitals administrative system reduced risk of contaminating the intervention and outcome measures [135]. External validity was strengthened by having joint method-training involving five surgeons and one anaesthesiologist from their respective specialties (clusters) and testing agreement with the method experts from Study III. Thus, verifying the in-hospital complications was performed in close collaboration between the surgeons and the clinical researchers.

Bias due to missing outcome data, and threats to both internal and external validity was considered non-existent, since it only comprised missed ASA classification for 16 surgical procedures in the total population of 18.687 procedures. Statistical power calculations were performed to strengthen external validity. The high quality of the dataset ensured reliable variables, increasing accuracy and precision, and thus decreasing chances of concluding outcomes based on systematic and random errors [128].

5.1.3 Reliability

In Study I, following the PRISMA guidelines [85] ensured reliability and transparency throughout the review and reporting on the results enabling other researchers to use the same search strategy, inclusion and exclusion criteria.

In Study II, WHO guidelines on how to translate and adapt instruments to new settings were used [121]. The study included transparent description of the processes involved in translation, testing the content in clinical practice, focus groups, panels of experts, back translation and final approval, and openly reporting detailed adjustments to the checklist content, ensured reliability of the Norwegian version of the SURPASS checklists.

In order to assess reliability of the extraction method of the ICD-10 complication codes, used in Study III and IV, one hundred random patient records without any complication codes were manually reviewed to find if there were complications described and/or coded without the extraction procedures having been able to identify them. There were no missing ICD 10-codes and the extraction procedures were regarded as reliable.

Reliability in Study III was measured using Cohen's Kappa (κ) analysis [127]. In Study III, classification was performed with a standard instrument using the hospitals' established GTT expert teams, thus strengthening the reliability of the classifications [45]. Tests on agreement were performed between two GTT teams, and three ICD-10 raters, and finally between the GTT and the ICD-10 methods both before and after having verified in-hospital complications. Comparing different methods to test agreement is an established approach [41, 50, 137, 138]. A systematic review of 25 patient record review studies having used both the GTT method and the Harvard Medical Practice Study to identify complications showed good reliability (κ =0.65) [45]. None of the included studies reported on validity. However, in our Study III, validity and reliability of identifying in-hospital complications were confirmed, thus ICD-10 codes may be utilised in large scale studies (in Norway) providing codes representing complications having emerged in-hospital are reported separately.

Cohens Kappa tests were repeated in Study IV to measure agreement on having verified complications as having emerged in-hospital. Altogether 10 raters classified complications. Involving too many raters may threaten consistency and reliability of verifying in-hospital complications [139]. However, studies using only one rater have also shown discrepancies when the rater is introduced to exactly the same situation more than once [140]. We did not perform test-retests on agreement (Study III and IV).

This may be regarded as a limitation [129]. Still, the interrater reliability test results were revealed among the raters and thoroughly discussed in plenum until a consensus on classification was reached.

Using a study design with control hospitals increased reliability of our study results, since we were able to investigate changes of outcome measures in another population in the same time period.

5.2 DISCUSSION OF RESULTS

5.2.1 Systematic review of effects of safety checklists in medicine

Study I found that safety checklists increased patient safety by reduction of complications, mortality and increased use of guidelines and protocols, in addition to have a positive impact on human factors. Effects on LOS were reported with variable results, associated with checklists. Positive effects on patient outcomes of using safety checklists has also been reported in other reviews [27, 61, 63-67, 69, 74, 76, 77, 80]. Study I identified few studies using RCT- or longitudinal designs. Other reviews also raise a call for more robust study designs to test effect of checklist interventions [63, 65, 67, 70, 71, 84]. None of the studies identified in Study I utilised designs with a possibility to adjust for secular trends, which may confound results. A SWCCT/ or a stepped wedge cluster controlled RCT design may adjust for time trends, and may be advantageous in health care settings involving continuous advancements and change [135]. During the last five years, two large studies with a longitudinal [90, 91] and one with a pre-post-design [87] have shown weak or no effects of checklist use. However, a recent longitudinal Scottish study including 12,667,926 hospital admissions attributed a significant 36.6 % relative reduction of mortality to use of the WHO SSC [141]. Although implementation processes were not main objects in our study, our review points to challenges of implementing checklists in clinical practice. Other reviews also address the complexities of implementing checklists [79, 81, 84]. Both Study I and the recent updated literature review found that the SURPASS checklists were the only system with validated safety checklists throughout the surgical pathway: To our knowledge, this is still the case.

5.2.2 Validating the pre- and postoperative SURPASS checklists in combination with the WHO SSC

The WHO SSC was well established in the operating theatres before commencing the present PhD study. When aiming to increase patient safety, the comprehensive pre- and postoperative SURPASS checklists were identified as the only validated system with published effects on patient outcomes and deemed feasible to complement the existing WHO SSC.

Forward translation of the SURPASS checklists followed by text adjustments and attributing checkpoints to the responsible healthcare provider in the local context were accomplished by using the recent WHO's guideline on translating and adaptation of instruments from one language to another [121]. When testing the checklist contents in clinical practice, all health care providers were sufficiently compliant with checklist use except the operating theatre nurses, probably due to practical problems and misunderstandings when using a paper-checklist. This was considered a limitation. Also, a low compliance rate would have been disclosed earlier with electronic checklist use.

Eight focus groups, one for each individual SURPASS checklist user/profession were conducted. Having more than one focus group per profession might have revealed more information [142]. However, the focus groups were one out of six steps in the validation process. Thus, findings from the focus groups guided further adjustments to the checklist content. Scoring of checklist content relevance indicated good content validity (range 0.83 to 1.00) for the eight expert panels [143]. Still, some of the checklist items received a low score. This feedback provided valuable information on modifying the content.

A limitation of using expert panels may be that feedback is based on subjective views of the panel experts [144]. Seven or more raters are advised upon to prevent over emphasising results from single raters [130]. However, here six experts in each panel (except for the operating theatre nurses) for this complex construct reached a high content validity score, which may have gained representativeness [145]. Altogether, we regarded this as sufficient due to acceptable scoring results. Using a native Dutch person, with excellent English language skills, and years of experience as an anaesthesiologist in Norwegian hospitals was considered a major strength in the back translation process, in accordance with the WHO guidelines [121]. This reduced any translation flaws due to unfamiliarity and insensitivity with nuances in the language in surgical settings [146]. Final approval of the checklist content from the original developer was the last step in the validation process and important to ensure the meaning and intent of the original Dutch SURPASS checklists [146].

Although having instructed the personnel that the checklists should be validated in order to become the first general Norwegian SURPASS versions, involving only personnel providing neurosurgical procedures, may be regarded a limitation. However, development and validation of the original SURPASS checklists were performed with gastroenterology, vascular and orthopaedic procedures in one hospital in the Netherlands [57]. The Norwegian version of the SURPASS checklists in combination with the WHO SSC was found reliable and valid. Experience from the validation process in Study II was regarded valuable for adapting the checklist content to new settings in study IV.

5.2.3 Accuracy of ICD-10 complication codes

Generally, in order to study effects on outcomes (errors or survival) from any checklist use, outcomes must somehow be registered and counted. Most studies take use of already registered diagnostic and procedure coding for various medical or administrative purposes. Such coding was never intended to be used in quality improvement, and neither to describe complications in sufficient details. Hence using these extracted codes “unfiltered” introduces a large bias in studies reporting on various complications as outcome measures. Many methods could theoretically be used to overcome this, but most would require an enormous parallel registration with impact on available resources. Since GTT has been used extensively to document complications during hospital stay [73]it was a deemed useful to conduct a comparative study between ICD-10 coding and GTT use. To our knowledge there are few comparable publications having done this. In our study, we found that using extracted ICD-10 codes overestimated the number of in-hospital complications by 55 per cent when compared to using verified in-hospital codes only. After manually verifying ICD-10 codes not present at admission, there was a significantly increased agreement between ICD-codes and GTT investigation in identifying complications. Monitoring complications using ICD-10 complication codes without verifying and separating out complications as having emerged in-hospital, may inform inaccurately. This could further lead to implementation of interventions with limited ability to actually improve in-hospital patient safety [45]. Hence, ICD-10 complication codes may be used to register in-hospital complications, providing a verification procedure is done (Study III). Again, this method was used for accurate in-hospital complication measures in Study IV.

Even if our study used one of the largest samples of ICD-10 codes for complications, we still have found missing codes, like D62 Acute Postoperative Haemorrhage that should have been included. This may explain that some of the GTT complications registered were not picked up by the ICD-10 method, and could possibly have increased classification agreement between the two methods.

Overall, we had a moderate agreement between the GTT and the ICD-10 methods after the verification procedure. Study III shows that 94/212 (44.3 %) (GTT) and 23/141 (16.3 %) (ICD-10 codes) complications were not classified with both methods. There are also generic differences in what describes a complication when using the two methods. The GTT classifier (in the expert team) takes the patient view, hence, if the patient experiences an undesired condition it may be evaluated as a complication. The ICD-10 classifier (discharging physician) takes the viewpoint of the care provider and may have other classification criteria than GTT in similar situations not qualifying for an ICD-10 code.

On the other hand, the GTT method does not include errors of omission, whereas this may be reflected in an ICD-10 code.

Our study did not perform a grading of preventability, and this may be regarded as a limitation [31]. Although such classification is subjective and complex, it may point to relevant areas and inform on necessary adjustments to improve patient safety. Several studies report using tools to classify preventability [147-149]. Sweden and Finland include preventability scoring when using the GTT method [150]. However, grades of preventability may differ between surgical specialities and where in the surgical pathway the complication originated [147]. Preventability grading may increase safety awareness and foster a culture of safety learning, as reported by others [150].

5.2.4 Effects on patient outcome of adding the SURPASS checklists to the WHO SSC

The WHO SSC has been implemented in thousands of hospitals worldwide [18], and WHO SSC use has resulted in reducing complications by 42% on average in the present hospital [19]. To our knowledge, there are no other studies who have further added validated checklists for the total patient pathway (such as the SURPASS to the WHO SSC) to evaluate possible additional patient benefits. We have demonstrated reductions in in-hospital complications, emergency re-operations and 30-day readmissions. Our study has several strengths, including use of validated SURPASS checklists (in combination with the WHO SSC), facilitation of implementation and analyses by using a prospective SWCCT design, use of external controls, and a longitudinal data collection of 29-months.

De Vries et al. (2010) showed effects from the SURPASS checklist system on gastrointestinal, vascular, renal and endocrine surgical procedures [16]. A small Indian SURPASS study described effects in elective and emergency procedures, not disclosing the surgical procedures included [17]. Our study demonstrated effects of adding the pre- and postoperative SURPASS checklists to the already established WHO SSC in neurosurgical, orthopaedic and gynaecological procedures. The Dutch and Norwegian studies have relatively comparable health care systems, whereas the Indian study has a great diversity in health care facilities.

Our study showed that in-hospital complications decreased significantly, with full use of the preoperative SURPASS checklists in a fully adjusted analysis, OR 0.70, P=0.036, even with the WHO SSC already in place. This is in line with the original Dutch SURPASS study by de Vries et al. (2010), reporting a total portion of patients with one or more complications decreasing from 15.4 to 10.6 per 100 patients (P<0.001) [16]. The Indian SURPASS study by Mehta et al. 2018, also found a decreased complication rate from 66.7 to 51.1 % (P=0.008) in elective cases and 77.2 to 67.5 % (P=0.024) for emergency cases [17].

The effects of WHO SSC use on complications have been studied in numerous studies (24 original studies included in the updated review (table 1, page 13).

Several systematic reviews report favourable reductions in complications from checklist use [38, 64, 76, 77, 80, 81]. However, findings of no effects on complications in some of the included studies were also reported, and therefore concluded on there being variable results as to complication outcomes [67].

Four meta-analyses with syntheses on effects of checklist use on complications in surgery concluded on significant reductions [61, 63, 65, 66]. Borchard et al. (2012) had included different surgical safety checklists. Bergs et al. (2014) and Gillespie et al. (2014), concentrated on effects of WHO SSC use and had included the same four studies, but with extra studies each, not captured by the other. In the largest meta-analysis so far, Abbot et al. (2018) also confirmed a protective effect on complications from using the WHO SSC.

In our study, emergency reoperations were significantly reduced (OR 0.42, P=0.004) when all the preoperative SURPASS checklists had been used, confirming de Vries et al.'s (2010) findings of reductions in reoperations from 3.7 % to 2.5 %, P=0.005 [16]. The Indian SURPASS study did not find any changes in reoperations [17].

Our updated review (table 1, page 13) found several original studies reporting reductions in reoperations with WHO SSC use [10, 19, 87, 107], but also studies reporting no such effects [89, 92, 97-99, 101, 111]. All studies, except one [107], reported on reoperations as a sub-analysis, and not as a main outcome.

One meta-analysis included two original studies investigating effects on unplanned reoperations, finding pooled results to be non-significant [63].

We found a reduction in unplanned readmissions within 30-days (OR 0.32, P=0.001) with full compliance to the postoperative SURPASS checklists. The original Dutch and the Indian SURPASS studies did not report on unplanned readmissions, so ours is the first to investigate effects of SURPASS checklists use on this. While several WHO SSC studies have shown a reduction in readmissions [87, 91, 98, 108], other such studies showed no such change [88, 105].

One study was designed to measure effects on readmissions only, from having used a locally developed checklist for the patients to use [86] and found a reduction of readmission to hospital from 28% to 20%, p=0.04 in patients with ileostomy surgery. To our knowledge, this is the only publication showing effects of using patient checklists. Whether such checklists also may have an effect on other safety outcomes still needs further investigation.

Three systematic reviews [67, 71, 84] included altogether four original studies on changes in readmission rates. The original studies presented variable conclusions, two showing reductions in readmissions to hospital, and two without significant changes. However, it was not possible to perform a synthesis of results due to heterogeneity.

In our study, we also investigated length of hospital stay (LOS). There was an increased risk of being discharged earlier when comparing admissions throughout the study period, but without association to SURPASS checklists compliance (5.8 to 5.6 days, p=0.425). Our National Government´s increased focus on early discharge from hospital in the "Cooperation Reform" ("Samhandlings-reformen") may have influenced these findings. Neither de Vries et al. (2010) nor Mehta et al. (2018) investigated effects of the SURPASS checklists on LOS.

WHO SSC use has been studied, both with findings of significant reductions [19, 87, 89, 105, 106] and no change in LOS after checklist introduction [93, 94, 98, 109].

One review from de Jager et al. (2016), reported variable effects on LOS with WHO SSC use. None of the identified meta-analyses reported on LOS.

Our study could not confirm that there was an association between compliance to SURPASS checklists and reduced mortality. De Vries et al (2010), in their conclusion, reported that using the SURPASS checklists was associated with a decreased in-hospital mortality from 1.5 to 0.8, p=0.003 per 100 patients [16]. Mehta et al. (2018), found no change in mortality after SURPASS introduction [17].

WHO SSC use has been studied for effects on mortality with findings of significant reductions in a great number of studies [10, 11, 62, 88, 94, 102, 105, 106, 141, 151]. Still, several other studies reported no such mortality effects of WHO SSC use [19, 87, 89, 91, 93, 95, 97-100, 110-112].

An Israeli cross-sectional study having included 380 patients before and 380 patients after implementing the WHO SSC, showed an increase in mortality from 0.8% to 2.7%, p=0.049 [92]. At the outset they describe a power analysis on how to detect post-operative fever as a surrogate for mortality. The authors did not provide clear explanations to the increased mortality. Although these findings should not be ignored, a stronger study design with power calculations to detect mortality seems to be more appropriate.

Other studies reporting on effects of different kinds of checklists, reported no associations to mortality with checklist use [90, 101, 118].

Five systematic reviews summarised that safety checklist use reduced mortality, although having identified studies without such effects [38, 76, 77, 80, 81]. De Jager et al. (2016) reported that the included studies were too heterogeneous to make effect evaluations, concluding that more rigorous studies are needed to evaluate effects on mortality [71].

In 2012 and 2014 two meta-analyses reported significant reductions on mortality from checklist use [65, 66]. This was contrasted in 2014 in a separate meta-analysis with a conclusion of no effects [63], and then again contradicted in 2017 and 2018 with two meta-analyses showing protective effects on mortality from checklist use [61, 67].

Reflections on issues regarding our findings from implementing the pre- and postoperative SURPASS checklists:

- First, due to resources available, the pilot periods for the different clusters varied from 3 weeks to 12 months. Spending time on building ownership and adaptations to the new checklists and tailoring checklist content to all personnel groups (operating theatre nurses, surgeons, anaesthesiologists, ward nurses and PACU nurses) involved in each surgical specialty (neurosurgery, orthopaedics and gynaecology), is in line with advices in the literature [152]. Strong involvement from the implementation/ research team in the tailoring process ensured the original SURPASS checklist content. Regular compliance reports were provided and discussed with department managers.

Indeed, implementation of a complex intervention in complex settings requires appropriate and supportive implementation resources and thorough consideration of time needed for implementation [153-155].

- Second, actual and sustainable compliance to checklists.

Compliance rates in our study varied greatly. Compliance to checklist use was also a major concern in de Vries et al.'s (2010) study with inclusion of 26% of the patients in the post implementation group for their analysis (having required a median 80% checklist compliance) [16].

For analysis in the present study, we included all full compliant checklists (all items used) and analysed proportions of checklists used as to possible effects. However, generally, low compliance rates may underestimate effects of the checklist intervention and this must be taken into account.

Several studies have used aggregated data, without being able to link actual checklist compliance to patient outcome. Our high quality dataset here strengthens the reliability of our findings. However, although some of the managers here performed local investigations on their own personnel's attitudes towards completion of the new SURPASS checklists, this was not facilitated on a systematic level for all personnel groups. To get a better understanding of facilitators and barriers to checklist compliance requires further studies.

Incentives or internal orders making compliance to checklists compulsory, may result in sky-high compliance rates being reported, still without effects on patient safety to show for [87, 90]. We endorse strong involvement from top-level managers. Still, sufficient implementation resources, education and follow-up on checklist fidelity are emphasised [155]. However, high compliance rates per se do not necessarily mean increased patient safety [156, 157].

- Third, understanding of underlying processes.

Complexity in health care is great, with systems prone to human performance deficiencies. Safety checklists may aid human memory and capacity to prevent patient harm on a system level [158]. Our study provides detailed descriptions specifying different outcomes likely to be influenced by compliance to different parts of the SURPASS checklists. This is regarded as an enhancement compared to previous SURPASS reports. Exactly which processes that may have been improved by using the SURPASS checklists are not known. However, in a secondary follow up analysis of compliance to the WHO SSC, more information as to care processes and patient outcomes have been revealed [104]. Here, there were increased use of forced air warming blankets and more timeliness of antibiotic administrations, which in turn could be linked to less blood transfusions and less surgical infections. Inclusion of process measures to increase understanding of effects is recommended [153, 154].

It may be difficult to study isolated effects of checklist use due to confounding factors. Health care reforms focusing on increasing quality and hospital values have shown to reduce readmission rates [159]. In Norway, national interventions to be regarded as possible confounding factors may be the national Patient Safety Campaign (2011-2013), and the Patient Safety Program (2014-2018) [60], both commenced within the time-frame of the study. Using the SWCCT design facilitated the ability to statistically adjust for time of the year; hence, secular changes, such as the national programs, were adjusted for statistically. In addition, every cluster acted as their own control at different points of time in the stepped wedge design [160].

- Fourth, understanding actual effects.

There was an overall increase in complications during the study period, both in intervention clusters and control hospitals. Intention to treat analysis showed increased complications in unadjusted analyses. Analysing effects of preoperative SURPASS checklist compliance on complications in unadjusted analyses did not reveal significant changes, whereas, adjusted analyses showed a significant reduction of complications. Since the pattern of increased complications was present also in the control hospitals, this may reflect increased focus on coding practices [161]. Although, we have not studied coding practices per se, clinicians and directors involved in our study have confirmed an increased attention towards practice of coding.

Our study did not find changes in LOS or mortality associated with checklist compliance. Whether LOSs for this particular patient population has reached a potential minimum, without probability of further significant reductions, remains unclear.

Several studies showing no mortality effects have not reported sample size power calculations and/ or were underpowered to show possible effects [17, 89, 93, 98, 100, 101, 110-112], or had performed calculations on one primary outcome, but still reported on other outcomes requiring larger sample sizes [92, 97].

However, large scale studies also report no effects of checklist interventions. O'Leary et al. (2016) reflected that a possible explanation of no change in their study was that the population they investigated was quite healthy at the outset (children), or that there might be a "ceiling effect" in populations with low baseline outcome measures [89]. A recent sufficiently powered retrospective study by Haynes et al. (2017), reported reductions in mortality related to WHO SSC compliance, but no effects on the rate of reoperations [88]. The study design did not make it possible to investigate underlying processes to explain findings. However, the authors suggest that secular trends during period of the study could have been a confounding factor. Due to the SWCCT design of our study and use of logistic regression in our analyses, we were able to adjust for such secular trends, and we regarded this as a strength to our study.

We had low rates of mortality in our intervention clusters, both before and after the intervention. Mortality in high-risk surgery has been reported to decline over time [162]. If a "ceiling effect" on mortality had already been reached in this population is unclear. However, surgical specialties with higher baseline mortality rates due to more comorbidities, may have more to gain. This remains to be investigated.

In general, depending on the outcome measure and population under investigation a thorough planning of design and sample power calculations is advised.

6. CONCLUSIONS AND IMPLICATIONS

6.1 Conclusions

- Patient safety is strengthened with the use of safety checklists. Using checklists in medicine facilitates better compliance to practice guidelines, improves on human factors, such as understanding of daily goals, communication, teamwork and information transfer, and reduces adverse events, complications, and mortality. (Study I)
- The first Norwegian version of the pre- and postoperative SURPASS checklists were validated in combination with the already existing WHO SSC following six steps as recommended in WHO guidelines. (Study II)
- Using two methods to detect complications revealed more information than one method alone. Comparing findings from the record review method GTT with the ICD-10 complication code method disclosed a stronger complication agreement when ICD-10 codes representing complications present on admission were excluded. ICD-10 complication codes may present reliable, valid and accurate complication measures to inform on in-hospital complications, provided the codes are verified as reflecting complications having emerged in-hospital. (Study III)
- Patient safety improves even more when adding the pre- and postoperative SURPASS checklists to the already established WHO SSC. Adjusted analyses show that full compliance to the preoperative SUPRASS checklists decreased in-hospital complications and emergency reoperations, and full compliance to the post-operative SUPRASS checklists decreased unplanned 30-day readmissions to hospital significantly. Full use of the pre- and postoperative SURPASS checklists in combination with the already established WHO SSC results in better on patient outcomes. (Study IV)

6.2 Implications for clinical practice

- We recommend the pre- and postoperative SURPASS checklists to be added to the WHO SSC for all surgical specialties.
- The pre- and postoperative SURPASS checklists should be tailored to every new setting (department, speciality) in order to increase involvement and sense of ownership to the checklists implementation.
- Ensuring transfer of information from one care provider to the next is imperative in surgery and requires close teamwork.
- Guidelines and protocols must be thoroughly implemented before introducing a check-item to be completed on a checklist.
- When deciding on targeted patient safety interventions, concurrent use of the GTT and verified ICD-10 complication codes may yield valuable information targeting local and national patient safety interventions.
- Checklist systems may also be suitable for other than patients in surgery e.g. in interventional radiology and medicine. The postoperative checklists, with adaptations, may be of value to all hospitalised patients before discharge.
- Continuous focus on how to use the checklists correctly and updating the content rigorously to prevent checklist burnout is necessary.

6.3 Implications for further research

- Although use of the SURPASS checklists has been shown to significantly increase patient safety, only three studies have investigated effects of implementing the SURPASS checklists so far. We need more high quality studies with strong study designs, proper sample size calculations, and rigorous reporting to make replications possible.
- All studies on in-hospital complications using ICD-10 codes should use a verification procedure for complications having emerged in-hospital.
- In-depth understanding of facilitators and barriers to SURASS checklist compliance are warranted.
- Investigate underlying care processes to understand effects of the SURPASS checklist.
- Investigate long-term sustainability and high fidelity of checklist compliance.
- Investigate degree of preventability of complications to tailor patient safety instruments and checklists.
- Few studies have investigated effects of checklists on unplanned readmissions to hospital, thus, more studies are needed.

7. REFERENCES

1. World Health Organization. Safe Surgery Saves Lives. Second Clobal Patient Safety Challenge. Accessed 14th September 2019 https://www.who.int/patientsafety/safesurgery/knowledge_base/SSSL_Brochure_finalJun08.pdf.
2. Panagioti M, Khan K, Keers RN, Abuzour A, Phipps D, Kontopantelis E, Bower P, Campbell S, Haneef R, Avery AJ, Ashcroft DM. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *BMJ* 2019;**366**: l4185.
3. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991;**324**(6): 377-384.
4. Kohn LT, Corrigan JM, Donaldson MS, Editors. To Err is Human: Building a Safer Healthcare System. Accecced 14th September 2019 http://wps.pearsoneducation.nl/wps/media/objects/13902/14236351/H%2007_To%20Err%20Is%20Human.pdf.
5. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;**322**(7285): 517-519.
6. Baines RJ, Langelaan M, de Bruijne MC, Asscheman H, Spreeuwenberg P, van de Steeg L, Siemerink KM, van Rosse F, Broekens M, Wagner C. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf* 2013;**22**(4): 290-298.
7. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Quality & safety in health care* 2008;**17**(3): 216-223.
8. World Health Organization. Patient safety. Safe Surgery. Why safe surgery is important. Accessed 14th September 2019 https://www.who.int/patientsafety/safesurgery/en/.
9. World Health Organization. WHO Surgical Safety Checklist. Accessed 14th September 2019 http://apps.who.int/iris/bitstream/10665/44186/2/9789241598590_eng_Checklist.pdf.
10. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009;**360**(5): 491-499.
11. van Klei WA, Hoff RG, van Aarnhem EE, Simmermacher RK, Regli LP, Kappen TH, van Wolfswinkel L, Kalkman CJ, Buhre WF, Peelen LM. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. *Ann Surg* 2012;**255**(1): 44-49.
12. Dubose J, Teixeira PG, Inaba K, Lam L, Talving P, Putty B, Plurad D, Green DJ, Demetriades D, Belzberg H. Measurable outcomes of quality improvement using

a daily quality rounds checklist: one-year analysis in a trauma intensive care unit with sustained ventilator-associated pneumonia reduction. *J Trauma* 2010;**69**(4): 855-860.
13. Agarwal S, Frankel L, Tourner S, McMillan A, Sharek PJ. Improving communication in a pediatric intensive care unit using daily patient goal sheets. *J Crit Care* 2008;**23**(2): 227-235.
14. Greenberg CC, Regenbogen SE, Studdert DM, Lipsitz SR, Rogers SO, Zinner MJ, Gawande AA. Patterns of communication breakdowns resulting in injury to surgical patients. *J Am Coll Surg* 2007;**204**(4): 533-540.
15. Griffen FD, Stephens LS, Alexander JB, Bailey HR, Maizel SE, Sutton BH, Posner KL. The American College of Surgeons' closed claims study: new insights for improving care. *J Am Coll Surg* 2007;**204**(4): 561-569.
16. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med* 2010;**363**(20): 1928-1937.
17. Mehta N, Amaranathan A, Jayapal L, Kundra P, Nelamangala Ramakrishnaiah VP. Effect of Comprehensive Surgical Safety System on Patients' Outcome: A Prospective Clinical Study. *Cureus* 2018;**10**(5): e2601.
18. World Health Organization. Patient Safety: surgical safety Web map. Accessed 14th September 2019 http://maps.cga.harvard.edu/surgical_safety/.
19. Haugen AS, Softeland E, Almeland SK, Sevdalis N, Vonen B, Eide GE, Nortvedt MW, Harthug S. Effect of the World Health Organization Checklist on Patient Outcomes: A Stepped Wedge Cluster Randomized Controlled Trial. *Ann Surg* 2015;**261**(5): 821-828.
20. World Health Organization. Patient safety definition. Accessed 14th September 2019 2019 http://www.euro.who.int/en/health-topics/Health-systems/patient-safety.
21. Saunes IS, Svendsby PO, Mølstad K, Thesen J. Kartlegging av begrepet pasientsikkerhet [In Norwegian]. Norwegian Knowledge Centre for the Health Services. Accessed 14th September 2019 https://www.fhi.no/publ/2010/kartlegging-av-begrepet-pasientsikkerhet-----/.
22. Emanuel L, Berwick D, Conway J, Combes J, Hatlie M, Leape L, Reason J, Schyve P, Vincent C, Walton M. What Exactly Is Patient Safety? In: *Advances in Patient Safety: New Directions and Alternative Approaches (Vol 1: Assessment)*, Henriksen K, Battles JB, Keyes MA, Grady ML (eds). Agency for Healthcare Research and Quality: Rockville, 2008.
23. Vincent C, Amalberti R. Safety in healthcare is a moving target. *BMJ Qual Saf* 2015;**24**(9): 539-540.
24. World Health Organization. World Alliance for Patient Safety. Accessed 14th September 2019 https://www.who.int/patientsafety/en/brochure_final.pdf.
25. Hollnagel E, Wears RL, Braithwaite J. From Safety-I to Safety-II: A White Paper; 2015.
26. Reason J. *Human error*. Cambridge University Press: New York, 1990.

27. Collins SJ, Newhouse R, Porter J, Talsma A. Effectiveness of the surgical safety checklist in correcting errors: a literature review applying Reason's Swiss cheese model. *AORN J* 2014;**100**(1): 65-79.
28. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: turning patient safety on its head. *Int J Qual Health Care* 2015;**27**(5): 418-420.
29. Grober ED, Bohnen JMA. Defining medical error. *Can J Surg* 2005;**48**(1): 39-44.
30. Rodziewicz TL, Hipskind JE. Medical Error Prevention. In. Treasure Island, Florida, USA: StatPearls Publishing; 2018.
31. Griffin F, Resar R. Global Trigger Tool for measuring adverse events (2nd ed.). Accessed 14th September 2019 http://www.ihi.org/resources/Pages/IHIWhitePapers/IHIGlobalTriggerToolWhitePaper.aspx.
32. Classen DC, Lloyd RC, Provost L, Griffin FA, Resar R. Development and Evaluation of the Institute for Healthcare Improvement Global Trigger Tool. *Journal of patient safety* 2008;**4**(3): 169-177.
33. Irwin RS, Lilly CM, Mayo PH, Rippe JM. *Irwin and Rippe's Intensive Care Medicine* (8th ed). Wolters Kluwer. Lippincott Williams & Wilkins: Philadelphia, 2017.
34. Kristensen S, Mainz J, Bartels P. *A Patient Safety Vocabulary Safety Improvement for Patients in Europe: SimPatIE - Work Package 4*. ESQH-Office for Ouality Indicators, Central Jutland Region, Regionshuset, 2007.
35. Mosby. *Mosby's Dictionary of Medicine, Nursing & Health Professions* (10th ed). Elsevier: Philadelphia, USA, 2016.
36. Gawande A. *The Checklist Manifesto. How to get things right*. Holt and Company: Metropilitan books: New York, 2009.
37. Hales BM, Pronovost PJ. The checklist - a tool for error management and performance improvement. *J Crit Care* 2006;**21**(3): 231-235.
38. Thomassen O, Storesund A, Softeland E, Brattebo G. The effects of safety checklists in medicine: a systematic review. *Acta Anaesthesiol Scand* 2014;**58**(1): 5-18.
39. Shojania KG, Dixon-Woods M. Estimating deaths due to medical error: the ongoing controversy and why it matters. *BMJ Qual Saf* 2017;**26**(5): 423-428.
40. Hibbert PD, Molloy CJ, Hooper TD, Wiles LK, Runciman WB, Lachman P, Muething SE, Braithwaite J. The application of the Global Trigger Tool: a systematic review. *Int J Qual Health Care* 2016;**28**(6): 640-649.
41. Olsen S, Neale G, Schwab K, Psaila B, Patel T, Chapman EJ, Vincent C. Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Quality & safety in health care* 2007;**16**(1): 40-44.
42. Catchpole K, Mishra A, Handa A, McCulloch P. Teamwork and error in the operating room: analysis of skills and roles. *Ann Surg* 2008;**247**(4): 699-706.

43. Donaldson LJ, Panesar SS, Darzi A. Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010-2012. *PLoS Med* 2014;**11**(6): e1001667.
44. Clavien PA, Barkun J, de Oliveira ML, Vauthey JN, Dindo D, Schulick RD, de Santibanes E, Pekolj J, Slankamenac K, Bassi C, Graf R, Vonlanthen R, Padbury R, Cameron JL, Makuuchi M. The Clavien-Dindo classification of surgical complications: five-year experience. *Ann Surg* 2009;**250**(2): 187-196.
45. Hanskamp-Sebregts M, Zegers M, Vincent C, van Gurp PJ, de Vet HC, Wollersheim H. Measurement of patient safety: a systematic review of the reliability and validity of adverse event detection with record review. *BMJ Open* 2016;**6**(8): e011078.
46. Norwegian Directorate of Health. Measuring patient harm with Global Trigger Tool. Accessed 14th September 2019 https://www.pasientsikkerhetsprogrammet.no/om-oss/english.
47. Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, Whittington JC, Frankel A, Seger A, James BC. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)* 2011;**30**(4): 581-589.
48. World Health Organization. International Statistical Classification of Diseases and Related Health Problems (ICD-10) 10th ed. Accessed 14th September 2019 http://www.who.int/classifications/icd/ICD10Volume2_en_2010.pdf.
49. Norwegian Directorate of Health. Norwegian Patient Register (NPR). Accessed 14th September 2019 https://helsedirektoratet.no/norsk-pasientregister-npr.
50. Naessens JM, Campbell CR, Huddleston JM, Berg BP, Lefante JJ, Williams AR, Culbertson RA. A comparison of hospital adverse events identified by three widely used detection methods. *Int J Qual Health Care* 2009;**21**(4): 301-307.
51. Olsen J, Basso O, Sorensen HT. What is a population-based registry? *Scand J Public Health* 1999;**27**(1): 78.
52. Nordic Medico-Statistical Committee. Health Statistiscs for the Nordic Countries 2017. Accessed 14th September 2019 http://www.nowbase.org/publications/health-statistics-nordic-countries.
53. Wolff AM, Taylor SA, McCabe JF. Using checklists and reminders in clinical pathways to improve hospital inpatient care. *Med J Aust* 2004;**181**(8): 428-431.
54. Berenholtz SM, Pronovost PJ, Lipsett PA, Hobson D, Earsing K, Farley JE, Milanovich S, Garrett-Mayer E, Winters BD, Rubin HR, Dorman T, Perl TM. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med* 2004;**32**(10): 2014-2020.
55. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, Sexton B, Hyzy R, Welsh R, Roth G, Bander J, Kepros J, Goeschel C. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006;**355**(26): 2725-2732.
56. Lingard L, Regehr G, Orser B, Reznick R, Baker GR, Doran D, Espin S, Bohnen J, Whyte S. Evaluation of a preoperative checklist and team briefing among

surgeons, nurses, and anesthesiologists to reduce failures in communication. *Arch Surg* 2008;**143**(1): 12-17.
57. de Vries EN, Hollmann MW, Smorenburg SM, Gouma DJ, Boermeester MA. Development and validation of the SURgical PAtient Safety System (SURPASS) checklist. *Quality & safety in health care* 2009;**18**(2): 121-126.
58. Koetser IC, de Vries EN, van Delden OM, Smorenburg SM, Boermeester MA, van Lienden KP. A checklist to improve patient safety in interventional radiology. *Cardiovasc Intervent Radiol* 2013;**36**(2): 312-319.
59. Rudiger-Sturchler M, Keller DI, Bingisser R. Emergency physician intershift handover - can a dINAMO checklist speed it up and improve quality? *Swiss Med Wkly* 2010;**140**: w13085.
60. Norwegian Directorate of Health. The Norwegian Pateint Safety Programme: In safe hands. Accessed 14th September 2019 https://www.pasientsikkerhetsprogrammet.no/om-oss/english/the-norwegian-patient-safety-programme-in-safe-hands.
61. Abbott TEF, Ahmad T, Phull MK, Fowler AJ, Hewson R, Biccard BM, Chew MS, Gilles M, Pearse R. The surgical safety checklist and patient outcomes after surgery: a prospective observational cohort study, systematic review and meta-analysis. *Brit J Anaesth* 2018;**120**(1): 146-155.
62. Jammer I, Ahmad T, Aldecoa C, Koulenti D, Goranovic T, Grigoras I, Mazul-Sunko B, Matos R, Moreno R, Sigurdsson GH, Toft P, Walder B, Rhodes A, Pearse RM. Point prevalence of surgical checklist use in Europe: relationship with hospital mortality. *Br J Anaesth* 2015;**114**(5): 801-807.
63. Gillespie BM, Chaboyer W, Thalib L, John M, Fairweather N, Slater K. Effect of using a safety checklist on patient complications after surgery: a systematic review and meta-analysis. *Anesthesiology* 2014;**120**(6): 1380-1389.
64. Treadwell JR, Lucas S, Tsou AY. Surgical checklists: a systematic review of impacts and implementation. *BMJ Quality & Safety* 2014;**23**(4): 299-318.
65. Bergs J, Hellings J, Cleemput I, Zurel O, De Troyer V, Van Hiel M, Demeere JL, Claeys D, Vandijck D. Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications. *Br J Surg* 2014;**101**(3): 150-158.
66. Borchard A, Schwappach DL, Barbir A, Bezzola P. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012;**256**(6): 925-933.
67. Boyd J, Wu G, Stelfox H. The Impact of Checklists on Inpatient Safety Outcomes: A Systematic Review of Randomized Controlled Trials. *J Hosp Med* 2017;**12**(8): 675-682.
68. Lau CSM, Chamberlain RS. The World Health Organization Surgical Safety Checklist Improves Post-Operative Outcomes: A Meta-Analysis and Systematic Review. *Surgical Science* 2016;**7**(4): 206-217.
69. Russ S, Rout S, Sevdalis N, Moorthy K, Darzi A, Vincent C. Do safety checklists improve teamwork and communication in the operating room? A systematic review. *Ann Surg* 2013;**258**(6): 856-871.

70. Ko HC, Turner TJ, Finnigan MA. Systematic review of safety checklists for use by medical care teams in acute hospital settings-limited evidence of effectiveness. *BMC Health Serv Res* 2011;**11**: 211.
71. de Jager E, McKenna C, Bartlett L, Gunnarsson R, Ho YH. Postoperative Adverse Events Inconsistently Improved by the World Health Organization Surgical Safety Checklist: A Systematic Literature Review of 25 Studies. *World J Surg* 2016;**40**(8): 1842-1858.
72. de Vries EN, Prins HA, Bennink MC, Neijenhuis P, van Stijn I, van Helden SH, van Putten MA, Smorenburg SM, Gouma DJ, Boermeester MA. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. *BMJ Qual Saf* 2012;**21**(6): 503-508.
73. de Vries EN, Dijkstra L, Smorenburg SM, Meijer RP, Boermeester MA. The SURgical PAtient Safety System (SURPASS) checklist optimizes timing of antibiotic prophylaxis. *Patient Saf Surg* 2010;**4**(1): 6.
74. Segall N, Bonifacio AS, Schroeder RA, Barbeito A, Rogers D, Thornlow DK, Emery J, Kellum S, Wright MC, Mark JB. Can we make postoperative patient handovers safer? a systematic review of the literature. *Anesth Analg* 2012;**115**(1): 102-115.
75. Nagpal K, Vats A, Lamb B, Ashrafian H, Sevdalis N, Vincent C, Moorthy K. Information transfer and communication in surgery: a systematic review. *Ann Surg* 2010;**252**(2): 225-239.
76. Cadman V. The impact of surgical safety checklists on theatre departments: a critical review of the literature. *Journal of Perioperative Practice* 2016;**26**(4): 62-71.
77. Fudickar A, Horle K, Wiltfang J, Bein B. The effect of the WHO Surgical Safety Checklist on complication rate and communication. *Dtsch Arztebl Int* 2012;**109**(42): 695-701.
78. McDowell DS, McComb SA. Safety checklist briefings: a systematic review of the literature. *AORN J* 2014;**99**(1): 125-137.
79. Mitchell B, Cristancho S, Nyhof BB, Lingard LA. Mobilising or standing still?A narrative review of Surgical Safety Checklist knowledge as developed in 25 highly cited papers from 2009 to 2016. *BMJ Quality & Safety* 2017;**26**(10): 837-844.
80. Patel J, Ahmed K, Guru KA, Khan F, Marsh H, Shamim Khan M, Dasgupta P. An overview of the use and implementation of checklists in surgical specialities - a systematic review. *Int J Surg* 2014;**12**(12): 1317-1323.
81. Tang R, Ranmuthugala G, Cunningham F. Surgical safety checklists: a review. *ANZ J Surg* 2014;**84**: 148-154.
82. Bergs J, Lambrechts F, Simons P, Vlayen A, Marneffe W, Hellings J, Cleemput I, Vandijck D. Barriers and facilitators related to the implementation of surgical safety checklists: a systematic review of the qualitative evidence. *BMJ Qual Saf* 2015;**24**(12): 776-786.
83. Cadman V. Use of the WHO surgical safety checklist in low and middle income countries: a review of the literature. *J Perioperative Practice* 2018: 1750458918776551.

84. Lagoo J, Lopushinsky SR, Haynes AB, Bain P, Flageole H, Skarsgard ED, Brindle ME. Effectiveness and meaningful use of paediatric surgical safety checklists and their implementation strategies: a systematic review with narrative synthesis. *BMJ Open* 2017;**7**(10): e016298.
85. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol* 2009;**62**(10): e1-34.
86. Hardiman KM, Reames CD, McLeod MC, Regenbogen SE. Patient autonomy-centered self-care checklist reduces hospital readmissions after ileostomy creation. *Surgery* 2016;**160**(5): 1302-1308.
87. Urbach DR, Govindarajan A, Saskin R, Wilton AS, Baxter NN. Introduction of surgical safety checklists in Ontario, Canada. *N Engl J Med* 2014;**370**(11): 1029-1038.
88. Haynes AB, Edmondson L, Lipsitz SR, Molina G, Neville BA, Singer SJ, Moonan AT, Childers AK, Foster R, Gibbons LR, Gawande AA, Berry WR. Mortality Trends After a Voluntary Checklist-based Surgical Safety Collaborative. *Ann Surg* 2017;**266**(6): 923-929.
89. O'Leary JD, Wijeysundera DN, Crawford MW. Effect of surgical safety checklists on pediatric surgical complications in Ontario. *CMAJ* 2016;**188**(9): E191-198.
90. Reames BN, Krell RW, Campbell DA, Dimick JB. A Checklist-Based intervention to improve surgical outcomes in Michigan evaluation of the keystone surgery program. *JAMA Surg* 2015;**150**(3): 208-215.
91. Rodella S, Mall S, Marino M, Turci G, Gambale G, Montella MT, Bonilauri S, Gelmini R, Zuin P. Effects on Clinical Outcomes of a 5-Year Surgical Safety Checklist Implementation Experience: A Large-scale Population-Based Difference-in-Differences Study. *Health Serv Insights* 2018;**11**: 1-13.
92. Boaz M, Bermant A, Ezri T, Lakstein D, Berlovitz Y, Laniado I, Feldbrin Z. Effect of Surgical Safety checklist implementation on the occurrence of postoperative complications in orthopedic patients. *Isr Med Assoc J* 2014;**16**(1): 20-25.
93. Igaga EN, Sendagire C, Kizito S, Obua D, Kwizera A. World Health Organization Surgical Safety Checklist: Compliance and Associated Surgical Outcomes in Uganda's Referral Hospitals. *Anesth Analg* 2018;**127**(6): 1427-1433.
94. Chaudhary N, Varma V, Kapoor S, Mehta N, Kumaran V, Nundy S. Implementation of a Surgical Safety Checklist and Postoperative Outcomes: a Prospective Randomized Controlled Study. *J Gastrointest Surg* 2015;**19**(5): 935-942.
95. Anwer M, Manzoor S, Muneer N, Qureshi S. Compliance and Effectiveness of WHO Surgical Safety Check list: A JPMC Audit. *Pak J Med Sci* 2016;**32**(4): 831-835.
96. Askarian M, Kouchak F, Palenik CJ. Effect of surgical safety checklists on postoperative morbidity and mortality rates, Shiraz, Faghihy Hospital, a 1-year study. *Qual Manag Health Care* 2011;**20**(4): 293-297.

97. Kwok AC, Funk LM, Baltaga R, Lipsitz SR, Merry AF, Dziekan G, Ciobanu G, Berry WR, Gawande AA. Implementation of the World Health Organization surgical safety checklist, including introduction of pulse oximetry, in a resource-limited setting. *Ann Surg* 2013;**257**(4): 633-639.
98. Lepanluoma M, Takala R, Kotkansalo A, Rahi M, Ikonen TS. Surgical safety checklist is associated with improved operating room safety culture, reduced wound complications, and unplanned readmissions in a pilot study in neurosurgery. *Scand J Surg* 2014;**103**(1): 66-72.
99. Lubbeke A, Hovaguimian F, Wickboldt N, Barea C, Clergue F, Hoffmeyer P, Walder B. Effectiveness of the surgical safety checklist in a high standard care environment. *Med Care* 2013;**51**(5): 425-429.
100. Mayer EK, Sevdalis N, Rout S, Caris J, Russ S, Mansell J, Davies R, Skapinakis P, Vincent C, Athanasiou T, Moorthy K, Darzi A. Surgical Checklist Implementation Project: The Impact of Variable WHO Checklist Compliance on Risk-adjusted Clinical Outcomes After National Implementation: A Longitudinal Study. *Ann Surg* 2016;**263**(1): 58-63.
101. Rosenberg NM, Urman RD, Gallagher S, Stenglein J, Liu X, Shapiro FE. Effect of an office-based surgical safety system on patient outcomes. *Eplasty* 2012;**12**: e59.
102. Weiser TG, Haynes AB, Dziekan G, Berry WR, Lipsitz SR, Gawande AA. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. *Ann Surg* 2010;**251**(5): 976-980.
103. Bliss LA, Ross-Richardson CB, Sanzari LJ, Shapiro DS, Lukianoff AE, Bernstein BA, Ellner SJ. Thirty-day outcomes support implementation of a surgical safety checklist. *J Am Coll Surg* 2012;**215**(6): 766-776.
104. Haugen AS, Waehle HV, Almeland SK, Harthug S, Sevdalis N, Eide GE, Nortvedt MW, Smith I, Softeland E. Causal Analysis of World Health Organization's Surgical Safety Checklist Implementation Quality and Impact on Care Processes and Patient Outcomes: Secondary Analysis From a Large Stepped Wedge Cluster Randomized Controlled Trial in Norway. *Ann Surg* 2019;**269**(2): 283-290.
105. Bock M, Fanolla A, Segur-Cabanac I, Auricchio F, Melani C, Girardi F, Meier H, Pycha A. A Comparative Effectiveness Analysis of the Implementation of Surgical Safety Checklists in a Tertiary Care Hospital. *JAMA Surgery* 2016;**151**(7): 639-646.
106. de Jager E, Gunnarsson R, Ho YH. Implementation of the World Health Organization Surgical Safety Checklist Correlates with Reduced Surgical Mortality and Length of Hospital Admission in a High-Income Country. *World J Surg* 2019;**43**(1): 117-124.
107. Lepanluoma M, Rahi M, Takala R, Loyttyniemi E, Ikonen TS. Analysis of neurosurgical reoperations: use of a surgical checklist and reduction of infection-related and preventable complication-related reoperations. *J Neurosurg* 2015;**123**(1): 145-152.
108. McCarroll ML, Zullo MD, Dante Roulette G, Mendise TM, Ferris E, Zolton J, Andrews SJ, von Gruenigen VE. Development and implementation results of an

interactive computerized surgical checklist for robotic-assisted gynecologic surgery. *J Robot Surg* 2015;**9**(1): 11-18.
109. Morgan PJ, Cunningham L, Mitra S, Wong N, Wu W, Noguera V, Li M, Semple J. Surgical safety checklist: implementation in an ambulatory surgical facility. *Can J Anaesth* 2013;**60**(6): 528-538.
110. Rodrigo-Rincon I, Martin-Vizcaino MP, Tirapu-Leon B, Zabalza-Lopez P, Zaballos-Barcala N, Villalgordo-Ortin P, Abad-Vicente FJ, Gost-Garde J. The effects of surgical checklists on morbidity and mortality: a pre- and post-intervention study. *Acta Anaesthesiol Scand* 2015;**59**(2): 205-214.
111. Sewell M, Adebibe M, Jayakumar P, Jowett C, Kong K, Vemulapalli K, Levack B. Use of the WHO surgical safety checklist in trauma and orthopaedic patients. *Int Orthop* 2011;**35**(6): 897-901.
112. Tillman M, Wehbe-Janek H, Hodges B, Smythe WR, Papaconstantinou HT. Surgical care improvement project and surgical site infections: can integration in the surgical safety checklist improve quality performance and clinical outcomes? *J Surg Res* 2013;**184**(1): 150-156.
113. Westman M, Marttila H, Rahi M, Rintala E, Loyttyniemi E, Ikonen T. Analysis of hospital infection register indicates that the implementation of WHO surgical safety checklist has an impact on early postoperative neurosurgical infections. *J Clin Neurosci* 2018;**53**: 188-192.
114. Zingiryan A, Paruch JL, Osler TM, Hyman NH. Implementation of the surgical safety checklist at a tertiary academic center: Impact on safety culture and patient outcomes. *Am J Surg* 2017;**214**(2): 193-197.
115. Hawranek M, Gasior PM, Buchta P, Gierlotka M, Czapla K, Tajstra M, Pyka L, Lekston A, Polonski L, Gasior M. Periprocedural checklist in the catheterisation laboratory is associated with decreased rate of treatment complications. *Kardiol Pol* 2015;**73**(7): 511-519.
116. Hazelton JP, Orfe EC, Colacino AM, Hunter K, Capano-Wehrle LM, Lachant MT, Ross SE, Seamon MJ. The impact of a multidisciplinary safety checklist on adverse procedural events during bedside bronchoscopy-guided percutaneous tracheostomy. *J Trauma Acute Care Surg* 2015;**79**(1): 111-115.
117. Lee RP, Venable GT, Vaughn BN, Lillard JC, Oravec CS, Klimo P, Jr. The Impact of a Pediatric Shunt Surgery Checklist on Infection Rate at a Single Institution. *Neurosurgery* 2018;**83**(3): 508-520.
118. Rose MR, Rose KM. Use of a Surgical Debriefing Checklist to Achieve Higher Value Health Care. *Am J Med Qual* 2018;**33**(5): 514-522.
119. Williams AK, Cotter RA, Bompadre V, Goldberg MJ, Steinman SS. Patient Safety Checklists: Do They Improve Patient Safety for Supracondylar Humerus Fractures? *J Pediatr Orthop* 2017;**39**(5): 232-236.
120. The World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013;**310**(20): 2191-2194.

121. World Health Organization. Process of translation and adaption of instruments. Accessed 14th September 2019 http://www.who.int/substance_abuse/research_tools/translation/en/#.
122. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004;**24**(2): 105-112.
123. Davis LL. Instrument review: Getting the most of a panel of experts. *Appl Nurs Res* 1992;**5**(4): 194-197.
124. Khuri SF, Daley J, Henderson W, Barbour G, Lowry P, Irvin G, Gibbs J, Grover F, Hammermeister K, Stremple JF, et al. The National Veterans Administration Surgical Risk Study: risk adjustment for the comparative assessment of the quality of surgical care. *J Am Coll Surg* 1995;**180**(5): 519-531.
125. de Vries EN, Eikens-Jansen MP, Hamersma AM, Smorenburg SM, Gouma DJ, Boermeester MA. Prevention of surgical malpractice claims by use of a surgical safety checklist. *Ann Surg* 2011;**253**(3): 624-628.
126. The Norwegian Tax Administration. The National Registry. Accessed 14th September 2019 https://www.skatteetaten.no/en/person/national-registry/.
127. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;**33**(1): 159-174.
128. Rothman KJ, Greenland S, Lash TL. *Modern Epidemiology* (3rd ed.). Lippincott Williams & Wilkins: Philadelphia, 2008.
129. Polit DF, Beck CT. *Nursing Research: Generating and Assessing Evidence for Nursing Practice* (10th ed.). Wolters Kluwer: Philadelphia, 2017.
130. Squires A, Aiken LH, van den Heede K, Sermeus W, Bruyneel L, Lindqvist R, Schoonhoven L, Stromseng I, Busse R, Brzostek T, Ensio A, Moreno-Casbas M, Rafferty AM, Schubert M, Zikos D, Matthews A. A systematic survey instrument translation process for multi-country, comparative health workforce studies. *Int J Nurs Stud* 2013;**50**(2): 264-273.
131. Song JW, Chung KC. Observational studies: cohort and case-control studies. *Plast Reconstr Surg* 2010;**126**(6): 2234-2242.
132. Thomassen O, Espeland A, Softeland E, Lossius HM, Heltne JK, Brattebo G. Implementation of checklists in health care; learning from high-reliability organisations. *Scand J Trauma Resusc Emerg Med* 2011;**19**(53): 1-7.
133. Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, Lilford RJ. An epistemology of patient safety research: a framework for study design and interpretation. Part 2. Study design. *Quality & safety in health care* 2008;**17**(3): 163-169.
134. Burns PB, Rohrich RJ, Chung CR. The Levels of Evidence and their role in Evidence-Based Medicine. *Plast Reconstr Surg* 2011;**128**(1): 305-310.
135. Hemming K, Taljaard M, McKenzie JE, Hooper R, Copas A, Thompson JA, Dixon-Woods M, Aldcroft A, Doussau A, Grayling M, Kristunas C, Goldstein CE, Campbell MK, Girling A, Eldridge S, Campbell MJ, Lilford RJ, Weijer C, Forbes AB, Grimshaw JM. Reporting of stepped wedge cluster randomised trials: extension

of the CONSORT 2010 statement with explanation and elaboration. *BMJ* 2018;**363**: k1614.
136. World Health Organization. Implementation manual - WHO surgical safety checklist. Accessed 14th September 2019 http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf.
137. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004;**240**(2): 205-213.
138. Naessens JM, Campbell CR, Berg B, Williams AR, Culbertson R. Impact of diagnosis-timing indicators on measures of safety, comorbidity, and case mix groupings from administrative data sources. *Med Care* 2007;**45**(8): 781-788.
139. McHugh ML. Interrater reliability: the kappa statistic. *Biochem Med (Zagreb)* 2012;**22**(3): 276-282.
140. Bonnyman AM, Webber CE, Stratford PW, MacIntyre NJ. Intrarater reliability of dual-energy X-ray absorptiometry-based measures of vertebral height in postmenopausal women. *J Clin Densitom* 2012;**15**(4): 405-412.
141. Ramsay G, Haynes AB, Lipsitz SR, Solsky I, Leitch J, Gawande AA, Kumar M. Reducing surgical mortality in Scotland by use of the WHO Surgical Safety Checklist. *Br J Surg* 2019;**106**(8): 1005-1011.
142. Carlsen B, Glenton C. What about N? A methodological study of sample-size reporting in focus group studies. *BMC Med Res Methodol* 2011;**11**(26): 1-10.
143. Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Res Nurs Health* 2007;**30**(4): 459-467.
144. Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and Implementation Content Validity Study: Development of an instrument for measuring Patient-Centered Communication. *J Caring Sci* 2015;**4**(2): 165-178.
145. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health* 2006;**29**(5): 489-497.
146. Sperber AD. Translation and validation of study instruments for cross-cultural research. *Gastroenterology* 2004;**126**: 124-128.
147. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. *Med J Aust* 1995;**163**(9): 458-471.
148. Perez Zapata AI, Gutierrez Samaniego M, Rodriguez Cuellar E, Andres Esteban EM, Gomez de la Camara A, Ruiz Lopez P. Detection of adverse events in general surgery using the " Trigger Tool" methodology. *Cir Esp* 2015;**93**(2): 84-90.
149. Flaatten H, Brattebo G, Alme B, Berge K, Rosland JH, Viste A, Bertelsen B, Harthug S, Aardal S. Adverse events and in-hospital mortality: an analysis of all deaths in a Norwegian health trust during 2011. *BMC Health Serv Res* 2017;**17**: 465.
150. Doupi P, Svaar H, Bjørn B, Deilkås E, Nylèn U, Rutberg H. Use of the Global Trigger Tool in patient safety improvement efforts: Nordic experiences. *Cognition, Technology & Work* 2016;**17**(1): 45-54.

151. Wang H, Zheng T, Chen D, Niu Z, Zhou X, Li S, Zhou Y, Cao S. Impacts of the surgical safety checklist on postoperative clinical outcomes in gastrointestinal tumor patients: A single-center cohort study. *Medicine* 2019;**98**(28): 1-9.
152. Edmondson A, Bohmer RM, Pisano GP. Disrupted routines: Team learning and new technology implementation in hospitals. *Adm Sci Q* 2001;**46**(4): 685-716.
153. Stephens T, Pearse RM. Learning from the EPOCH trial (Editorial). What we have learnt from a trial of an intervention to improve survival following emergency laparotomy. *Anaesth Crit Care Pain Med* 2019;**38**(4): 321-322.
154. Peden CJ, Stephens T, Martin G, Kahan BC, Thomson A, Rivett K, Wells D, Richardson G, Kerry S, Bion J, Pearse RM. Effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery (EPOCH): a stepped-wedge cluster-randomised trial. *Lancet* 2019;**393**(10187): 2213-2221.
155. Russ SJ, Sevdalis N, Moorthy K, Mayer EK, Rout S, Caris J, Mansell J, Davies R, Vincent C, Darzi A. 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;**261**(1): 81-91.
156. Leape LL. The checklist conundrum. *N Engl J Med* 2014;**370**(11): 1063-1064.
157. Berry W, Haynes A, Lagoo J. The Surgical Checklist: It Cannot Work If You Do Not Use It. *JAMA Surg* 2016;**151**(7): 647.
158. Suliburk JW, Buck QM, Pirko CJ, Massarweh NN, Barshes NR, Singh H, Rosengart TK. Analysis of Human Performance Deficiencies Associated With Surgical Adverse Events. *JAMA Netw Open* 2019;**2**(7): e198067.
159. Ryan AM, Krinsky S, Adler-Milstein J, Damberg CL, Maurer KA, Hollingsworth JM. Association Between Hospitals' Engagement in Value-Based Reforms and Readmission Reduction in the Hospital Readmission Reduction Program. *JAMA Intern Med* 2017;**177**(6): 862-868.
160. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015;**350**: h391.
161. Office of the Auditor General of Norway. The Office of the Auditor General's investigation of medical coding practice within the health enterprises. Document 3:5 (2016-2017). Accessed 14th September 2019 https://www.riksrevisjonen.no/globalassets/reports/en-2016-2017/codingpracticehealthenterprises.pdf.
162. Finks JF, Osborne NH, Birkmeyer JD. Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med* 2011;**364**(22): 2128-2137.

8. APPENDICES

8.1 Modified WHO SSC

Preparation
Before induction of anaesthesia

Has the patient confirmed?
- Identity
- Operation site
- Type of procedure

Is the operation site marked?
- Yes
- Not applicable

Has anaesthesia been checked and medication controlled?
- Yes

Does the patient have:

Known allergy?
- Yes
- No

Difficult airways / risk of aspiration?
- Yes, and equipment/ assistance is available
- No

Risk of >500 mL blood loss (>7 mL/kg in children?)
- Yes, and adequate intravenous access and fluid is available
- No

Risk of hypothermia?
- Yes, and actions are planned or implemented
- No

Are the required diagnostic images available?
- Yes
- Not applicable

Time-out
Before starting the operation

Has everyone in the team been presented by name and function?
- Yes

The surgeon, anaesthesia professional and surgical nurse have orally confirmed:
- The patient's name?
- Planned procedure, operation site, and body side?
- Is the patient correctly positioned?

Are any critical events expected?

Surgeon:
- What is the expected blood loss?
- Are there any risk factors that the team should be aware of?
- Is any special equipment or additional diagnostic procedure needed?
- What is the expected duration of the operation?

Anaesthesiologist and nurse:
- What is the patient's ASA classification?
- Are there any special risk factors related to anaesthesia that the team should be aware of?

Surgical nurse:
- Is instrument sterility confirmed (including indicators)?
- Are there challenges associated with use of the equipment?

Have prophylactic measures been taken against infections?
- Not applicable
- Antibiotic prophylaxis completed within the last 60 minutes?
- Have measures been implemented to keep the patient warm?
- Hair removal completed?
- Blood sugar check completed?

Is thrombosis prophylaxis required?
- Yes
- No

Termination
Before the team leaves the operating room

The team reviews orally:
- Which procedure has been performed?
- Is the number of instruments, dressings/drapes and needles correct (or not applicable)?
- Are biological samples correctly labeled, including the patient's identity?
- Have there been problems with the equipment that should be reported?
- What is important for postoperative treatment of this patient?

Remarks/ findings:

Which procedure has been performed?:

Date, patient name and national identifying number.

The checklist is not comprehensive and it may be modified to fit local practice. National Unit for Patient Safety, Draft 17 July 2009

1

8.2 Search strategy for updated systematic literature review to PhD thesis.

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily,

1946 to November 14, 2018

15. Nov. 2018

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1 Checklist/ (5189)

2 (checklist$ or check-list$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (36735)

3 ("goal$ sheet$" or goal-sheet$ or "goal$ worksheet$").mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (24)

4 (checksheet$ or check-sheet$ or ticklist$ or tick-list$ or "cognitive aid$" or "cognitive tool$" or "memory aid$" or "memory tool$" or mnemonic).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (4144)

5 2 or 3 or 4 (40801)

6 exp Safety/ (72903)

7 exp Quality Assurance, Health Care/ (306731)

8 exp Medical Errors/ (105492)

9 exp Risk Management/ (269630)

10 6 or 7 or 8 or 9 (691408)

11 safety.mp. (486169)

12 10 or 11 (1078952)

13 5 and 12 (6188)

14 exp Specialties, Surgical/ (188884)

15 surgery.fs. (1863162)

16 (surger* or surgical or surgeon* or operation* or operative).ti,ab,kw. (2068424)

17 14 or 15 or 16 (3109718)

18 13 and 17 (1552)

Comment:
In contrast to the search in 2012, we did not make any restrictions to humans. Checking the tag “animal”, there were 13 hits.

Database: Embase (OVID) <1974 to 2018 November 14

15. Nov. 2018

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1 exp checklist/ (19279)

2 (checklist$ or check-list$).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (52931)

3 ("goal$ sheet$" or goal-sheet$ or "goal$ worksheet$").mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (62)

4 (checksheet$ or check-sheet$ or ticklist$ or tick-list$ or "cognitive aid$" or "cognitive tool$" or "memory aid$" or "memory tool$" or mnemonic).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] (4935)

5 1 or 2 or 3 or 4 (57742)

6 exp safety/ (446099)

7 exp quality control/ (352373)

8 exp medical error/ (121370)

9 exp risk management/ (39947)

10 safety.mp. (986217)

11 6 or 7 or 8 or 9 or 10 (1479562)

12 5 and 11 (9451)

13 exp surgery/ (4307600)

14 su.fs. (1897515)

15 (surger* or surgical or surgeon* or operation* or operative).ti,ab,kw. (2696492)

16 13 or 14 or 15 (5384394)

17 12 and 16 (2949)

18 limit 17 to conference abstract (928)

19 17 not 18 (2021)

Comment:

In contrast to the search in 2012, we did not make any restrictions to humans. Checking the tag "animal", there were 4 hits.

Cochrane Library (Wiley) 15. nov. 2018

#1 MeSH descriptor: [Checklist] explode all trees 223
#2 (checklist* or check-list* or "goal* sheet*" or goal-sheet* or "goal* worksheet*" or checksheet* or check-sheet* or ticklist* or tick-list* or "cognitive aid*" or "cognitive tool*" or "memory aid*" OR "memory tool*" or mnemonic):ti,ab,kw (Word variations have been searched) 4680
#3 #1 or #2 4680
#4 MeSH descriptor: [Safety] explode all trees 3619
#5 MeSH descriptor: [Quality Assurance, Health Care] explode all trees 3064
#6 MeSH descriptor: [Medical Errors] explode all trees 2800
#7 MeSH descriptor: [Risk Management] explode all trees 8469
#8 (safety or quality):ti,ab,kw (Word variations have been searched) 249528
#9 #4 or #5 or #6 or #7 or #8 259759
#10 #3 and #9 1606
#11 safety 161341
#12 #4 or #5 or #6 or #7 or #11 173739
#13 #3 and #12 692
#14 MeSH descriptor: [Specialties, Surgical] explode all trees 1709
#15 MeSH descriptor: [] explode all trees and with qualifier(s): [surgery - SU] 53883
#16 (surger* or surgical or surgeon* or operation* or operative):ti,ab,kw (Word variations have been searched) 198496
#17 #14 or #15 or #16 198917
#18 #10 and #17 255

8.3 Ethical approvals and amendments to original study protocol.

REK-Approval date	**11.09.2012**	**22.03.2013**	**03.06.2015**	**14.12.2018**
	Record number	Amendment 1	Amendment 2	Amendment 3
	2012/560/REK West	Collect data from control clusters at trial hospitals and control hospital in retrospect. Only those patients receiving the checklist-intervention will be informed and given the opportunity to reserve data from the study. Patients constituting controls (before intervention and control-hospitals) will not receive information of the study and care as usual will be provided. Postpone the finalisation of the studies.	Head and neck department declined to participate. Increase the study population in intervention clusters and control hospitals due to strengthening the power with inclusion of more patients. Postpone the finalisation of the studies.	Postpone the finalisation of the studies.

Førde - Approval date	**29.10.2012**	**22.07.2013**	**09.06.2015**	**12.12.2018**
	Record number	Amendment 1	Amendment 2	Amendment 3
	ePhorte 2012/3060	Patients from Førde (control hospital) will not receive information of the study, care as usual will be provided. Postpone the finalisation of the studies.	Increase the study population in Førde (control hospital) due to strengthening the power. Postpone the finalisation of the studies.	Postpone the finalisation of the studies.
Fonna, Haugesund Approval date	**07.12.2012**	**12.08.2013**	**04.08.2015**	**21.12.2018**
	Record number	Amendment 1	Amendment 2	Amendment 3

	ePhorte 2015/2384-1	Patients from Fonna, Haugesund (control hospital) will not receive information of the study, care as usual will be provided. Postpone the finalisation of the studies.	Increase the study population in Fonna, Haugesund (control hospital) due to strengthening the power. Postpone the finalisation of the studies.	Postpone the finalisation of the studies.

8.4 International Classification of Diseases-10 codes indicating a complication (Paper III & IV)

No	Category	Subcategory	ICD-10 Complication code
1	**Respiratory**	Pneumonia	J15, J18
		Respiratory other (asthma, pleural effusion, pneumothorax, respiratory failure, pulmonary oedema, phlebitis and thrombophlebitis)	J45, J80-84, J90, J91, J93, J96, R06, R09
2	**Cardiac**	Cardiac arrhythmia	I44, I48, I49
		Congestive heart failure	I50, I51
		Cardiac other (angina pectoris, cardiac arrest, myocardial infarction, acute ischemic heart disease, cardiovascular shock)	I20-24, I46, R96, T81.1
3	**Infections**	Sepsis	A40, A41, R65
		Surgical site	T81.4-6, T82.7, T85.7, T88.0
		Urinary tract	N30, N39
		Infections other (other bacterial intestinal infections , E-coli, Clostridium difficile, meningitis, pericarditis, nosocomial infection)	A04, G00, I31, O86, Y95
4	**Rupture**	Surgical wound rupture	T81.3
5	**Nervous system**	Delirium, somnolence, other	F05, R40, R29
		Cerebral infarction	I63
6	**Bleeding**	Bleeding	J94, T80.3-4, T81.0, T82.8
7	**Embolism**	Arterial-, venous-, lung- and air embolies	I26, I80, T80.0, T81.7
8	**Nutrition**	Malnutrition, other nutritional deficiencies	E40-E46, E50-E64
		Other disorders of fluid, electrolyte and acid-base balance	E87
9	**Anaesthesia**	Anaesthesia	T88.2-9, Y48
10	**Mechanical implantation**	Mechanical implantation	T82, T83.0-4, T84.0-4, T85.0-6
11	**Fall**	Fall	W0n
12	**Other**	Other (severe stress, disorders of arteries, pressure ulcer, acute renal failure, other disorders of kidney and ureter, complications following abortion and ectopic and molar pregnancy,	F43, I77, L89, N17, N28, O08, R41-46, R57, T78, T79,

		symptoms and signs involving cognition, perception, emotional state and behaviour, shock, allergy, compartment syndrome, anaphylactic shock, accidental puncture, unintended injury during procedures and surgery, reattachment and amputated body part, aspiration, medication errors, vaccinations, non-performed medical or surgical procedure, failure in equipment and devices)	T81.2, T81.8-9, T87, W7n, Y4n, Y57, Y59-66, Y69-84

Published in: **Storesund, A**, Haugen, A.S, Hjortås, M, Nortvedt, M.W, Flaatten, H, Eide, G.E, Boermeester, M.A, Sevdalis, N, Søfteland, E. Accuracy of surgical complication rate estimation using ICD-10 codes. Brit J Surgery, 2019; 106: 236-244. https://onlinelibrary.wiley.com/doi/abs/10.1002/bjs.10985

8.5 SURPASS checklist content (Paper II)

Supplemental digital content 1[i]. Checklist content tested and back translated in one Norwegian neurosurgical department in June-July 2012.

Tested checklist content			Back translated checklist content
Completed by	Original item Number *		
Operating theatre nurse			
	1	Information in Operating Theatre schedule controlled	Operating Theatre schedule controlled
	2	Required implants present (correct side)	Required implants present (correct side)
	3	Required instruments present	Required instruments present
	4 & a)	Required equipment available and positioning planned	Required equipment available and positioning planned
	b)	Patient registered in Radiology system and relevant imaging present (from Ward doctor, item 3)	Patient registered in Radiology system and relevant images present
	a)	Information in Operating Theatre schedule checked 07.30 am operating day	-
Ward doctor			
	1	Patient examined by ward doctor	Patient seen by ward doctor
	2	Medical data seen by ward doctor	Medical data seen by ward doctor
	a)	Current medications assessed and transferred to medical records	Current medications assessed and transferred to medical records
	4	Relevant consultations by other specialists performed	-
	8	Timely cessation of anticoagulants checked	Timely cessation of anticoagulants

	a)	Admission note written within 01.00 pm	Admission note written
	a)	Still indication for surgery	c)
	a)	Contraindication for surgery	-
Tested checklist content			Back translated checklist content
Completed by	Original item Number *		
Surgeon			
	1	Patient seen by surgeon	Patient seen and informed by surgeon
	2	Medical data and information in electronic operating planning system documented and correct/ changes updated (procedure, positioning, surgical technique, instruments, implants, side-marking, infection control measures required, allergies, antibiotics- and thrombosis prophylaxis)	Medical data and information in electronic operating planning system correct (procedure, side-marking, positioning, instruments, implants, infection control measures required, allergies, antibiotics- and thrombosis prophylaxis, postoperative ICU bed arranged) d)
	b)	Medication prescribed and transferred to medical records (including special medication, antibiotics- and thrombosis prophylaxis) (from Ward doctor, item 7)	Supplemental medication for the procedure prescribed
	4	Operative site and side discussed with patient and marked (changes communicated to OR)	Operative site and side discussed with patient and marked
	b)	Relevant images present and assessed (from Ward doctor, item 3)	Relevant images present and assessed
	b)	Preoperative advice from anaesthesiologist or other disciplines executed/report not yet available (from Ward doctor, item 5)	Preoperative advice from anaesthesiologist/ other disciplines executed/ report not yet available
	b)	Postoperative/ ICU-bed arranged (from Ward doctor, item 9)	-

	5 & 6	In case of local anaesthesia without anaesthesiologist: comorbidities and allergies (known and registered)	Local anaesthesia without anaesthesiologist: comorbidities known and registered
	b)	Local anaesthesia without anaesthesiologist: Premedication considered and ordered. Changes of medications in regards to the operation (from Anaesthesiologist, item 7)	-
			Still indication for surgery
			Relevant laboratory tests executed and assessed
Tested checklist content			Back translated checklist content
Completed by	Original item Number *	Tested checklist content	Checklist content after validation and back translation
Anaesthesio-logist			
	1	Patient assessed by anaesthesiologist	Patient assessed by anaesthesiologist
	2 & 4	Medical data seen (procedure details, patient records, pre-assessments, comorbidity, known allergies)	Medical data assessed (comorbidity, known allergies, surgical procedure, pre-assessment, laboratory results)
	3 & 5	ASA-classifications and laboratory results evaluated	ASA-classifications performed
	6	Additional investigations and consultations executed/not yet available	Extra examinations required before anaesthesia
	7	Current medication controlled and premedication prescribed	Current medication controlled and premedication prescribed
	9	Anaesthesia technique discussed with patient	Anaesthesia technique discussed with patient

	a)		Former anaesthesia complications controlled
Ward nurse			
	1	Patient prepared for procedure and anaesthesia according to local routines (hygiene, elimination, fasting, valuables)	Patient prepared for procedure and anaesthesia according to local routines
	a)	Operation planning system controlled/ check with anaesthesia personnel	-
	b)	Blood-type, cross-typing, relevant laboratory tests executed (from Anaesthesiologist, item 8)	Blood-type, cross-typing, relevant laboratory checks, blood products ordered
	a)	Incision site marked by surgeon	Incision site marked by surgeon
Tested checklist content			Back translated checklist content
Completed by	Original item Number *		
	7	Name tags on both wrists	Name tags on both wrists
	8	Jewellery, piercings removed	Jewellery, piercings, make-up, nail polish removed, d)
	a)	Make-up, nail polish removed	-
	a)	Surgical site hair removed	Surgical site hair removed
	a)	Blood pressure, pulse, saturation completed. Body temperature controlled 1 hour before surgical procedure	Weight, blood pressure, pulse, saturation. Body-temperature controlled 1 hour before surgical procedure
	a)	Compression socks applied	Compression socks applied
	8	Dentures removed (denture-box)	Dentures removed

	2 a)	Pre medication orders administered day of surgery	Pre medication orders administered
	a)	Patient has emptied bladder	Patient has emptied bladder
	9	All records with patient (clinical, outpatient, anaesthesia, nursing). Correct documents sent to OT (medication records, ECG, ID- tags, checklists)	All records with patient
	10	Preoperative SURPASS checklists completed and signed	Preoperative SURPASS checklists completed and signed
	6 e)		Nutritional status screened
Recovery nurse			
	1	Patient discharged according to local protocol and procedures	Patient discharged according to local protocol and procedures
	2, 3 & 5	Reported on medication, infusion fluids, laboratory results	Reported on medication, oxygenation, infusion fluids, laboratory results
Tested checklist content			Back translated checklist content
Completed by	Original item Number *		
	4 a)	Reported on central nervous system, circulation, respiration, elimination (awareness, pacemaker, PEEP, infection control measures)	Reported on awareness, circulation, respiration, pain, infection control measures, b)
	6 a)	Reported on wound care, drains, mobilization, diet/nutrition	Reported on wound care, drains, diet/nutrition, elimination, mobilization, b)
	7 a)	Reported on special conditions (adverse events, allergic reactions, medication)	Reported on adverse events

	a)	Patient (next of kin) informed by anaesthesiologist/surgeon of adverse events	Patient (next of kin) informed by anaesthesiologist/ surgeon of adverse events
	a)	Relatives informed of transfer to ward	-
Discharging ward doctor			
	1	Pathology results discussed/ not yet available	Pathology results discussed/ not yet available
	2	Instructions concerning wound care	Instructions concerning wound care, and suture removal explained to patient/ next of kin
	4	Instructions concerning drains, feeding tube	Instructions concerning drains, feeding tube
	5 a)	Instructions concerning anticoagulant- and thrombosis prophylaxis	Instructions concerning anticoagulant- and thrombosis prophylaxis
	7 b)	Follow up appointment surgeon/ other specialties (ward nurse, item9)	Follow up appointment surgeon/ primary care physician/ other specialties
		Tested checklist content	Back translated checklist content
Completed by	Original item Number *		
	9	Discharge summary completed (in case of transfer to other hospital, rehabilitation centre, nursing home, home care etc.)	Discharge summary completed (in case of transfer to other hospital, rehabilitation centre, nursing home)
	8	Discharge note completed	Discharge note completed

	6	Medication list controlled, medication orders, medical certificate handed over to patient (compare to medication on admission)	Medication list controlled and updated, instructions regarding administration
	a)	Information on medication: (pain relief, other relevant medication, dosage, treatment schedule etc)	Medical prescriptions and medical certificate completed
	b)	-	Provision of instructions concerning activity and complications at home (ward nurse, item 6)
Discharging ward nurse			
	1	SURPASS checklist for discharging ward doctor completed and signed	Controlled that instructions concerning wound care and suture removal have been explained to patient (+next of kin)
	3	Instructions concerning wound care and suture removal explained to patient (+next of kin)	Instructions regarding nutrition/diet explained
	4	Instructions regarding nutrition/diet explained	Signed medication list, prescriptions, medical certificate, discharge report and discharge summary
	6	Instructions concerning complications at home explained to patient (+next of kin)	Nurse briefing written and copy of laboratory results for nursing home/ homecare/ other hospital/ rehabilitation centre
	8	Signed medication list and prescriptions, medical certificate, discharge summary	SURPASS checklist for discharging ward doctor completed and signed
	10	Nurse briefing written and copy of medication list for nursing home/ homecare/ other hospital/ rehabilitation centre	

* Refer to original SURPASS checklists in English language

a) New item
b) Item moved from original checklist to another health care provider on testing checklist
c) Tested item moved to different health care provider in back translated checklist

d) Item is a combination of two tested items
e) Not tested, but added in validated checklists due to new mandatory hospital protocol

[i] Published in: Storesund, A, Haugen, AS, Wæhle, HV, Mahesparan, R, Boermeester, MA, Nortvedt, MW, Søfteland, E. Validation of a Norwegian version of Surgical Patient Safety System (SURPASS) in combination with the World Health Organizations' Surgical Safety Checklist (WHO SSC). BMJ Open Quality, 2019; 8: e000488. https://bmjopenquality.bmj.com/content/8/1/e000488.citation-tools

PAPERS I-IV

I

Acta Anaesthesiol Scand 2014; **58:** 5–18

ACTA ANAESTHESIOLOGICA SCANDINAVICA
doi: 10.1111/aas.12207

Review Article

The effects of safety checklists in medicine: a systematic review

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Background: Safety checklists have become an established safety tool in medicine. Despite studies showing decreased mortality and complications, the effects and feasibility of checklists have been questioned. This systematic review summarises the medical literature aiming to show the effects of safety checklists with a number of outcomes.
Methods: The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement was used. All studies in which safety checklists were used as an additional tool designed to assure that an operation or task was performed as planned were included.
Results: The initial search extracted 7408 hits. Twenty-nine articles met the inclusion criteria. Five additional studies were identified by a cross-referencing search. Four groups were made according to outcome measures. One group ($n = 7$) had 'hard' outcome measures, such as mortality and morbidity. The remaining studies, reporting 'softer' process-related measures, were divided into three categories: adherence to guidelines ($n = 6$), human factors ($n = 16$), and reduction of adverse events ($n = 5$). The main findings were improved communication, reduced adverse events, better adherence to standard operating procedures, and reduced morbidity and mortality. None of the included studies reported decreased patient safety or quality after introducing safety checklists.
Conclusion: Safety checklists appear to be effective tools for improving 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. None of the included studies reported negative effects on safety.

Accepted for publication 4 September 2013

The extreme complexity of modern medicine has led to an increased risk of harming the patient.[1] The incidence of such harm is quite variable; however, 5–10% of hospitalised patients worldwide are exposed to some form of adverse events.[2] In retrospect, a substantial proportion of these incidents have been judged to be preventable, owing to potentially controllable contributing factors.[3,4] Reducing the incidence of adverse events involves many stakeholders and requires a systemic approach to patient safety issues.[5] Safety checklists have been used for decades in other high-risk industries and have demonstrated to be effective tools in ensuring safe operations.[6,7]

The systematic use of safety checklists in medicine has rapidly increased since the publication of results from the World Health Organization (WHO) Surgical Safety Checklist trials and the Surgical Patient Safety System (SURPASS), which halved the post-operative mortality in eight hospitals worldwide and in six hospitals in the Netherlands, respectively.[8,9] Despite these two major projects, there is still scepticism towards safety checklist use in medicine. The external validity of the results has also been questioned.[10–12]

The purpose of this review was to summarise the medical literature aiming to show the effects of safety checklists with various outcomes.

Methods

Definitions

Safety checklists. There is no uniform definition regarding what a *safety checklist* is in the medical literature.[13] Safety checklists differ from protocols, algorithms, and guidelines in that such tools often describe a procedure in detail, more like a cake recipe.[14] In this review, we defined a safety checklist as an additional tool designed to ensure that an operation, procedure, or task is performed as planned by checking that all of the important preparations have been completed beforehand.

Effects. All quantitative measures were included, such as process-related events, adherence to best practice or local protocols, incidence of communication errors, number of missing or malfunctioning equipment, incidence of so-called risk-sensitive events, timing of antibiotic prophylaxis, and patient outcome measures, such as incidence of complications (including morbidity and mortality).

Inclusion and exclusion criteria

In addition to safety checklists, daily goals sheets, round checklists, and handover protocols (if designed as a safety checklist) were included. All times and all languages were included. All studies with quantitative outcome measures, regardless of study design, were also included. Studies in which the informants' self-perceived experiences were measured quantitatively and studies in which data were obtained from questionnaires with quantitative outcome measures were likewise included.

Studies in which the checklists introduced new methods, procedures, or actions were excluded because our aim was to evaluate the isolated effects of safety checklists, not the possible effects of new clinical measures. Case reports, editorials, letters, commentaries, reviews, overviews, and conference abstracts were also excluded. Furthermore, studies were excluded if the intervention concurrently consisted of a bundle of actions (e.g. 'ventilator bundles') such that the sole effect of the safety checklist could not be isolated, or if the study was performed in a simulation setting. Titles containing the word 'checklist' as used in 'screening checklists', 'diagnostic checklists', 'development behaviour checklist', and 'evaluation checklist', as well as studies containing the word 'safety' as used in 'health workers own safety', 'radiation safety', and 'food safety', were excluded. Titles that obviously did not match the review's aim were also excluded.

Search strategy

The reporting of the reviewed literature ensured transparency, following the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.[15]

We used relevant subject headings and text words covering 'checklists', 'safety', 'quality control', 'risk management', and 'medical error' adapted to the different databases (the corresponding author can be contacted for further information and search strategy details). The search was performed in 25 May 2012 in MEDLINE (Ovid: 1946–present), Cochrane Library (Reviews: 2005–present; Other Reviews: 1994–present; Trials: 1898–present), Web of Science [Science Citation Index Expanded (SCI-EXPANDED): 1945–present; Social Sciences Citation Index (SSCI): 1956–present; Arts & Humanities Citation Index (A&HCI): 1975–present] and Excerpta Medica Database (EMBASE) (Ovid: 1980–present). In EMBASE and MEDLINE, we limited the search to humans. The search was developed by OT and AS, and performed in cooperation with the Bergen University library.

An additional cross-referencing search was completed in 19 October 2012.

Study selection

Two of the authors (OT and AS) independently screened all identified titles to include or exclude each individual paper. If in doubt, the abstract was retrieved. If still in doubt, the whole article was reviewed. The full text articles were independently reviewed, and disagreement regarding inclusion or exclusion was resolved in consensus with all authors.

Study quality

Based on the Meta-Analysis Of Observational Studies in Epidemiology (MOOSE) guidelines, Quality of Reporting of Meta-analyses (QUORUM) statement, and Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist, Nagpal et al. have developed a set of quality assessment criteria that were deemed suitable for the heterogeneity in design of the included articles.[16] Accordingly, the studies were assessed using a three-point ordinal scale from 0 to 2 (0 = criteria not met, 1 = criteria partially met, 2 = criteria definitely met) for nine items, adding to a maximum score of 18. The quality assessment was performed independently by OT and AS. Disagreement of ≥ 3 points was resolved in consensus with all authors. Seven studies were discussed to reach consensus.

Results

Search results

The initial search extracted 7408 hits after duplication check. Of these, 7294 titles and abstracts were excluded; 114 received a full text review, of which 29

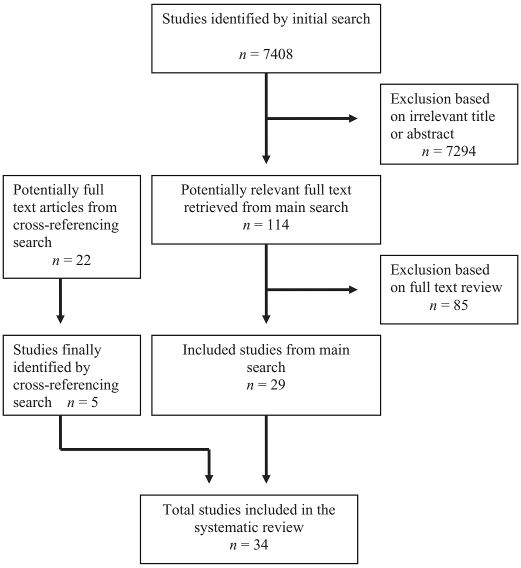

Fig. 1. Search strategy.

articles finally met the inclusion criteria. Twenty-two additional studies were identified by a cross-referencing search. OT and AS had different opinions on the inclusion of six studies. A total of five of these studies were included after all authors reached a consensus. Therefore, a total of 34 articles were included in the systematic review (Fig. 1).

To provide an overview of the variety of articles, four categories were decided upon according to the reported outcome measures. Group 1 ($n = 7$) had 'hard' patient outcome measures, such as mortality and complications. The remaining studies with 'softer' outcome measures were divided into three categories: Group 2 ($n = 6$), adherence to guidelines; Group 3 ($n = 16$), human factors; and Group 4 ($n = 5$), reduction of adverse events.

Effects of safety checklists

All of the included studies reported increased patient quality or safety after the implementation of safety checklists.

In the patient outcome group (Table 1), four studies reported statistically significant reductions in post-intervention mortality.[8,9,17,18] Three of these had used the WHO surgical safety checklist,[8,17,18] one had used the SURPASS checklist.[9] Six studies in all showed a significant decrease in post-operative complications.[8,9,17,19–21]

The other three groups, 27 (79%) of the included studies, have 'softer' process-related measures. In Table 2, some examples were improvement in compliance with antibiotic prophylaxis use,[22–24] timing of deep venous thrombosis prophylaxis,[25] compliance with deep venous thrombosis prophylaxis guidelines,[26] and adherence to practice guidelines[27](Table 2).

The 16 studies in Table 3 had a variety of primary and secondary outcome measures, such as improvement in communication,[28–32] team performance,[33] understanding of daily goals,[34–36] information flow,[37–40] perception of safety,[41,42] and safety attitudes and behaviours.[43] The studies in Table 4 aimed to identify or reduce the incidence of adverse events.[44–48]

Type of checklist, setting, and date

Of the 34 studies included in this review, 11 reported on effects of the WHO Safe Surgery Checklist, and three reported on effects of the SURPASS checklist. Some of the WHO Safe Surgery Checklists were locally adapted to be more suitable for each study site. In addition, the effects of 20 locally developed safety checklists were identified.

Twenty-two (65%) of the included studies have been performed in operating rooms (ORs). The SURPASS checklist is the most overriding system, covering a large part of the entire surgical pathway (from the ward through the OR and post-operative care, and back to the ward). Other checklists focus mainly on specific tasks or procedures, such as the pre-induction phase in anaesthesia or completeness of equipment in laparoscopic surgery.

The included studies were published from 2003 to 2012. Twenty-three (68%) of the included studies were published after the first publication of the WHO Safe Surgery Checklist in The New England Journal in 2009.

Study design

The included studies had a large variability in design. In some of the studies, the design was not specified in the article, but these were classified based on the information given in the text. In other studies, the authors of the articles classified the same study designs differently. In these studies, AS and OT reclassified the designs in order to present the studies in a comparable format.

Discussion

The initial search yielded 7408 hits. This high number was likely caused by the various definitions

Table 1

Effects of safety checklist on mortality and complications.

Patient outcome: mortality and complications

Author Country Year	Setting	Participants (patients)	Intervention (type of checklist)	Study design	Outcome measures		Main results	Quality score
					Mortality	Complications		
Haynes AB[8] USA 2009	OR	3733 pre-intervention 3955 post-intervention 8 countries, 8 hospitals worldwide	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	x	x	In-hospital mortality decreased from 1.5% to 0.8% ($P = 0.003$). Complications fell from 11.0% to 7.0% ($P < 0.001$).	17/18
Weiser TG[17] USA 2010	OR	842 pre-intervention 908 post-intervention 8 countries, 8 hospitals worldwide	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	x	x	In-hospital mortality decreased form 3.7% to 1.4% ($P = 0.0067$). Complications reduced from 18.4% to 11.7% ($P = < 0.001$).	17/18
de Vries EN[9] The Netherlands 2010	Surgical pathway	3760 pre-intervention 3820 post-intervention 6 Dutch interventions 5 control hospitals	SURgical PAtient Safety System (SURPASS) checklist	Prospective pre- and post-intervention study	x	x	In-hospital mortality decreased from 1.5% (95% CI, 1.2 to 2.0) to 0.8% (95% CI, 0.2 to 1.2) ($P = 0.003$). Overall complications reduced from 27.3% (95% CI, 25.9 to 28.7) to 16.7% (95% CI, 15.6 to 17.9) per 100 patients ($P = < 0.001$).	16/18
DuBose J[21] USA 2010	ICU	577 pre-intervention 570 post-intervention 1 American hospital	Quality rounds checklist	Prospective pre- and post-intervention study	x	x	A decrease in ventilator-associated pneumonia from 12.41 to 8.74 per 1000 ventilator days ($P = 0.008$). No significant difference in gastrointestinal haemorrhage, pulmonary embolism, or death.	11/18
Askarian M[19] Iran 2011	OR	144 pre-intervention 150 post-intervention 1 Iranian hospital	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study		x	Decline in complications from 22.9% to 10% ($P = 0.03$).	13/18
Bliss LA[20] USA 2012	OR	73 intervention 2079 historical control 1 American hospital	WHO Surgical Safety Checklist	Prospective cohort study		x	Overall adverse events were reduced from 23.6% for historical control cases to 8.2% when using checklists ($P < 0.001$).	12/18
van Klei WA[18] The Netherlands 2012	OR	14,362 pre-intervention 11,151 post-intervention 1 Dutch hospital	WHO Surgical Safety Checklist	Retrospective pre- and post-intervention study	x		In-hospital mortality was significantly reduced from 3.13% to 2.85%, (odds ratio = 0.85; 95% CI, 0.73–0.98).	14/18

OR, operating room; ICU, intensive care unit; *P*, statistical significance; CI, confidence interval; OD, odds ratio.

Table 2

Effects of safety checklists on adherence to guidelines.

Adherence to guidelines

Author Country Year	Setting	Participants (patients)	Intervention (type of checklist)	Study design	Outcome measures	Main results	Quality score
Rosenberg AD[23] USA 2008	OR	40 pre-intervention 319 post-intervention 1 American hospital	Time out checklist	Prospective pre- and post-intervention study	Number of patients receiving antibiotic prophylaxis (AP) within 1 h before incision	After checklist implementation, the percentage of patients that received AP increased from 65% to 99.1% ($P < 0.001$).	8/18
Byrnes MC[25] USA 2009	ICU	632 pre-intervention 653 post-intervention 1 American hospital	ICU checklist	Prospective pre- and post-intervention study	Time to deep venous thrombosis prophylaxis (DVTP), use of physical therapy (PT), transferred to telemetry (TM) and central catheter days (CCD)	Time to DVTP reduced from 1.8 days to 1.4 days ($P = 0.08$). PT use increased from 27% to 42% of all patients ($P < 0.001$). TM use increased from 16% to 35% ($P < 0.001$). CCD decreased from 6.1 days to 5.4 days ($P = 0.11$).	13/18
de Vries EN[22] The Netherlands 2010	OR	369 pre-intervention 403 post-intervention 1 Dutch hospital	SURPASS checklist	Retrospective pre- and post-intervention study	Timing of antibiotic prophylaxis (AP)	Time interval between AP administration and incision increased from 23.9 min (SD = 37.1) to 29.9 min (SD = 31.9) ($P = 0.047$). Number of patients that did not receive AP until post-incision fell from 12.1% to 7.1% ($P = 0.04$).	14/18
Dhillon *P*[27] Ireland 2011	Ward	34 study patients 53 control patients 1 Irish hospital	Ward round checklist	Randomised controlled trial	Adherence to Good Surgical Practice Guidelines (GSPG)	In the checklist group, 91% exhibited adherence to GPSG (vs. 55% of the control group). No statistical tests were performed.	6/18
Lingard L[24] Canada 2011	OR	259 pre-intervention 283 post-intervention 3 Canadian hospitals	Team briefing checklist	Retrospective pre- and post-intervention study	Timing of antibiotic prophylaxis (AP) according to accepted treatment guidelines	AP administered within 1 h prior to incision increased from 77.6% to 87.6% ($P < 0.01$).	16/18
Truran *P*[26] England 2011	OR	233 pre-intervention 137 post-intervention 1 English hospital	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	Compliance with venous thromboembolism (VTE) guidelines	Compliance to VTE guidelines increased from 93.1% to 97.9% ($P = 0.046$).	9/18

OR, operating room; ICU, intensive care unit; SURPASS, Surgical Patient Safety System; SD, standard deviation; *P*, statistical significance; CI, confidence interval.

Table 3

Effects of safety checklists on human factors.

Author Country Year	Setting	Participants (patients)	Intervention (type of checklist)	Study design	Outcome measures	Main results	Quality score
Human factors							
Pronovost P[34] USA 2003	ICU	Staff members Numbers not described 1 American hospital	Daily goals form	Prospective cohort study	Understanding daily goals, length of stay (LOS)	Understanding of daily goals increased from 10% to 95% for both residents and nurses. LOS decreased from 2.2 days to 1.1 days. Descriptive analysis, no statistical tests performed.	6/18
Narasimhan M[35] USA 2006	ICU	Staff members Numbers not described 1 American hospital	Daily goals worksheet	Longitudinal study	Understanding goals of care, communication, length of stay (LOS)	Understanding daily goals scores increased from 3.9 (SD = 1.02) to 4.8 (SD = 0.39) for nurses ($P = 0.001$), and from 4.6 (SD = 0.67) to 4.9 (SD = 0.32) for physicians ($P = 0.03$). Communication scores increased from 3.6 (SD = 0.87) to 4.3 (SD = 0.87) for nurses ($P = 0.03$) and from 3.4 (SD = 0.90) to 4.7 (SD = 0.48) for physicians ($P = 0.01$). LOS decreased from 6.4 to 4.3 days ($P = 0.02$).	10/18
Catchpole KR[40] England 2007	Surgery handover to ICU	Handovers 23 pre-intervention 27 post-intervention 1 English hospital	Post-surgical handover protocol	Prospective pre- and post-intervention study	Technical errors, information omissions, duration of handover	Mean number of technical errors decreased from 5.42 (95% CI ± 1.24) to 3.15 (95% CI ± 0.71) per handover ($P < 0.001$). Mean number of information omissions reduced from 2.09 (95% CI ± 1.14) to 1.07 (95% CI ± 0.55) per handover (not significant). The mean handover duration was reduced from 10.8 min (95% CI ± 1.6) to 9.4 min (95% CI ± 1.29) (not significant).	11/18
Phipps LM[28] USA 2007	PICU	Nurses 26 pre-intervention, 22 post-intervention 1 American hospital	Daily goals sheet	Prospective pre- and post-intervention study	Perception of communication	85% of nurses reported improved communication between nurses and physicians; 73% of nurses reported improved communication between nurses on different shifts. Better perception of team work among the PICU staff workers, mean score increased from 3.31 to 3.64 ($P < 0.05$).	13/18
Agarwal S[36] USA 2008	PICU	Staff members 419 pre-intervention 387 post-intervention 1 American hospital	Daily goals sheet	Prospective pre- and post-intervention study	Understanding of daily patient care goals and length of stay (LOS)	Mean scores improved understanding of patient care goals for nurses from 4.2 (SD = 0.8) to 4.5 (SD = 0.6) ($P < 0.001$), and for physicians from 4.0 (SD = 0.6) to 4.7 (SD = 0.5) ($P < 0.001$). Unchanged LOS.	16/18

Lingard L[29] Canada 2008	OR	Surgical procedures 86 pre-intervention, 86 post-intervention 1 Canadian hospital	Team briefing checklist	Prospective pre- and post-intervention study	Number of communication failures per surgical procedure	The mean number of communication failures decreased from 3.95 (SD 3.20) to 1.31 (SD 1.53) ($P < 0.001$).	15/18
Stahl K[39] USA 2009	ICU	Trauma and surgical ICU teams Numbers not described 1 American hospital	ICU handoff checklist	Prospective cohort study	Loss of critical information	Critical information loss, such as information about laboratory or test results, antibiotics/cultures/medicines, nutrition/ventilation, tubes/CVP/intravenous orders, was reduced from 20.1% to 3.6% ($P < 0.001$).	14/18
Rudiger-Sturchler M[37] Switzerland 2010	ED	Handover sessions 519 pre-intervention 492 post-intervention 1 Swiss hospital	dINAMO checklist	Prospective pre- and post-intervention survey	Loss of information between physician shifts and during handover time	Decline in missing information from mean 3.4 items daily to mean 1.2 items daily ($P = 0.003$); 26% reduction of mean handover time ($P < 0.001$).	12/18
Nilsson L[42] Sweden 2010	OR	331 staff members 2 Swedish hospitals	Time out checklist	Post-intervention study	Perception of safety aspects	Overall, 1 year after the time out checklist was introduced, 65% of the staff perceived a stronger team feeling, 86% perceived better problem solving, and 28% perceived better information about the patient.	9/18
Haynes AB[41] USA 2011	OR	Staff members 281 pre-intervention 257 post-intervention 8 countries, 8 hospitals worldwide	WHO Surgical Safety Checklist	Prospective pre- and post-intervention survey	Safety Attitude Questionnaire (SAQ) score	Increased mean SAQ score from 3.91 (SD = 0.63) to 4.01 (SD = 0.56) ($P = 0.013$).	14/18
Calland JF[43] USA 2011	OR	Laparoscopic cholecystectomies 24 interventions 23 controls 1 American hospital	The surgeons checklist	Randomised controlled trial	Safety-related behaviours	Five of six measures on team communication and coordination before the procedure increased ($P < 0.001$) and review after the procedure also increased ($P < 0.05$) in the intervention group compared to controls.	13/18
Kearns RJ[30] Scotland, UK 2011	OR	Staff members 53 pre-intervention 46 post-intervention One Scottish hospital	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	Communication and familiarity in OR	69.6% of all staff perceived better communication; 50% felt more familiar with other team members in the OR ($P = 0.026$).	10/18

Table 3 *Continued*

Effects of safety checklists on human factors.

Author Country Year	Setting	Participants (patients)	Intervention (type of checklist)	Study design	Outcome measures	Main results	Quality score
Takala RSK[31] Finland 2011	OR	Operations 901 pre-intervention, 847 post-intervention 4 Finnish hospitals	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	Communication failures, discussion of critical events	The proportion of operations with failed communication fell from 4.8% to 2.0% ($P < 0.05$). Discussions between anaesthesiologists and surgeons about possible critical events increased for anaesthesiologists from 22.0% to 42.6%, ($P < 0.001$), and for surgeons from 34.7% to 46.2%, ($P < 0.001$).	13/18
Helmio *P*[32] Finland 2011	OR	Surgical procedures 288 pre-intervention, 412 post-intervention 1 Finnish hospital	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	Awareness of safety-related issues and communication between team members	Anaesthesiologist: Increased awareness of medical history, medication, and allergies ($P < 0.001$). All OR team members verified patient identity more often ($P < 0.001$), communication improved for anaesthesiologists ($P = 0.0064$), for circulating nurses ($P < 0.001$), and for surgeons (not significant).	16/18
Böhmer AB[33] Germany 2012	OR	Staff members – anaesthesia and surgery 71 pre- and post-intervention 1 German hospital	WHO Surgical Safety Checklist	Prospective pre- and post-intervention study	Safety aspects of staff members' evaluation of security, standards and teamwork	Anaesthesia: Familiarity in OR increased ($P = 0.008$); verification of patient written consent increased ($P < 0.001$). Better teamwork in the OR increased ($P < 0.001$). Surgery: Correct patient identification increased from mean ($P = 0.03$); correct surgery rose ($P < 0.001$); knowledge of comorbidity rose ($P = 0.046$). Better teamwork in the OR rose (not significant).	9/18
Petrovic MA[38] USA 2012	OR to ICU	Patient handoffs 30 pre-intervention, 30 post-intervention 1 American hospital	Handover protocol	Prospective pre- and post-intervention study	Numbers of team members bedside and missed information	The presence of all team members at the bedside at the same time increased from 0% to 68% ($P < 0.001$). Missed information decreased from 26% to 16% in the surgery report ($P = 0.03$), but did not change significantly for the anaesthesia report. Total information sharing increased from 78% to 84% ($P = 0.01$)	10/18

ICU, intensive care unit; PICU, paediatric intensive care unit; ED, emergency department; OR, operating room; SD, standard deviation; *P*, statistical significance; CI, confidence interval.

Table 4

Effects of safety checklists on the reduction of adverse events.

Reduction of adverse events							
Author Country Year	Setting	Participants (patients)	Intervention (type of checklist)	Study design	Outcome measures	Main results	Quality score
Verdaasdonk EGG[44] The Netherlands 2008	OR	Laparoscopic cholecystectomies 30 intervention 30 controls 1 Dutch hospital	Pre-operative checklist	Prospective pre- and post-intervention study	Incidents of equipment failure per procedure	Incidents of equipment failure decreased from 87% to 47% ($P = 0.003$).	11/18
Buzink SN[45] The Netherlands 2010	OR	Laparoscopic procedures 15 chart-based OR-setting, 15 integrated OR setting, 15 OR setting with checklists 1 Dutch hospital	Pre-operative checklist (The Pro/cheQ tool checklist)	Randomised trial	Equipment- and instrument- related risk-sensitive events (RSE)	After implementation of the checklist, RSE in both chart-based and integrated OR settings was reduced from 87% to 47%. Descriptive statistics.	13/18
Thomassen O[48] Norway 2010	OR	502 operations 1 Norwegian hospital	Pre-anaesthesia induction checklist	Post-intervention study	Missing items in pre-anaesthetic setup	One or more missing items in 17% of operations.	10/18
de Vries EN[46] The Netherlands 2012	Surgical pathway	6313 surgical checklists 6 Dutch hospitals	SURPASS checklist	Post-intervention study	Number of patient safety incidents, as well as nature and timing of incidents	One or more incidents were intercepted in 40.6% of checklists. The majority of incidents (54.8%, 95% CI 16.47 to 17.6) originated pre-operatively, and 31.0% (95% CI 15.10 to 16.50) occurred during the post-operative phase.	18/18
Nakayama DK[47] USA 2012	NICU, PICU, ED, radiology, general paediatric ward	903 intra-hospital transfers involving paediatric surgical patients 1 American hospital	Intra-hospital transfer checklist	Longitudinal study	Number of intra-hospital transfer problems	Incidents of intra-hospital transfer problems fell from 9.9% to 1.0% ($P = < 0.001$).	9/18

CI, confidence interval; NICU, neonatal intensive care unit; PICU, paediatric intensive care unit; OR, operating room; *P*, statistical significance.

and understandings of the terms 'safety' and 'checklist'. Given the definition of safety checklist as adopted in this review, 7294 articles were excluded because of the wording of the title and/or the abstract. If the inclusion criteria were expanded with no limitations as to whether a checklist's introduction also included new actions or procedures, the number of articles would have increased. However, then, it would have been difficult to evaluate checklist effects per se, which was our primary aim. We also believe that the inclusion of all studies with a quantitative design, not only randomised controlled trials (RCTs), should increase transferability to clinical quality improvement.[49]

Negative effects of safety checklist

None of the included studies reported decreased patient quality or safety after the implementation of safety checklists. It is possible that studies showing no or negative effects have been performed but not published. Underreporting of such research is well documented.[50] Studies with results supporting a hypothesis have a 50% higher likelihood of being published than studies with negative or neutral outcomes.[51] Such biased reporting can lead to overestimation of the benefits of any treatments or measures.

We did not identify any quantitative studies focusing on workflow or time use before and after the implementation of safety checklists; however, we know from qualitative research and reports that checklists influence workflow and can be either welcomed or seen as a hurdle.[52–54] Interestingly, a high WHO checklist compliance rate is not necessarily equal to having a strong influence on the *patient safety culture* as reported by personnel in the ORs.[55]

Outcome and process-related measures

The studies in Table 1 have 'hard' outcome measures. The measures of the studies in Tables 2–4 are not directly associated with decreased mortality or morbidity. Process-related measures, such as changes in communication, leadership, coordination, situational awareness, and shared mental models, are aspects of human factors that are relevant to patient safety and have been shown to improve medical management.[56,57] One of the included 'hard' outcome measure studies[9] also measured the incidence of adverse events on the same material in another study;[46] it provided insight that the prevention of adverse events, a 'soft' measure, caused a reduction in mortality.

Study quality

Guidelines regarding quality assessment in systematic reviews are mostly developed to evaluate RCTs.[58] Currently, no quality assessment tool is regarded as a 'gold standard' for observational studies.[59] Although the studies included in this review vary widely in study design, settings, number of participants, and outcome measures, they have all been assessed using the same quality assessment tool.[16] However, not all of the nine assessment criteria could be applied to any of the studies included because of study design (e.g. power calculation not being applicable to descriptive statistics). This may also imply a false low total score simply because one or several of the criteria were unsuitable.

Long-term effects

All of the articles that have been included in this review report on relatively short-term effects of safety checklists. The maximum retrospective follow-up reported after checklist use was 18 months,[18] while the maximum prospective follow-up after checklist implementation was 13 months.[21] It remains unclear whether any effects will persist when checklists are well established in daily workflow. A newly published paper reports positive effects 2 years after implementation of the WHO safety checklist.[60] Additional studies are needed to determine whether a safety checklist is a feasible and effective safety strategy in the long run. Long-term implementation success has been achieved in other high-reliability organisations.[61] These organisations have successfully created a sustainable safety checklist culture by focusing on checklist acceptance among all stakeholders, regular simulation training, checklist design, and the importance of validation and revision.[62]

Study settings

Complicated procedures and operations are performed in most medical specialities in a variety of locations, hospitaly and pre-hospitaly. The settings for the included studies are ORs, intensive care units, patient surgical pathways, wards, and emergency departments. The feasibility and the effect of safety checklists in other specialities remain to be investigated. It also remains to investigate whether an extension of the checklist concept following the surgical pathways gives the same effects outside the Netherlands.

Nearly all of the included studies have been performed in high-income countries. Low perioperative mortality and low complication rates require a high number of patients and extensive resources in order to demonstrate significant results, if any (study power). In hospitals that have higher mortality and complication rates at the outset, such studies would demand fewer study subjects or patients to demonstrate any effect.

Safety checklist implementation

Why do all healthcare workers not embrace the idea of safety checklists? Most certainly, the implementation of checklists is not simply a matter of handing them out and demanding that personnel to follow them.[63] Such implementation requires a thorough plan and that all stakeholders be engaged in the process.[62] While this review has not focused on the implementation process, several studies in this review do include findings describing the processes and cultural challenges that arise during the implementation of safety checklists.[64–66]

While some claim that checklists are not cost-effective,[67] others state that checklists represent a cost-saving strategy.[68] None of the included studies in this review have presented the costs of the intervention. More likely, the costs of checklist development and implementation are lower in a clinical setting than in the context of many other new interventions or medications.

Quality improvement research: bias and effect

Checklists have been criticised because it is difficult to establish causal links between them and their effects on outcomes.[69] Some have also raised questions whether the demonstrated effects are real, or suggest that they might instead be results due to the so-called Hawthorne phenomenon.[70] In traditional biomedical research, as in an RCT, the aim is to study the effect of a single intervention while minimising every possible bias by keeping all other factors similar. In quality improvement research, the aim is usually to implement and measure the effect of an intervention in a real and 'messy' clinical setting, which by definition is filled with bias. Acknowledging this, we have chosen to include all quantitative study designs, not only RCTs, even though many coexisting factors may have influenced the observed effects.

The WHO encourages local adaption of the Safe Surgery Checklist and an implementation process that is sensitive to local circumstances. Then, isolated effects of the safety checklist itself will differ because the implementation process may vary from place to place. However, a checklist must reflect local needs in order to be both feasible and effective.[52]

Strengths and limitations

During the first step of this study, 7294 articles were excluded. One limitation to this review is that some studies might have been overlooked during this first step because their titles did not capture our attention to be included. A reduction of a large number of articles from the initial search to only a few finally included studies in well-known in literature reviews.[71,72] The fact that only five studies were added as a result of cross-referencing and the use of other sources reflects high levels of sensitivity and precision during the process, and should indicate the study's strength. Another study limitation is caused by variations of the quality of the included studies (and therefore scores from 6 to 18 out of 18 points). Although some regard the inclusion of studies with a variety of settings and designs as a limitation, others consider it a strength.[69]

Conclusion

This systematic review found that safety checklists are effective safety tools in various clinical settings. Their use has reduced mortality and morbidity. In addition, safety checklists strengthen compliance with guidelines, improve human factors, and reduce the incidence of adverse events. None of the included studies reported that safety checklists have any negative effects on patient safety issues.

Acknowledgements

The authors would like to sincerely thank Regina Küfner Lein at the Bergen University Library for her thorough guidance in designing the search strategy and performing the main search. AS was supported by a research grant from the Western Regional Health Trust of Norway (grant number 911755).

Conflict of interests: Authors declare no conflicts of interest.

References

1. Kohn L, Corrigan J, Donaldson M. To err is human. Building a safer health system. Washington, DC: National Academy Press, 2000.
2. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care 2008; 17: 216–23.
3. Wilson RM, Michel P, Olsen S, Gibberd RW, Vincent C, El-Assady R, Rasslan O, Qsous S, Macharia WM, Sahel A, Whittaker S, Abdo-Ali M, Letaief M, Ahmed NA, Abdellatif A, Larizgoitia I, WHO Patient Safety EMRO/AFRO Working Group. Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. BMJ 2012; 344: e832.

4. Hogan H, Healey F, Neale G, Thomson R, Vincent C, Black N. Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. BMJ Qual Saf 2012; 21: 737–45.
5. Longo DR, Hewett JE, Ge B, Schubert S. The long road to patient safety: a status report on patient safety systems. JAMA 2005; 294: 2858–65.
6. Morath J. To do no harm. San Francisco, CA: Jossey-Bass, 2005.
7. Degani A. Cocpit checklists: concept, design and use. Hum Factors 1993; 35: 28–43.
8. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA, Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 2009; 360: 491–9.
9. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA, SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010; 363: 1928–37.
10. Pysyk CL, Davies JM. Using the surgical safety checklist. Acta Anaesthesiol Scand 2013; 57: 135–7.
11. Rogers J. Have we gone too far in translating ideas from aviation to patient safety? Yes. BMJ 2011; 342: c7309.
12. Vats A, Vincent CA, Nagpal K, Davies RW, Darzi A, Moorthy K. Practical challenges of introducing WHO surgical checklist: UK pilot experience. BMJ 2010; 340: b5433.
13. Shillito J, Arfanis K, Smith A. Checking in healthcare safety: theoretical basis and practical application. Int J Health Care Qual Assur 2010; 23: 699–707.
14. Hales BM, Pronovost PJ. The checklist-a tool for error management and performance improvement. J Crit Care 2006; 21: 231–5.
15. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, Clarke M, Devereaux PJ, Kleijnen J, Moher D. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 2009; 339: b2700.
16. Nagpal K, Vats A, Lamb B, Ashrafian H, Sevdalis N, Vincent C, Moorthy K. Information transfer and communication in surgery: a systematic review. Ann Surg 2010; 252: 225–39.
17. Weiser TG, Haynes AB, Dziekan G, Berry WR, Lipsitz SR, Gawande AA. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. Ann Surg 2010; 251: 976–80.
18. van Klei WA, Hoff RG, van Aarnhem EE, Simmermacher RK, Regli LP, Kappen TH, van Wolfswinkel L, Kalkman CJ, Buhre WF, Peelen LM. Effects of the introduction of the WHO 'Surgical Safety Checklist' on in-hospital mortality: a cohort study. Ann Surg 2012; 255: 44–9.
19. Askarian M, Kouchak F, Palenik CJ. Effect of surgical safety checklists on postoperative morbidity and mortality rates, Shiraz, Faghihy Hospital, a 1-year study. Qual Manag Health Care 2011; 20: 293–7.
20. Bliss LA, Ross-Richardson CB, Sanzari LJ, Shapiro DS, Lukianoff AE, Bernstein BA, Ellner SJ. Thirty-day outcomes support implementation of a surgical safety checklist. J Am Coll Surg 2012; 215: 766–76.
21. DuBose JJ, Inaba K, Shiflett A, Trankiem C, Teixeira PG, Salim A, Rhee P, Demetriades D, Belzberg H. Measurable outcomes of quality improvement using a daily quality rounds checklist: one-year analysis in a trauma intensive care unit with sustained ventilator-associated pneumonia reduction. J Trauma 2010; 69: 855–60.
22. de Vries EN, Dijkstra L, Smorenburg SM, Meijer RP, Boermeester MA. The SURgical PAtient Safety System (SURPASS) checklist optimizes timing of antibiotic prophylaxis. Patient Saf Surg 2010; 4: 6.
23. Rosenberg AD, Wambold D, Kraemer L, Begley-Keyes M, Zuckerman SL, Singh N, Cohen MM, Bennett MV. Ensuring appropriate timing of antimicrobial prophylaxis. J Bone Joint Surg Am 2008; 90: 226–32.
24. Lingard L, Regehr G, Cartmill C, Orser B, Espin S, Bohnen J, Reznick R, Baker R, Rotstein L, Doran D. Evaluation of a preoperative team briefing: a new communication routine results in improved clinical practice. BMJ Qual Saf 2011; 20: 475–82.
25. Byrnes MC, Schuerer DJ, Schallom ME, Sona CS, Mazuski JE, Taylor BE, McKenzie W, Thomas JM, Emerson JS, Nemeth JL, Bailey RA, Boyle WA, Buchman TG, Coopersmith CM. Implementation of a mandatory checklist of protocols and objectives improves compliance with a wide range of evidence-based intensive care unit practices. Crit Care Med 2009; 37: 2775–81.
26. Truran P, Critchley RJ, Gilliam A. Does using the WHO surgical checklist improve compliance to venous thromboembolism prophylaxis guidelines? Surgeon 2011; 9: 309–11.
27. Dhillon P, Murphy RK, Ali H, Burukan Z, Corrigan MA, Sheikh A, Hill AD. Development of an adhesive surgical ward round checklist: a technique to improve patient safety. Ir Med J 2011; 104: 303–5.
28. Phipps LM, Thomas NJ. The use of a daily goals sheet to improve communication in the paediatric intensive care unit. Intensive Crit Care Nurs 2007; 23: 264–71.
29. Lingard L, Regehr G, Orser B, Reznick R, Baker GR, Doran D, Espin S, Bohnen J, Whyte S. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. Arch Surg 2008; 143: 12–17.
30. Kearns RJ, Uppal V, Bonner J, Robertson J, Daniel M, McGrady EM. The introduction of a surgical safety checklist in a tertiary referral obstetric centre. BMJ Qual Saf 2011; 20: 818–22.
31. Takala RS, Pauniaho SL, Kotkansalo A, Helmiö P, Blomgren K, Helminen M, Kinnunen M, Takala A, Aaltonen R, Katila AJ, Peltomaa K, Ikonen TS. A pilot study of the implementation of WHO surgical checklist in Finland: improvements in activities and communication. Acta Anaesthesiol Scand 2011; 55: 1206–14.
32. Helmio P, Blomgren K, Takala A, Pauniaho SL, Takala RS, Ikonen TS. Towards better patient safety: WHO Surgical Safety Checklist in otorhinolaryngology. Clin Otolaryngol 2011; 36: 242–7.
33. Böhmer AB, Wappler F, Tinschmann T, Kindermann P, Rixen D, Bellendir M, Schwanke U, Bouillon B, Gerbershagen MU. The implementation of a perioperative checklist increases patients' perioperative safety and staff satisfaction. Acta Anaesthesiol Scand 2012; 56: 332–8.
34. Pronovost P, Berenholtz S, Dorman T, Lipsett PA, Simmonds T, Haraden C. Improving communication in the ICU using daily goals. J Crit Care 2003; 18: 71–5.
35. Narasimhan M, Eisen LA, Mahoney CD, Acerra FL, Rosen MJ. Improving nurse-physician communication and satisfaction in the intensive care unit with a daily goals worksheet. Am J Crit Care 2006; 15: 217–22.
36. Agarwal S, Frankel L, Tourner S, McMillan A, Sharek PJ. Improving communication in a pediatric intensive care unit using daily patient goal sheets. J Crit Care 2008; 23: 227–35.
37. Rudiger-Sturchler M, Keller DI, Bingisser R. Emergency physician intershift handover – can a dINAMO checklist

speed it up and improve quality? Swiss Med Wkly 2010; 140: w13085.
38. Petrovic MA, Aboumatar H, Baumgartner WA, Ulatowski JA, Moyer J, Chang TY, Camp MS, Kowalski J, Senger CM, Martinez EA. Pilot implementation of a perioperative protocol to guide operating room-to-intensive care unit patient handoffs. J Cardiothorac Vasc Anesth 2012; 26: 11–16.
39. Stahl K, Palileo A, Schulman CI, Wilson K, Augenstein J, Kiffin C, McKenney M. Enhancing patient safety in the trauma/surgical intensive care unit. J Trauma 2009; 67: 430–3.
40. Catchpole KR, de Leval MR, McEwan A, Pigott N, Elliott MJ, McQuillan A, MacDonald C, Goldman AJ. Patient handover from surgery to intensive care: using Formula 1 pit-stop and aviation models to improve safety and quality. Paediatr Anaesth 2007; 17: 470–8.
41. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Dziekan G, Herbosa T, Kibatala PL, Lapitan MC, Merry AF, Reznick RK, Taylor B, Vats A, Gawande AA, Safe Surgery Saves Lives Study Group. Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention. BMJ Qual Saf 2011; 20: 102–7.
42. Nilsson L, Lindberget O, Gupta A, Vegfors M. Implementing a pre-operative checklist to increase patient safety: a 1-year follow-up of personnel attitudes. Acta Anaesthesiol Scand 2010; 54: 176–82.
43. Calland JF, Turrentine FE, Guerlain S, Bovbjerg V, Poole GR, Lebeau K, Peugh J, Adams RB. The surgical safety checklist: lessons learned during implementation. Am Surg 2011; 77: 1131–7.
44. Verdaasdonk EG, Stassen LP, Hoffmann WF, van der Elst M, Dankelman J. Can a structured checklist prevent problems with laparoscopic equipment? Surg Endosc 2008; 22: 2238–43.
45. Buzink SN, van Lier L, de Hingh IH, Jakimowicz JJ. Risk-sensitive events during laparoscopic cholecystectomy: the influence of the integrated operating room and a preoperative checklist tool. Surg Endosc 2010; 24: 1990–5.
46. de Vries EN, Prins HA, Bennink MC, Neijenhuis P, van Stijn I, van Helden SH, van Putten MA, Smorenburg SM, Gouma DJ, Boermeester MA. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. BMJ Qual Saf 2012; 21: 503–8.
47. Nakayama DK, Lester SS, Rich DR, Weidner BC, Glenn JB, Shaker IJ. Quality improvement and patient care checklists in intrahospital transfers involving pediatric surgery patients. J Pediatr Surg 2012; 47: 112–18.
48. Thomassen O, Brattebo G, Softeland E, Lossius HM, Heltne JK. The effect of a simple checklist on frequent pre-induction deficiencies. Acta Anaesthesiol Scand 2010; 54: 1179–84.
49. Ko HC, Turner TJ, Finnigan MA. Systematic review of safety checklists for use by medical care teams in acute hospital settings-limited evidence of effectiveness. BMC Health Serv Res 2011; 11: 211.
50. Luijendijk HJ, Koolman X. The incentive to publish negative studies: how beta-blockers and depression got stuck in the publication cycle. J Clin Epidemiol 2012; 65: 488–92.
51. Krzyzanowska MK, Pintilie M, Tannock IF. Factors associated with failure to publish large randomized trials presented at an oncology meeting. JAMA 2003; 290: 495–501.
52. Thomassen O, Brattebo G, Heltne JK, Softeland E, Espeland A. Checklists in the operating room: help or hurdle? A qualitative study on health workers' experiences. BMC Health Serv Res 2010; 10: 342.
53. Gillespie BM, Chaboyer W, Wallis M, Fenwick C. Why isn't 'time out' being implemented? An exploratory study. Qual Saf Health Care 2010; 19: 103–6.
54. Mahajan RP. The WHO surgical checklist. Best Pract Res Clin Anaesthesiol 2011; 25: 161–8.
55. Haugen AS, Søfteland E, Eide GE, Sevdalis N, Vincent CA, Nortvedt MW, Harthug S. Impact of the World Health Organization's Surgical Safety Checklist on safety culture in the operating theatre: a controlled intervention study. Br J Anaesth 2013; 110: 807–15.
56. Brattebo G. Education and training teamwork using simulation. In: Flaatten H, Moreno R, Putensen C, Rhodes A eds. Organisation and management of intensive care. Berlin: Medizinisch Wissenschaftliche verlagsgesellschaft, 2010: 323–33.
57. Westli HK, Johnsen BH, Eid J, Rasten I, Brattebo G. Teamwork skills, shared mental models, and performance in simulated trauma teams: an independent group design. Scand J Trauma Resusc Emerg Med 2010; 18: 47.
58. Borchard A, Schwappach DL, Barbir A, Bezzola P. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. Ann Surg 2012; 256: 925–33.
59. Sanderson S, Tatt ID, Higgins JP. Tools for assessing quality and susceptibility to bias in observational studies in epidemiology: a systematic review and annotated bibliography. Int J Epidemiol 2007; 36: 666–76.
60. Böhmer AB, Kindermann P, Schwanke U, Bellendir M, Tinschmann T, Schmidt C, Bouillon B, Wappler F, Gerbershagen MU. Long-term effects of a perioperative safety checklist from the viewpoint of personnel. Acta Anaesthesiol Scand 2013; 57: 150–7.
61. Gawande A. The checklist manifesto: how to get things right. New York: Metropolitan Books, 2009.
62. Thomassen O, Espeland A, Softeland E, Lossius HM, Heltne JK, Brattebo G. Implementation of checklists in health care; learning from high-reliability organisations. Scand J Trauma Resusc Emerg Med 2011; 19: 53.
63. Laurance J. Peter Pronovost: champion of checklists in critical care. Lancet 2009; 374: 443.
64. Conley DM, Singer SJ, Edmondson L, Berry WR, Gawande AA. Effective surgical safety checklist implementation. J Am Coll Surg 2011; 212: 873–9.
65. Fudickar A, Horle K, Wiltfang J, Bein B. The effect of the WHO Surgical Safety Checklist on complication rate and communication. Dtsch Arztebl Int 2012; 109: 695–701.
66. Fourcade A, Blache JL, Grenier C, Bourgain JL, Minvielle E. Barriers to staff adoption of a surgical safety checklist. BMJ Qual Saf 2012; 21: 191–7.
67. Sanders RD, Jameson SS. A surgical safety checklist. N Engl J Med 2009; 360: 2373.
68. Semel ME, Resch S, Haynes AB, Funk LM, Bader A, Berry WR, Weiser TG, Gawande AA. Adopting a surgical safety checklist could save money and improve the quality of care in U.S. hospitals. Health Aff (Millwood) 2010; 29: 1593–9.
69. Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, Lilford RJ. An epistemology of patient safety research: a framework for study design and interpretation. Part 2. Study design. Qual Saf Health Care 2008; 17: 163–9.
70. Landsberger H. Hawthorne revisited. Management and the worker: its critics, and developments in human relations in industry. New York: Conrnell University, 1958.
71. Tannvik TD, Bakke HK, Wisborg T. A systematic literature review on first aid provided by laypeople to trauma victims. Acta Anaesthesiol Scand 2012; 56: 1222–7.

72. Heier HE, Bugge W, Hjelmeland K, Soreide E, Sorlie D, Haheim LL. Transfusion vs. alternative treatment modalities in acute bleeding: a systematic review. Acta Anaesthesiol Scand 2006; 50: 920–31.

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BMJ Open Quality

Validation of a Norwegian version of SURgical PAtient Safety System (SURPASS) in combination with the World Health Organizations' Surgical Safety Checklist (WHO SSC)

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To cite: Storesund A, Haugen AS, Wæhle HV, *et al*. Validation of a Norwegian version of SURgical PAtient Safety System (SURPASS) in combination with the World Health Organizations' Surgical Safety Checklist (WHO SSC). *BMJ Open Quality* 2019;**8**:e000488. doi:10.1136/bmjoq-2018-000488

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bmjoq-2018-000488).

Received 25 July 2018
Revised 31 October 2018
Accepted 26 November 2018

Check for updates

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ABSTRACT

Introduction Surgical safety checklists may contribute to reduction of complications and mortality. The WHO's Surgical Safety Checklist (WHO SSC) could prevent incidents in operating theatres, but errors also occur before and after surgery. The SURgical PAtient Safety System (SURPASS) is designed to intercept errors with use of checklists throughout the surgical pathway.

Objective We aimed to validate a Norwegian version of the SURPASS' preoperative and postoperative checklists for use in combination with the already established Sign In, Time Out and Sign Out parts of the WHO SSC.

Methods and materials The validation of the SURPASS checklists content followed WHOs recommended guidelines. The process consisted of six steps: forward translation; testing the content; focus groups; expert panels; back translation; and approval of the final version. Qualitative content analysis was used to identify codes and categories for adaption of the SURPASS checklist items throughout Norwegian surgical care. Content validity index (CVI) was used by expert panels to score the relevance of each checklist item. The study was carried out in a neurosurgical ward in a large tertiary teaching hospital in Norway.

Results Testing the preoperative and postoperative SURPASS checklists was performed in 29 neurosurgical procedures. This involved all professional groups in the entire surgical patient care pathway. Eight clinical focus groups revealed two main categories: 'Adapt the wording to fit clinical practice' and 'The checklist items challenge existing workflow'. Interprofessional scoring of the content validity of the checklists reached >80% for all the SURPASS checklists.

Conclusions The first version of the SURPASS checklists combined with the WHO SSC was validated for use in Norwegian surgical care with face validity confirmed and CVI >0.80%.

Trial registration number NCT01872195.

INTRODUCTION

Surgical complications are a global concern. A review of closed healthcare claim cases including complications showed that it would be possible to prevent 50% of the cases.[1] A common problem which is known to complications is poor communication.[2] Tools such as safety checklists have been introduced to enhance teamwork, communication and reduce patient safety risks.[3] Use of checklists has been shown to reduce surgical complications and mortality.[4–6] WHO's Surgical Safety Checklist (WHO SSC) was introduced in the operating theatres (OTs) in two Norwegian hospitals in 2009–2010.[6] However, the in-hospital surgical pathway is comprehensive and consists of multidisciplinary involvement and interactions in OTs and in the admission phase, preoperative phase, postanaesthesia care unit (PACU) and postoperative ward care.[7] Transfers through different departments with loss of information throughout the clinical pathway may be a threat to patient safety.[8] Complications are known to occur also in the preoperative and postoperative phases of surgery.[9] Many risk factors have been described, such as failing to identify allergies,[10] lack of antibiotic prescriptions[11] and follow-up on venous thromboembolism risk and prophylaxis.[12] To our knowledge, there is only one validated checklist concept that systematically cover the total surgical pathway with personal checklists for the involved key personnel used through all critical transfer points in the care process: the Dutch SURgical PAtient Safety System (SURPASS) checklists.[13]

The SURPASS consists of 11 checklists covering the total surgical flow, from admission to discharge. Introduction of the SURPASS checklists in six Dutch hospitals reduced complications from 27.3 (95% CI 25.9 to 28.7) to 16.7 (95% CI 15.6 to 17.9). The mortality was reduced from 1.5% (95%

CI 1.2 to 2.0) to 0.8% (95% CI 0.6 to 1.1).[5] The WHO SSC has been implemented in all hospitals in Norway as part of the Norwegian patient safety programme 'In Safe Hands'.[14] Due to mandatory use of the WHO SSC, it was not possible to introduce all parts of the more comprehensive SURPASS system. Nevertheless, it seemed to be feasible to introduce the preoperative and postoperative SURPASS checklists in combination with the WHO SSC in clinical practice. Thus, this needed further investigation. We aimed to translate the SURPASS' five preoperative and three postoperative checklists and validate the SURPASS version in combination with the already established Sign In, Time Out and Sign Out parts of the WHO SSC for use in Norwegian surgical care.

METHODS AND MATERIALS

Translation and validation of the SURPASS checklists content into Norwegian flow of surgical care followed the WHO guidelines,[15] recommended for translation and adaption of instruments. The process consisted of six steps: (1) forward translation; (2) testing the content; (3) focus groups; (4) expert panel; (5) back translation and (6) approval of the final version.

The study was carried out in a neurosurgical unit in a large tertiary teaching hospital in Norway, referral for 1.1 million inhabitants, performing all common neurosurgical procedures both in children and adults.

WHO Surgical Safety ChecklistSSC

The established WHO SSC consists of three checklists to be performed within the OT at three definite moments in surgery: before induction of anaesthesia, before incision and at the end of surgery.[16] The checklist was in 2009 translated to Norwegian[17] by clinical experts including surgeons, anaesthesiologists, nurse anaesthetists, OT nurses and quality improvement officers. It was back translated to English by native English-speaking personnel and became the official Norwegian version.[18] The WHO SSC was implemented in five surgical departments, including neurosurgery. Effects of using the checklists have been validated through previous published work.[6 17 19] Further implementation of the WHO SSC at the remaining surgical departments followed WHO's implementation guide with adaptation to local use.[20 21]

The SURPASS checklists

The SURPASS checklists consist of five preoperative, three intraoperative and three postoperative checklists. The preoperative and postoperative checklists are individualised to fit the healthcare providers' professional responsibility. The original version of the SURPASS checklists[13] was developed in three steps: (1) literature studies on human processes and adverse events after surgical procedures, (2) observations of safety risk events in clinical practice throughout the perioperative care and (3) practical and effectiveness evaluation of the checklists. The content was validated by observing safety deviations in clinical practice in comparison with checklist items.[13] This process was to ensure that practice and theory corresponded. The original preoperative and postoperative phases of SURPASS consisted of 63 checklist items. In addition, two items on the preoperative checklist for surgeons were to be used in case of local anaesthesia without anaesthesiologist.

In contrary to the WHO SSC, which are performed by the surgical team, the preoperative and postoperative SURPASS checklists are personalised and completed by individual health professionals in charge of specific care details through the surgical care pathway. We chose to add specifically the preoperative and postoperative parts of the SURPASS checklists to the already established intraoperative WHO SSC in our hospital and combine them in one comprehensive perioperative checklist.

Forward translation

An English translation of the content was provided from the SURPASS copyright holders[5] in addition to the original Dutch version. Translation of the checklist content into Norwegian was first carried out by professional translators (Semantix AS, Stavanger, Norway). Then, the translated and the English versions of the checklists were reviewed by three clinical experienced researchers (AS, ASH and ES). Cross-cultural adaptation of surgical workflow and logistics in checkpoints from Dutch to Norwegian standards were ensured in close collaboration with surgeons and healthcare personnel from the neurosurgical department testing the checklists. This also investigated the face validity and feasibility. Three items were left out from the original Dutch preoperative ward nurse checklist due to lack of local existing protocols and procedures at the time of investigations: screenings for decubitus; risk of patient falls; and delirium. All three screening protocols were under development and scheduled to be introduced at a later stage. One item for the discharging nurse concerning home regimen explained to patient was left out due to being covered in standard discharging procedures. Two new procedures were implemented that contribute to two new checklist items on the preoperative ward nurse checklist: body temperature controlled 1 hour before entrance to the OT (not in the original version) and patient identification tags on both wrists (in the original version: name tags and barcode on both wrists). One of the original checklists assigned to an anaesthesiologist or intensivist when transferring the patient from PACU or intensive care unit to hospital wards was changed and assigned to the PACU nurse.

Testing the content

Before testing the checklists, all groups of healthcare professionals received at least one educational session. The personnel involved in neurosurgery were ward doctors (neurosurgical resident/consultant in neurosurgery/final year student resident), ward nurses (registered nurses (RNs)), neurosurgeons, anaesthesiologists, OT nurses (RNs with graduate certificate in operating room processes), PACU nurses (RNs or graduate certificate in intensive care) and discharging doctors (neurosurgical resident/consultant in neurosurgery/final year student resident) and nurses (ward nurse and RNs). All personnel involved received information by email and informative posters that were displayed in the department. Training followed the principles of Conley and colleagues,[22] by explaining why the checklists were tested and showing how to use the different checklists. The implementation team consisted of key clinical personnel, the research group and the middle level of management for the involved groups. Paper version checklists were used individually by personnel at each preparatory step of the surgical pathway. All the checklists had user instructions attached. The lists were designed to check whether all necessary procedures had been completed, hence different from a to-do list.[23] During the test period, it was mandatory to use the preoperative parts of the checklists. In agreement with the department head, consequences of not completing the checklists resulted in delayed surgery.

During the test period, the checklist users were asked to write feedback notes on a daily basis regarding wording of the checklist items. This was to determine whether the wording was precise and to get an understanding of optimal time-points for completion of the checklists.

The implementation team was available to clarify doubts and follow-ups throughout the test period. All the surgeons were asked individually on their experiences of using the preoperative and discharging checklists.

Focus groups

After testing the checklists in clinical settings, we needed more systematic information regarding the checklist users' perspective on usage and existing workflow in relation to checklist compliance.[24] Eight focus groups were carried out by two moderators. We planned to perform interviews in small focus groups (two to five participants) with a strategic sample of healthcare professionals. Respondents being potential users of the SURPASS checklists, including surgeons, anesthesiologists, ward doctors, ward nurses, OT nurses and PACU nurses with mixed length of experiences, were selected. The interviews were scheduled to last up to 60 min. Trained interviewers and moderators (AS, HVW, ASH and ES) conducted the focus group interviews. The interviews were carried out in hospital settings close to the wards and OTs to minimise use of time away from clinical work. The checklist items formed the interview guide. Data from the interviews were noted as condensed meaning units on a paper form. The participants reported their clinical experience, sex and profession. We used qualitative content analysis to identify codes and categories to assess the items adaption to the existing work flow.[25]

Expert panels

Each item on the checklists were subsequently tested by expert panels for all the eight new SURPASS checklists using the content validity index (CVI).[26] To score the CVI, we used eight panels with experts. The experts were instructed to score the content from a general surgical angle—covering all the surgical areas, not merely neurosurgery. The CVI scoring was performed to test relevance and comprehensiveness of precise and clear wording of the checkpoints.[27] The experts rated each checkpoint item on a four-point scale: 1=not relevant, 2=somewhat relevant, 3=quite relevant and 4=highly relevant.[28] Item content validity scores (I-CVI) were used to guide revision of wording or questions of deleting items or text. To reveal the total content validity score of the checklist or scale (S-CVI), the proportion of experts who have scored 3 or 4 were calculated.[26]

Back-translation and final approval of the SURPASS checklists

Following a forward translation, testing of the content in clinical practice, focus groups and validation by expert panels, the checklists were back-translated from Norwegian to Dutch by a native Dutch speaker. The back-translated checklists, including both the SURPASS parts and the WHO SSC were presented to the Dutch SURPASS copyright holder for approval.

RESULTS

Forward translation

The content of the original SURPASS checklists has previously been published.[5] After forward translation of the checklist content, managers and the different clinical professionals ensured that the different checklist contents were assigned to the responsible healthcare professional following Norwegian standards and legislation. The item 'obtaining written consent' is not required by Norwegian legislation; thus, this checklist item was left out. Adjustments and cross-cultural adaptations to local workflows needed to be performed: for example, ward doctors in the Netherlands are to check on: relevant imaging present; in Norway, the surgeons assess the images and the OT nurses check for the presence of the images in the OT. Also for Dutch ward doctors: relevant laboratory checks, including cross-typing; in Norway, ward nurses check for cross-typing, while the surgeons and anaesthesiologists control the laboratory results. All healthcare professional groups engaged in neurosurgery each confirmed face validity and feasibility of their respective checklist items before the checklists were tested in clinical practice.

Testing the content

We tested the checklists in 29 neurosurgical procedures performed over 3 weeks in June and July 2012. In each surgical procedure, 11 checklists were used, which includes: the five new preoperative SURPASS checklists, the established three parts of WHO SSC and the three new postoperative SURPASS checklists. All the healthcare professional groups engaged in neurosurgery were represented. Compliance rates to the different checklists are presented in figure 1. The SURPASS checklists used here included 64 checklist items, in addition to two items on the preoperative checklist for surgeons to be used in case of local anaesthesia without an anaesthesiologist involved.

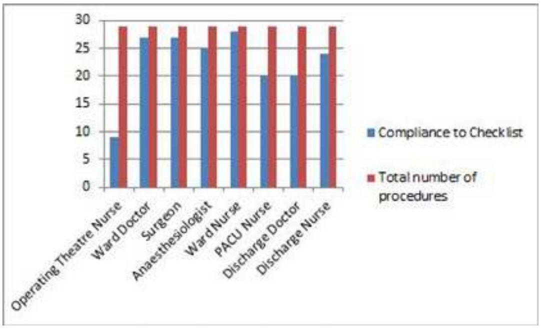

Figure 1 Compliance to the preoperative and postoperative SURPASS checklists according to professional background when testing the content in 29 neurosurgical procedures, June–July 2012, in one Norwegian hospital. PACU, postanaesthesia care unit.

The test revealed that some items had to be moved to other professional groups due to differences in national and local work assignments and work flow, and some items needed to be reformulated for clarity, specificity and simplicity.

Focus groups

The focus groups involved professionals having been assigned the five preoperative and three postoperative SURPASS checklists, with 2–5 professionals in each group. All the interviews, except one, had both an interviewer and a moderator. Two interviews had one healthcare provider involved, all together 25 different professionals participated. The participants had a wide range of working experience, from 6 months to 35 years, with 52% being females. Three identified codes 'change of wording'; 'responsibility' and 'organisation (of when to do the checklist)' constituted the main categories of 'Adapt the wording to fit clinical practice' and 'The checklist items challenge existing workflow' (figure 2).

Expert panels

Following careful text adjustments after testing the checklists in clinical practice, and adjusting items according to the suggestion from focus groups, the next step in the validation process was the CVI scoring. The expert panels' characteristics are shown in table 1.

Altogether 35 different healthcare personnel scored CVIs. Six surgeons and six ward nurses scored on both the preoperative and discharging checklist. The scorings on I-CVI and S-CVI are represented in table 2.

Examples of items having a low score (1 and 2): for surgeons: preoperative marking of the incision site; and preoperative hair removal. For ward nurses: marking of the incision site.

Back translation of the Norwegian validated version

Following careful adjustments after validation, the Norwegian version of the preoperative and postoperative parts of the SURPASS checklists finally consisted of 60 checklist items distributed on five preoperative and three postoperative checklists. In addition, one item was to be performed preoperatively by surgeons in case of local anaesthesia without an anaesthesiologist involved. All the

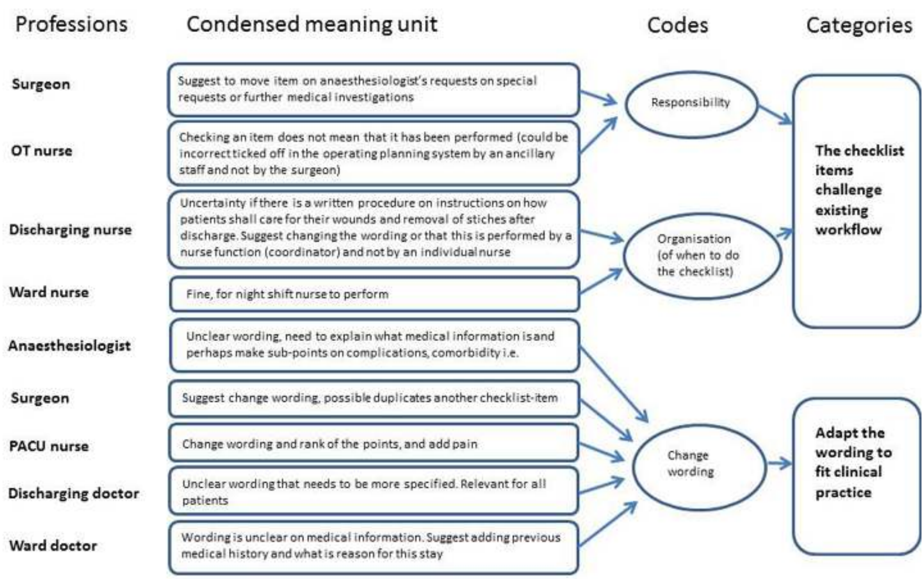

Figure 2 Qualitative content analyses to understand eight focus groups' perspectives on the tested preoperative and postoperative SURPASS checklist content for neurosurgical procedures in one Norwegian hospital. OT, operating theatre; PACU, postanaesthesia care unit.

Table 1 Characteristics of neurosurgical personnel scoring content validity index (CVI) of the preoperative and postoperative SURPASS checklists after testing, focus groups and adjustments according to feedback in the SURPASS validation study in a tertiary teaching hospital, in Norway, 2012

Profession (n)	Sex, female/ male	Age, mean years (range)	Worked in the profession, mean years	Worked as a junior, mean years	Worked as a specialist, mean years
Operating theatre nurse (5)	5/0	56 (48–61)	26	–	19
Ward doctor (6)	3/3	33.8 (29–39)	6.8	3.5	–
Surgeon (6)	0/6	48 (31–62)	20.3	3 (n=2)	24 (n=4)
Anaesthesiologist (6)	1/5	42 (31–64)	14	2 (n=1)	13.8 (n=5)
Ward nurse (6)	5/1	31.5 (26–39)	8.3	8.1	-
PACU nurse (6)	4/2	39.3 (33–54)	15.1	–	6.4
Discharging doctor (6)	0/6	48 (31–62)	20.3	–	15.6
Discharging nurse (6)	5/1	31.5 (26–39)	8.3	–	8.1

PACU, postanaesthesia care unit; SURPASS, SURgical PAtient Safety System.

original checklist items excluding the three ward nursing screenings and obtained consent were included in the Norwegian version. The content of the tested checklists and the corresponding content having been back translated are shown in online supplementary digital content 1. The back-translated checklists, including both the SURPASS parts and the WHO SSC, were approved by the Dutch SURPASS copyright holder.

DISCUSSION

The English version of SURPASS' five preoperative and three postoperative checklists were validated together with the established three parts of WHO SSC in a neurosurgical department in a tertiary hospital in Norway. The validation process consisted of six steps, including forward translation, testing the content, focus groups, expert panels, back translation and approval of the final version. There was a general positive attitude towards using checklists, although critique, reluctance and questions regarding the checklists themselves and on safety-effects were also raised. Checklist scepticism has also been documented for years in other healthcare settings.[22 29–32]

Before testing the content and the flow of checklists, there was a close collaboration with management and health personnel within each profession for all checklist parts. The Dutch and Norwegian standards of healthcare are very similar, but some differences in healthcare providers' responsibilities were disclosed. To overcome this, some items were assigned to other professions' checklists. From the literature and our previous experience on implementation of the WHO SSC, we observe that including key stakeholders at an early stage for buy-in and to increase ownership in the process is recommended.[33–35] Face validity and feasibility were confirmed before testing the content in clinical practice.

Testing the checklists in clinical practice revealed that there were still challenges concerning wording and the existing workflow. Several studies have identified that

Table 2 The item content validity index (I-CVI) and scale content validity index (S-CVI) scores by the neurosurgical experts evaluating the preoperative and postoperative SURPASS checklists after testing, focus groups and adjustments according to feedback in the SURPASS validation study in a tertiary teaching hospital, in Norway, 2012

Experts (n)	Checklist items rated	Items rated 1 or 2*	Items rated 3 or 4†	Calculating the mean I-CVI	S-CVI
Operating theatre nurse (5)	5	0	25	25/25	1.00
Ward doctor (6)	5	3	27	27/30	0.90
Surgeon (6)	9	9	45	45/54	0.83
Anaesthesiologist (6)	7	4	38	38/42	0.90
Ward nurse (6)	13	11	67	67/78	0.86
PACU nurse (6)	6	1	35	35/36	0.97
Discharge doctor (6)	10	10	50	50/60	0.83
Discharge nurse (6)	5	4	26	26/30	0.87

*1=not relevant; 2=somewhat relevant.
†3=quite relevant; 4=highly relevant.
PACU, postanaesthesia care unit; SURPASS, SURgical PAtient Safety System.

change of workflow following checklist implementation may represent a barrier to engage the healthcare providers.[35–38] Although many of the clinicians found a paper checklist most convenient for testing the content, there were logistic challenges that resulted in low compliance rates for the OT nurses. Some of the personnel were enthusiastic about systematically having a last check-up before transferring the patient. Some were engaged to give the test period a fair chance to succeed and were open-minded. Others were open on concerns, that is, another thing to spend time on in an already time-constraint environment. The managers were engaged and pointed out dedicated staff to follow up the test period. The implementation team involved and engaged the personnel thoroughly, on both group and individual levels and monitored the process closely. The WHO SSC was implemented in this hospital in 2009. It is mandatory to use, and it has a good compliance rate. However, discussions on issues regarding the WHO SSC were important, but the main focus was on testing the new SURPASS checklists.

To get a further insight into the challenges with the existing workflow and identify wording to be improved, we conducted focus group interviews. The focus groups had several suggestions for rephrasing list contents to adapt the wording and item content into clinical practice and workflow.

All the expert panels were instructed to score the CVI from a general surgical perspective. Still, the 'low relevance' scorings of specific checklist items were explained as not being important for the expert panel's surgical discipline. However, these items could be judged as highly relevant checkpoints for other surgical departments and should be tailored to these settings accordingly. Thus, despite a low score, these items were not removed from the checklists being back translated due to generalisation to other specialities. However, the items were removed from neurosurgery checklists as a local adjustment. All the eight checklist scores had a CVI >0.80. A 90% agreement on CVI is regarded satisfactory with some authors,[27] while others urge to have total agreement by all the experts if five or fewer experts.[39] However, if six or more experts are scoring, the I-CVI is regarded as valid when 80% reach agreement.[39 40] All the checklists reached an acceptable CVI score.

We recommend local adaptation and testing the content in new settings to disclose and terminate barriers before implementation of additional surgical checklists.

Strengths and limitations

A strength of this study is the inclusion of interprofessional key stakeholders in the early process of adjusting the content to Norwegian work assignments and flows. Another is the continuous process of testing the checklists in practice with all health professional groups represented. Generally, the similarities between Dutch and Norwegian surgical safety standards increased likelihood that the checklist contents followed existing workflow and procedures. Still, three items were not included on this checklist version due to lack of protocols and work processes corresponding to these items. All new protocols and work processes should of course be implemented properly before the checklists are introduced. Prior to checklist implementation, a thorough evaluation of context, assessing corresponding work processes and procedures to checklist items has also been recommended in the literature.[35]

It may be a possible limitation that the Norwegian version of the SURPASS checklists was validated in one department only. However, the original SURPASS checklists was developed through a great variety of surgical procedures and settings, to make adaptation of the checklists to other hospital departments feasible.[13] Use of highly experienced and expert personnel when testing the checklists may be seen as a strength. Advices as to adaption and tailoring the content to the setting were followed.[21]

CONCLUSION

The SURPASS' preoperative and postoperative checklists were successfully validated for use in Norwegian surgical care with high face validity and content validity (CVI >80%) and in combination with the WHO operative checklist. Adding new checklists in combination with the already established Sign In, Time Out and Sign Out parts of the WHO SSC was feasible in neurosurgery.

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Acknowledgements We would like to thank the interprofessional personnel working with neurosurgical patients who have contributed with valuable information and input on the checklist content. Also, we are grateful for the moderating done by Anne Mette Espe during the focus groups and the checklist back translational work done by anaesthesiologist Geert de Pater.

Contributors AS, ASH, MAB and ES contributed with the conception and design of the study. AS, ASH, HVW, RM and ES: acquisition of data. AS, ASH, HVW, MWN, MAB and ES: analysis and interpretation of data. AS drafted the article and designed the figures. ASH, MWN and ES supervised the project. AS is the overall content guarantor for the manuscript.

Funding AS was supported by a research grant from the Western Norway Regional Health Authority Trust, the Patient Safety Program (grant number HV1173) and Norwegian Nurses Organisation (grant number 15/0023). ASH was supported by a postdoctoral fellow research grant from the Western Norway Regional Health Authority Trust, the Patient Safety Program (grant number HV1172). HVW was supported by a research grant from the Western Norway Regional Health Authority Trust, the Patient Safety Program (grant number HV1174).

Disclaimer The funders have not been involved in the study design, data collection, analysis, interpretation of data, writing of the report or to the decision to submit the paper for submission.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study was approved by the Western Norway Regional Ethical Research Committee (2012/560/REK West).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

REFERENCES

1. Griffen FD, Stephens LS, Alexander JB, *et al*. The American College of Surgeons' closed claims study: new insights for improving care. *J Am Coll Surg* 2007;204:561–9.
2. Kohn LT, Corrigan JM, Donaldson MS, *et al*. *To err is human: building a safer healthcare system. Institute of Medicine, ed*. Washington, DC: National Academy Press, 2000.
3. Lingard L, Regehr G, Cartmill C, *et al*. Evaluation of a preoperative team briefing: a new communication routine results in improved clinical practice. *BMJ Qual Saf* 2011;20:475–82.
4. Haynes AB, Weiser TG, Berry WR, *et al*. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009;360:491–9.
5. de Vries EN, Prins HA, Crolla RM, *et al*. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med* 2010;363:1928–37.
6. Haugen AS, Søfteland E, Almeland SK, *et al*. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. *Ann Surg* 2015;261:821–8.
7. Manser T, Foster S, Flin R, *et al*. Team communication during patient handover from the operating room: more than facts and figures. *Hum Factors* 2013;55:138–56.
8. Nagpal K, Vats A, Lamb B, *et al*. Information transfer and communication in surgery: a systematic review. *Ann Surg* 2010;252:225–39.
9. de Vries EN, Ramrattan MA, Smorenburg SM, *et al*. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care* 2008;17:216–23.
10. Bochner BS, Lichtenstein LM. Anaphylaxis. *N Engl J Med* 1991;324:1785–90.
11. Bull AL, Russo PL, Friedman ND, *et al*. Compliance with surgical antibiotic prophylaxis--reporting from a statewide surveillance programme in Victoria, Australia. *J Hosp Infect* 2006;63:140–7.
12. Cohen AT, Tapson VF, Bergmann JF, *et al*. Venous thromboembolism risk and prophylaxis in the acute hospital care setting (ENDORSE study): a multinational cross-sectional study. *Lancet* 2008;371:387–94.
13. de Vries EN, Hollmann MW, Smorenburg SM, *et al*. Development and validation of the SURgical PAtient Safety System (SURPASS) checklist. *Qual Saf Health Care* 2009;18:121–6.
14. Norwegian Directorate of Health. In safe hands 24/7. 2015 http://www.pasientsikkerhetsprogrammet.no//om-oss/english (accessed 23 Jul 2018).
15. World Health Organization. Process of translation and adaption of instruments. 2018 http://www.who.int/substance_abuse/research_tools/translation/en/# (accessed 23 Jul 2018).
16. World Health Organization. WHO Surgical safety checklist. 2009 http://apps.who.int/iris/bitstream/10665/44186/2/9789241598590_eng_Checklist.pdf (accessed 23 Jul 2018).
17. Haugen AS, Søfteland E, Eide GE, *et al*. Impact of the World Health Organization's Surgical Safety Checklist on safety culture in the operating theatre: a controlled intervention study. *Br J Anaesth* 2013;110:807–15.
18. Norwegian Knowledge Centre for the Health Services. Sjekkliste for trygg kirurgi. 2010 http://www.who.int/patientsafety/safesurgery/tools_resources/SSC_bokm_al.pdf?ua=1 (accessed 23 Jul 2018).
19. Haugen AS, Wæhle HV, Almeland SK, *et al*. Causal Analysis of World Health Organization's Surgical Safety Checklist Implementation Quality and Impact on Care Processes and Patient Outcomes: Secondary Analysis From a Large Stepped Wedge Cluster Randomized Controlled Trial in Norway. *Ann Surg* 2017 [Epub ahead of print 6 Nov 2017].
20. Haugen AS, Bakke A, Løvøy T, *et al*. Preventing complications: the preflight checklist. *Eur Urol Focus* 2016;2:60–2.
21. World Health Organization. Implementation manual - WHO surgical safety checklist. 2008 http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf (accessed 23 July 2018).
22. Conley DM, Singer SJ, Edmondson L, *et al*. Effective surgical safety checklist implementation. *J Am Coll Surg* 2011;212:873–9.
23. Thomassen Ø, Storesund A, Søfteland E, *et al*. The effects of safety checklists in medicine: a systematic review. *Acta Anaesthesiol Scand* 2014;58:5–18.
24. Krueger RA, Casey MA. *Focus groups: a practical guide for applied research*. Los Angeles: Sage, 2015.
25. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004;24:105–12.
26. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health* 2006;29:489–97.
27. Waltz CF OLS, Lenz ER. *Measurement in nursing and health research*. 3rd edn. New York: Springer Publishing Company, 2005.
28. Davis LL. Instrument review: getting the most from a panel of experts. *Applied Nursing Research* 1992;5:194–7.
29. Thomassen O, Brattebø G, Heltne JK, *et al*. Checklists in the operating room: Help or hurdle? A qualitative study on health workers' experiences. *BMC Health Serv Res* 2010;10:342.
30. Fourcade A, Blache JL, Grenier C, *et al*. Barriers to staff adoption of a surgical safety checklist. *BMJ Qual Saf* 2012;21:191–7.
31. Russ SJ, Sevdalis N, Moorthy K, *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;261:81–91.
32. Borchard A, Schwappach DL, Barbir A, *et al*. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012;256:925–33.
33. Leape LL. The checklist conundrum. *N Engl J Med* 2014;370:1063–4.
34. Russ S, Rout S, Sevdalis N, *et al*. Do safety checklists improve teamwork and communication in the operating room? A systematic review. *Ann Surg* 2013;258:856–71.
35. Hull L, Athanasiou T, Russ S. Implementation science: a neglected opportunity to accelerate improvements in the safety and quality of surgical care. *Ann Surg* 2017;265:1104–12.
36. Bergs J, Lambrechts F, Simons P, *et al*. Barriers and facilitators related to the implementation of surgical safety checklists: a systematic review of the qualitative evidence. *BMJ Qual Saf* 2015;24:776–86.
37. De Bie AJR, Nan S, Vermeulen LRE, *et al*. Intelligent dynamic clinical checklists improved checklist compliance in the intensive care unit. *Br J Anaesth* 2017;119:231–8.
38. Gillespie BM, Marshall AP, Gardiner T, *et al*. Impact of workflow on the use of the Surgical Safety Checklist: a qualitative study. *ANZ J Surg* 2016;86:864–7.
39. Lynn MR. Determination and quantification of content validity. *Nurs Res* 1986;35:382–5.
40. Polit DF, Beck CT. *Nursing Research: generating and assessing evidence for nursing practice*. Philadelphia: Wolters Kluwer, 2017.

III

Original article

Accuracy of surgical complication rate estimation using ICD-10 codes

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Background: **The ICD-10 codes are used globally for comparison of diagnoses and complications, and are an important tool for the development of patient safety, healthcare policies and the health economy. The aim of this study was to investigate the accuracy of verified complication rates in surgical admissions identified by ICD-10 codes and to validate these estimates against complications identified using the established Global Trigger Tool (GTT) methodology.**

Methods: **This was a prospective observational study of a sample of surgical admissions in two Norwegian hospitals. Complications were identified and classified by two expert GTT teams who reviewed patients' medical records. Three trained reviewers verified ICD-10 codes indicating a complication present on admission or emerging in hospital.**

Results: **A total of 700 admissions were drawn randomly from 12 966 procedures. Some 519 possible complications were identified in 332 of 700 admissions (47·4 per cent) from ICD-10 codes. Verification of the ICD-10 codes against information from patients' medical records confirmed 298 as in-hospital complications in 141 of 700 admissions (20·1 per cent). Using GTT methodology, 331 complications were found in 212 of 700 admissions (30·3 per cent). Agreement between the two methods reached 83·3 per cent after verification of ICD-10 codes. The odds ratio for identifying complications using the GTT increased from 5·85 (95 per cent c.i. 4·06 to 8·44) to 25·38 (15·41 to 41·79) when ICD-10 complication codes were verified against patients' medical records.**

Conclusion: **Verified ICD-10 codes strengthen the accuracy of complication rates. Use of non-verified complication codes from administrative systems significantly overestimates in-hospital surgical complication rates.**

Paper accepted 26 July 2018

Published online 18 September 2018 in Wiley Online Library (www.bjs.co.uk). **DOI:** 10.1002/bjs.10985

Introduction

The Institute of Medicine's seminal report[1] on medical errors initiated safety awareness and implementation of preventive patient safety strategies. Patient harm remains a challenge in healthcare and up to 35 per cent of patients are exposed to complications during their hospital stay[2]. A majority of identified complications (over 65 per cent) are attributed to surgical care[3–5].

A number of methods have been used to detect adverse events, patient harm or complications. These include prospective observation of unfolding care processes[6], the Clavien–Dindo classification of complications[7], incident reporting[8], and retrospective review of patient records, such as the Harvard method[9] and the Global Trigger Tool (GTT) developed by the Institute for Healthcare Improvement (IHI)[10]. Under-reporting of complications in incident reporting systems remains a challenge[11]. Full record review is thought to identify most complications, with the GTT method revealing ten times more complications than other methods[12]. The GTT involves searching for 'trigger' words that can indicate a complication (such as decubitus, intubation, naloxone), tracking changes over time[13], and studying the effect of new interventions to improve patient safety[14]. The GTT is labour-intensive, and therefore mostly recommended for internal use. A less resource-demanding alternative is to use electronically extracted disease and complication codes from hospital administrative data that have already been entered into hospital databases[15,16].

ICD-9 and ICD-10 have been used by more than 100 countries, and contributed to more than 20 000 scientific publications[17]. In Norway, it has been mandatory to use the ICD-10 system since 1999. Discharging physicians have to code diseases and complications that are detected in patient records and hospital administrative systems. The codes are frequently also used for reimbursement. Comparing data on complications across nations based on ICD-10 codes is common, but, owing to variation in coding practices and poor quality of registered data, caution in interpreting patterns and comparisons is advised[18].

Surgical complications often have a significant personal, family, economic and thus wider societal impact. Reliable knowledge of codes indicating complications, and methods to apply them, are warranted. Concerns have been raised regarding the reliability and validity of different diagnostic codes, such as those for venous thromboembolism[19], stroke[20,21], sepsis[22], infections[23] and myocardial infarction[24].

Consistent knowledge of surgical complications may inform and could influence healthcare policies and facilitate future safety targets. The aim of the present study was to investigate the accuracy of using ICD-10-coded surgical complications compared with the GTT as a reference standard, by conducting a concurrent validation study of ICD-10-coded complications. The ICD-10 classification system and the GTT method were chosen as they are well established nationally and globally. The hypothesis was that ICD-10 codes identifying complications, as currently used, overestimate actual procedure-related complications, especially as those present on admission are not distinguished from complications that arise during the hospital stay.

Methods

This observational study with prospective data collection investigated perioperative complications in two Norwegian hospitals: one tertiary teaching hospital (referral for 1·1 million inhabitants) and one community hospital (referral for 110 000 inhabitants). A sample of surgical admissions was drawn randomly from a larger group comprising various surgical procedures. Adult surgical patients (aged at least 18 years) admitted for hospital care (lasting at least 24 h) between November 2012 and March 2015 were included from the two hospitals. Exclusion criteria were: rehabilitation admissions, ambulatory patients, donor surgery and patients who declined to participate in the study. The study was approved by the Western Norway Regional Ethical Research Committee (2012/560/REK West) and the data privacy unit at the central community hospital (Ref: 2012/3060). The study protocol was registered in ClinicalTrials.gov (NCT01872195).

Global Trigger Tool

The GTT was used to identify complications in patients' medical records. GTT-identified complications are covered by the IHI's definition of an adverse event: 'an unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or has a fatal outcome'[13]. The GTT method involves a two-stage review process performed by nurses and physicians. Reviewers searched for 'trigger' words that may or may not indicate patient harm. The Norwegian GTT protocol based on the IHI guidelines was followed[13]. Two GTT teams investigated patient records to identify any word from 55 predefined trigger words that could indicate patient harm. A positive trigger word led the two teams to classify the occurrence of complications from a list of 23 categories. Both teams consisted of registered nurses with clinical experience ranging from 7 to 35 years, and experience with use of the GTT ranging from beginner to 5 years. One team included a senior anaesthetist and the other a surgeon. The members of the two teams received a joint 2-h educational session delivered by two doctors experienced in use of the GTT. According to the GTT protocol, the teams reviewed medical summaries, medication logs, laboratory results, prescriptions, surgical procedural records, anaesthesia records, nursing registrations, discharge records, ICD-10 codes and other relevant documentation.

Severity of complications identified by the GTT was classified according to the international GTT template that is used routinely by Norwegian hospitals (not only as part of the present study): E, temporary harm – additional monitoring or treatment needed; F, temporary harm – initial or extended hospital stay; G, permanent harm; H, life-supporting treatment needed; and I, death[25]. In admissions with several GTT-identified complications describing the same injury, the complication contributing to the injury was allocated a severity level. An example is postoperative bleeding resulting in reoperation: this was analysed as one complication (bleeding) with one severity level (F).

ICD-10 complication codes

Primary outcomes were complications during in-hospital care. A complication was defined as an adverse outcome:

'an unintended and undesired occurrence in the healthcare process, which causes harm to the patient'[26]. The ICD-10 codes indicating complications were identified by using complications as classified by the American College of Surgeons' National Surgical Quality Improvement Program[27] and studies investigating surgical complications[28–30]. Based on previous research publications on checklists and surgical complications, 154 ICD-10 complication codes were included in this study (*Table S1*, supporting information).

The codes investigated were extracted electronically from patient medical records using the hospital administrative data systems for routinely collected data. All patient records with any identified ICD-10 complication code were reviewed to verify whether the ICD-10 complication code was already linked to the patient's condition at the time of admission or arose during the hospital stay. A complication resulting from a previous admission rather than the present one was not included as a complication in the admission analysed in the present study. Three clinical researchers (an intensive care nurse, a nurse anaesthetist and a senior intensivist), different from the GTT teams, independently reviewed the patient's medical records and verified the codes as indicative of a complication already being present on admission, or one that emerged during the hospital stay and/or at discharge. Admissions with one or two complications were classified by a single reviewer. All admissions with three or more complications were discussed between all three reviewers, and consensus was obtained to ensure agreement in number and types of complications. The ICD-10 complication code reviewers and the GTT record review teams were blinded to each other's reviews.

Reliability and validity

Reliability was assessed for both teams classifying complications using the GTT method in the same 20 random medical records. After classification, agreement on the presence of a complication, numbers of complications and levels of severity was tested. In addition, three clinical researchers, with no involvement in the GTT classification, reviewed the same discharge ICD-10 codes in 30 new random medical records. The agreement on patients having a complication or not during the hospital stay and number of complications was tested.

In the second phase, concurrent validity[31] was studied, comparing complications using the two different methods: GTT (reference standard) and ICD-10 complication codes. Validation here refers to agreement in identifying complications in the same admissions using the two different methods[32].

Statistical analysis

Sample size calculations were based on the assumption that 14 per cent of the study population would acquire a complication in hospital according to ICD-10 codes, based on available evidence[28,30]. Because patient record review is expected to reveal more complications[12], it was further assumed that, if an ICD-10 complication code were attributed to an admission, the risk of identifying a complication according to the GTT (patient harm of category E, F, G, H, I) would be twice the risk had no such code been present. Based on these assumptions, to obtain 90 per cent power and a significance level of 5 per cent, inclusion of at least 636 patient admissions was required.

A Venn diagram was used to illustrate associations between surgical complications identified by ICD-10 codes and GTT reviews. Cohen's κ and weighted κ statistics were used to test reliability, with assessment of the strength of agreement among the ICD-10 code reviewers and between the GTT teams by means of inter-rater reliability tests[33]. Standard classification of κ coefficient values was used: less than 0·20, poor agreement; 0·21–0·40, fair; 0·41–0·60, moderate; 0·61–0·80, good; and 0·81–1·00, very good[33].

Logistic regression was used to analyse the relationship between complications identified using a verified ICD-10 code compared with complications identified by the GTT review of patients' records; the results are reported as odds ratios (ORs) with 95 per cent confidence intervals. $P \leq 0{\cdot}050$ was considered statistically significant. Data were analysed using SPSS® version 24 for Windows® (IBM, Armonk, New York, USA). Weighted κ analysis was performed using Stata® version 14.0, and Venn diagrams were drawn using the Stata procedure pvenn (StataCorp, College Station, Texas, USA).

Results

A study sample of 700 surgical admissions in 695 patients was drawn randomly from a larger group of 12 966 surgical procedures. Some 87·4 per cent were from the tertiary hospital and 12·6 per cent from the community hospital. Surgical procedures in the community hospital included gastrointestinal surgery (such as appendicectomy and colonic resection) and urology (for example prostatectomy and ureteric stent). Those in the tertiary hospital included neurosurgery (such as disc herniation surgery, excision of intracranial lesion, evacuation of haematoma, external drainage), gynaecology (hysterectomy, oophorectomy, vaginal fistula repair, perineorrhaphy), orthopaedics (osteosynthesis or reposition of fractured limbs, hip or knee replacements, external fixation, malleolus surgery) and thoracic surgery (ascending aorta vascular prosthesis,

Table 1 Characteristics of 700 surgical patient admissions in two hospitals in western Norway from November 2012 to March 2015

	No. of patients (*n* = 700)
Age (years)	
18–64	417 (59·6)
≥ 65	283 (40·4)
Sex	
M	309 (44·1)
F	391 (55·9)
Duration of hospital stay (days)	
1	72 (10·3)
2–7	350 (50·0)
8–14	199 (28·4)
≥ 15	79 (11·3)
Incision time (min)	
≤ 30	83 (11·9)
31–60	125 (17·9)
61–180	392 (56·0)
≥ 181	100 (14·3)
ASA fitness grade	
I	115 (16·4)
II	305 (43·6)
III	249 (35·6)
IV	30 (4·3)
V	1 (0·1)
Urgency of surgery	
Elective	395 (56·4)
Emergency	305 (43·6)
Surgical specialty	
Neurosurgery	129 (18·4)
Orthopaedics	223 (31·9)
Gynaecology	111 (15·9)
Thoracic	149 (21·3)
General	88 (12·6)
Hospital type	
Tertiary	612 (87·4)
Central	88 (12·6)

Values in parentheses are percentages.

cardiopulmonary bypass, aortic valve replacement, circulatory anastomosis). Patient characteristics are shown in *Table 1*. Mean(s.d.) age was 58·3(18·1) (range 18–99) years. In total, the data set represented 5350 days of admission, with a median of 5·8 (i.q.r. 3·1–8·8) and mean(s.d.) of 7·6(8·3) days per stay.

Complications detected by the Global Trigger Tool method

Using the GTT method, a total of 331 (range 1–7) complications were identified in 212 of 700 admissions (30·3 per cent). Seventy-seven admissions were identified with more than one complication describing an injury. The distribution of the GTT complications is shown in *Table 2*. A majority were classified as temporary: E in 111 of 331 (33·5 per cent) and F in 200 (60·4 per cent). Thirteen (4·0 per cent) were regarded as representing permanent harm and classified as G. None were classified as H (life-supporting treatment needed) and complications in seven patients (2·1 per cent) were classified as I (death). Infection-related complications constituted 41·1 per cent and 26·0 per cent were classified as other surgical complications.

Table 2 Complications classified according to the Global Trigger Tool in 23 categories for the 212 of 700 patient admissions with patient harm in two hospitals in western Norway from November 2012 to March 2015

	One or more GTT complications*
Other surgical complications†	86 (26·0)
Surgical-site infection	35 (10·6)
Urinary tract infection	34 (10·3)
Low respiratory infection	30 (9·1)
Other infection	26 (7·9)
Postoperative bleeding/haematoma	24 (7·3)
Postoperative respiratory complication	23 (6·9)
Reoperation	20 (6·0)
Ventilator-associated pneumonia	10 (3·0)
Organ failure	10 (3·0)
Medication-related (including blood and fluid therapy)	9 (2·7)
Deteriorating chronic condition	6 (1·8)
Bleeding	5 (1·5)
Thrombosis/emboli	3 (0·9)
Decubitus	2 (0·6)
Other	2 (0·6)
Allergy	1 (0·3)
Fracture	1 (0·3)
Central venous line infection	1 (0·3)
Medical technical equipment failure	1 (0·3)
Postpartum/obstetric complication	1 (0·3)
Wrong surgical site	1 (0·3)
Fall	0 (0)
Total no. of complications	331 (100)

Values in parentheses are percentage of total number of complications. *Among 212 patient admissions. †Drop foot, rupture of dura, pleural fluid, necrosis, vision disturbances, infarction, atrial fibrillation, other. GTT, Global Trigger Tool.

ICD-10 complication code classification

Electronic extraction of ICD-10 codes identified 519 complication codes in 332 patient records of the 700 admissions (complication rate 47·4 per cent). After excluding codes representing complications already present on admission, 141 of 700 admissions (20·1 per cent) with a total of 298 complications were found to occur in hospital. The number of complications per hospital stay ranged from one to six. The distribution of the ICD-10 complication codes is summarized in *Table 3*. After verifying the complications, the order of frequency of complication types changed from cardiac, fall, respiratory and infections to cardiac, respiratory, infections and other. Of note, all 96 codes for patient falls

Table 3 Distribution of complications in 332 surgical admissions identified using ICD-10 complication codes, and distribution of verified complications in 141 surgical admissions from patients' records in two western Norwegian hospitals from November 2012 to March 2015

	Extracted ICD-10 codes (*n* = 332 admissions)	Verified ICD-10 codes (*n* = 141 admissions)
Respiratory	79 (15·2)	55 (18·5)
Pneumonia	21 (4·0)	20 (6·7)
Respiratory, other	58 (11·2)	35 (11·7)
Cardiac	151 (29·1)	95 (31·9)
Cardiac arrhythmia	65 (12·5)	49 (16·4)
Congestive heart failure	17 (3·3)	11 (3·7)
Cardiac, other	69 (13·3)	35 (11·7)
Infections	65 (12·5)	47 (15·8)
Sepsis	13 (2·5)	9 (3·0)
Surgical site	20 (3·9)	13 (4·4)
Urinary tract	24 (4·6)	20 (6·7)
Infections, other	8 (1·5)	5 (1·7)
Surgical wound rupture	5 (1·0)	4 (1·3)
Nervous system	13 (2·5)	11 (3·7)
Delirium, somnolence, other	3 (0·6)	2 (0·7)
Cerebral infarction	10 (1·9)	9 (3·0)
Bleeding	17 (3·3)	15 (5·0)
Embolism	5 (1·0)	2 (0·7)
Nutrition	28 (5·4)	23 (7·7)
Malnutrition, other nutritional deficiencies	12 (2·3)	11 (3·7)
Other disorders of fluid, electrolyte and acid–base balance	16 (3·1)	12 (4·0)
Anaesthesia	3 (0·6)	3 (1·0)
Mechanical implantation	16 (3·1)	7 (2·3)
Fall	96 (18·5)	0 (0)
Other complications	41 (7·9)	36 (12·1)
Total no. of complications	519 (100)	298 (100)

Values in parentheses are percentage of total number of complications. Detailed list of included ICD-10 complication codes can be found in *Table S1* (supporting information).

were found to represent falls occurring before, and not during, the hospital stay.

Reliability analysis

Analysis of agreement in classifying complications in 20 random medical records using the GTT method revealed that the two teams reached 85 per cent agreement in terms of the presence of a complication, 65 per cent regarding numbers of complications and 75 per cent on the levels of severity. The κ values for inter-rating agreement between the teams were 0·700, 0·504 (weighted) and 0·688 (weighted) respectively. Three clinical researchers reviewed the same discharge ICD-10 codes in 30 random medical records. Agreement was 91 per cent in terms of patients having a complication or not during the hospital stay, and 77 per cent for agreement on actual number of complications. Accordingly, the κ values for inter-rater reliability were 0·816 and 0·731 respectively.

Validating complications by ICD-10 *versus* Global Trigger Tool

To investigate concurrent validity, it was determined whether admissions with ICD-10 complications were the same admissions as those identified as having one or more complications by the GTT methodology. The similarity between the two classification methods increased from 68·3 per cent before clinical verification of the ICD-10 complication codes to 83·3 per cent after excluding ICD-10 codes representing complications already present on admission (*Fig. 1*).

Logistic regression was used to quantify the importance of clinically verifying ICD-10 complication codes rather

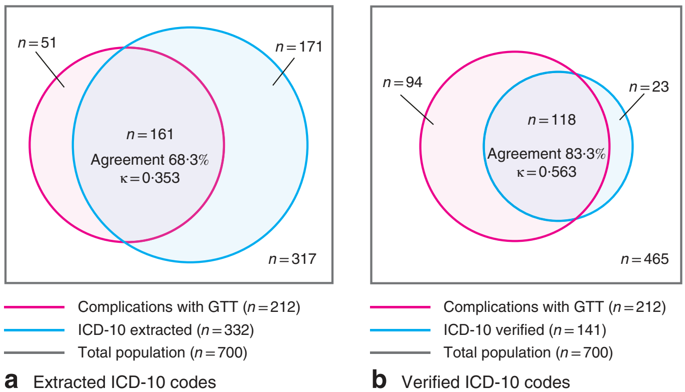

Fig. 1 Agreement between methods of identifying admissions with complications *versus* no complications: **a** using ICD-10 codes extracted from administrative data and **b** using ICD-10 codes verified from patients' records. GTT, Global Trigger Tool

than using them without verification. Admissions with unverified ICD-10 codes (332) were at increased odds of also having a GTT-identified complication (OR 5·85, 95 per cent confidence interval 4·06 to 8·44), whereas admissions with verified ICD-10 codes (141) increased the odds substantially (OR 25·38, 15·41 to 41·79). Ninety-four admissions with complications according to GTT methodology did not have an ICD-10 code reflecting a complication (*Fig. 1*).

Discussion

This study found that complications during the hospital stay were overestimated when crude ICD-10 codes were used in surgical admissions. By excluding codes representing conditions already present on admission, the complication rate decreased from 47·4 to 20·1 per cent. This provides quantifiable evidence of the detrimental impact of coding practices on the ability of ICD-10 codes to indicate a true complication in patient care. Based on the present findings, it does not appear feasible to detect and disclose all complications and level of severity using a single method. A substantial decrease in complications was found with accurate ICD-10-verified complication codes compared with ICD-10 codes present on admission. These findings support the hypothesis of the study. The GTT method is designed to inform about local complications and patient safety initiatives over longer periods of time[13], whereas the ICD-10 (if used accurately) may be used both locally and in large epidemiological studies to inform on larger patient safety interventions.

The complication rate obtained using the GTT in the present study was 30·3 per cent of all admissions. This is at the upper end of the range reported in studies included in a recent systematic review[2]. That review, however, included studies across both medical and surgical specialties. Focusing solely on surgical patient populations, as in the present study, would be expected to result in higher rates than in mixed patient populations[5]. Regarding level of severity, the majority of complications identified by the GTT (93·9 per cent) were found to be associated with temporary harm. Similar findings regarding severity have been documented elsewhere[34,35].

In the present study, the agreement between the ICD-10 and GTT methods increased from 68·3 to 83·3 per cent following clinical researchers' verification of the ICD coding. Other studies[7,15,36] have investigated complications using different detection methods. The high rates of agreement here might be explained by avoidance of use of complications reported voluntarily by healthcare personnel as a comparator. There is evidence for under-reporting of complications in voluntary reporting systems[12], which would likely lead to lower agreement between methods. The present analysis included a large number of complication codes (154 in total), which might have increased the number of complications identified, thus offering a broader perspective on surgical complication analyses. Moreover, a large number of clinically reviewed patient records were included, which is likely to have increased the number of complications found and analysed by this methodology compared with smaller studies[35].

A total of 94 admissions with GTT-identified complications were not identified by ICD-10 codes. There may be several reasons for this discrepancy. In a busy clinical practice, physicians may fail to use correct ICD-10 codes owing to lack of training in the use of such codes and/or time constraints, as pointed out in a national report[37]. The finding also demonstrates differences in methodology between the two systems for identifying complications. The GTT method may include complications before admission if they are linked to medical treatment[13], whereas the ICD-10 codes should consider only complications that emerge in hospital to be 'true' complications. The present findings have significant practical implications. If hospitals are to work on preventing or addressing patient safety risks, reliable knowledge of risk factors will be needed. Deriving such knowledge and developing patient safety programmes based solely on administratively collected complication data does not represent an effective strategy, based on the present findings. More accurate evidence concerning in-hospital complications is needed to tailor surgical patient safety interventions. Examples from this study suggest that a focus on respiratory and cardiac complications, infections and nutrition is needed. It was also shown here that all patient falls occurred before admission. These findings are important as ICD-10 coding is widely used to report on complications, carry out research, and to inform healthcare policies and hospital funding[17]. Yet few studies have reported similar procedures for clinical verification of ICD-10-coded patient-level data[30]. Such studies are urgently required to inform decision-making and funding. On a practical level, an electronic 'flag' built into ICD-10 classification systems can be recommended, so that the coder can identify a 'complication' already present on admission. Such a flagging option is available in the USA, Canada and Australia[38]. This improves coding accuracy without the requirement for significant financial investment or training, thereby enhancing the value of inexpensive complication reports based on routinely collected data.

Prospective recording of complications on a severity scale, using a validated system such as the Clavien–Dindo classification[7], would be ideal. This would probably lead to the availability of more accurate and clinician-reported data in prospective databases of postoperative morbidity, which could offer a better picture of surgical care quality. However, this would have training and resource implications if introduced as standard practice, and this is not currently done routinely in Norwegian hospitals.

The present study has limitations. Only surgical patients were included, so the results cannot be extrapolated directly to the larger cohort of medical admissions. Second, a standard Norwegian version of the GTT protocol was used and not a trigger protocol especially designed for surgical patients, known as the Surgical Trigger Toolkit. This was because the expert GTT teams had already been trained to use the standard version; in addition, there is no validated Norwegian version of the Surgical Trigger Toolkit available. However, the GTT actually covers all but two of the trigger words available in the Surgical Trigger Toolkit and hence the coverage is very similar. Third, the preventability of the identified complications was not investigated. Classifying preventability is not included as part of national GTT team training in Norway, nor is it recommended as a part of the GTT protocol[13]. Further research should analyse preventability in a similarly structured manner[2,39]. Furthermore, when studying in-hospital complications, those related to previous admissions had to be excluded. This may have led to under-reporting of complications, mainly owing to coding practices being related to each hospital admission and not to each patient throughout the healthcare pathway. Finally, as a result of natural differences between the ICD-10 and GTT systems, it may be questioned whether admissions identified by both methods actually had the same (type of) complications. Simply put, although an admission might have been identified as complicated by both tools, the type of complication identified by one of the two systems may have differed from that identified by the other. This would not affect overall complication rates, but could affect the types of complication found and consequently the hospital's targets for improvement.

The study also has strengths, including: bringing together two methods for assessing surgical safety; the overall high level of expertise among the reviewers; the inclusion of two separate hospitals; and the good reliability of the analyses. Regarding reliability, the inter-rater reliability analysis is a methodological strength. The GTT teams showed good agreement for detection and severity of complications, and moderate agreement regarding the number of complications present. The two GTT teams had expert members from both hospitals (with knowledge of local reporting practices). The inter-rater agreement among the ICD-10 reviewers was even stronger. This is a prerequisite for studies reporting data that require clinical judgement and the seniority of the reviewers ensured this.

The accuracy of ICD-10 complication codes is improved when in-hospital complications are verified with record reviews. Crude data with unverified ICD-10 codes significantly overestimate surgical complications within hospitals because complications present on admission are included. This can represent a severe bias for national and international comparisons of quality and safety of surgical care.

Acknowledgements

The authors thank the hospitals' management and staff for making the data collection possible; the professional GTT teams at Haukeland University Hospital (J. Veim, J. K. Kleiva and G. Gran) and Førde Health Trust (K. Furevik and W. B. Sjåstad) for the classification work; S. Harthug for constructive feedback; H. Waldeland, T.-L. Thorsen and N. E. J. Widnes for electronic data collection; and R. Küfner Lein at the University of Bergen Library for support with systematic searching and reference management.

A.S. was supported by a research grant from the Western Norway Regional Health Authority Trust, the Patient Safety Programme (grant number HV1173) and the Norwegian Nurses Organization (grant number 15/0023). A.S.H. was supported by a postdoctoral fellow research grant from the Western Norway Regional Health Authority Trust, the Patient Safety Programme (grant number HV1172). The research carried out by N.S. is supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. N.S. is director of King's Improvement Science, which is part of the NIHR Collaboration for Leadership in Applied Health Research and Care South London, and comprises a specialist team of improvement scientists and senior researchers based at King's College London. Its work is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust), Guy's and St Thomas' Charity, the Maudsley Charity and the Health Foundation. No funding source had any role in the design and conduct of the study; collection, management, analysis or interpretation of the data; or preparation, review or approval of the manuscript. The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR or the Department of Health. N.S. is the director of London Training & Safety Solutions, which delivers

team assessment and training to hospitals on a consultancy basis.
Disclsoure: The authors declare no other conflict of interest.

References

1 Kohn LT, Corrigan JM, Donaldson MS (eds). *To Err is Human. Building a Safer Healthcare System*; 1999. http://wps.pearsoneducation.nl/wps/media/objects/13902/14236351/H%2007_To%20Err%20Is%20Human.pdf [accessed 2 January 2018].
2 Hibbert PD, Molloy CJ, Hooper TD, Wiles LK, Runciman WB, Lachman P *et al.* The application of the Global Trigger Tool: a systematic review. *Int J Qual Health Care* 2016; **28**: 640–649.
3 Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. *Surgery* 1999; **126**: 66–75.
4 Zegers M, de Bruijne MC, de Keizer B, Merten H, Groenewegen PP, van der Wal G *et al.* The incidence, root-causes, and outcomes of adverse events in surgical units: implication for potential prevention strategies. *Patient Saf Surg* 2011; **5**: 13.
5 de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care* 2008; **17**: 216–223.
6 Olsen S, Neale G, Schwab K, Psaila B, Patel T, Chapman EJ *et al.* Hospital staff should use more than one method to detect adverse events and potential adverse events: incident reporting, pharmacist surveillance and local real-time record review may all have a place. *Qual Saf Health Care* 2007; **16**: 40–44.
7 Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004; **240**: 205–213.
8 Donaldson LJ, Panesar SS, Darzi A. Patient-safety-related hospital deaths in England: thematic analysis of incidents reported to a national database, 2010–2012. *PLoS Med* 2014; **11**: e1001667.
9 Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA *et al.* The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; **324**: 377–384.
10 Classen DC, Lloyd RC, Provost L, Griffin FA, Resar R. Development and evaluation of the Institute for Healthcare Improvement Global Trigger Tool. *J Patient Saf* 2008; **4**: 169–177.
11 Noble DJ, Panesar SS, Pronovost PJ. A public health approach to patient safety reporting systems is urgently needed. *J Patient Saf* 2011; **7**: 109–112.
12 Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N *et al.* 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)* 2011; **30**: 581–589.
13 Griffen F, Resar R. *Global Trigger Tool for Measuring Adverse Events (Second Edition)*; 2009. http://www.ihi.org/resources/Pages/IHIWhitePapers/IHIGlobalTriggerToolWhitePaper.aspx [accessed 2 January 2018].
14 Sharek PJ, Parry G, Goldmann D, Bones K, Hackbarth A, Resar R *et al.* Performance characteristics of a methodology to quantify adverse events over time in hospitalized patients. *Health Serv Res* 2011; **46**: 654–678.
15 Naessens JM, Campbell CR, Huddleston JM, Berg BP, Lefante JJ, Williams AR *et al.* A comparison of hospital adverse events identified by three widely used detection methods. *Int J Qual Health Care* 2009; **21**: 301–307.
16 Raleigh VS, Cooper J, Bremner SA, Scobie S. Patient safety indicators for England from hospital administrative data: case–control analysis and comparison with US data. *BMJ* 2008; **337**: a1702.
17 WHO. *History of the ICD*. http://www.who.int/classifications/icd/en/ [accessed 2 January 2018].
18 OECD. *Health at a Glance 2013: OECD Indicators;* 2013. http://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2013_health_glance-2013-en [accessed 2 January 2018].
19 Severinsen MT, Kristensen SR, Overvad K, Dethlefsen C, Tjønneland A, Johnsen SP. Venous thromboembolism discharge diagnoses in the Danish National Patient Registry should be used with caution. *J Clin Epidemiol* 2010; **63**: 223–228.
20 Sedova P, Brown RD Jr, Zvolsky M, Kadlecova P, Bryndziar T, Volny O *et al.* Validation of stroke diagnosis in the National Registry of Hospitalized Patients in the Czech Republic. *J Stroke Cerebrovasc Dis* 2015; **24**: 2032–2038.
21 Hall R, Mondor L, Porter J, Fang J, Kapral MK. Accuracy of administrative data for the coding of acute stroke and TIAs. *Can J Neurol Sci* 2016; **43**: 765–773.
22 Aardal S, Berge K, Breivik K, Flaatten HK. Medical records, DRG and intensive care patients. *Tidsskr Nor Laegeforen* 2005; **125**: 903–906.
23 Barber C, Lacaille D, Fortin PR. Systematic review of validation studies of the use of administrative data to identify serious infections. *Arthritis Care Res (Hoboken)* 2013; **65**: 1343–1357.
24 McCormick N, Lacaille D, Bhole V, Avina-Zubieta JA. Validity of myocardial infarction diagnoses in administrative databases: a systematic review. *PLoS One* 2014; **9**: e92286.
25 Hartwig SC, Denger SD, Schneider PJ. Severity-indexed, incident report-based medication error-reporting program. *Am J Hosp Pharm* 1991; **48**: 2611–2616.
26 Kristensen S, Mainz J, Bartels P. *A Patient Safety Vocabulary Safety Improvement for Patients in Europe: SimPatIE – Work Package 4;* 2007. http://www.zdravstvo-kvaliteta.org/attachments/article/18/Patient_safety_indicator_development [accessed 1 August 2018].
27 American College of Surgeons. *American College of Surgeons' National Surgical Quality Improvement Program*. http://www.facs.org/cqi/outcomes.html [accessed 3 January 2018].

28 de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH *et al.*; SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med* 2010; **363**: 1928–1937.
29 Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP *et al.*; Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009; **360**: 491–499.
30 Haugen AS, Søfteland E, Almeland SK, Sevdalis N, Vonen B, Eide GE *et al.* Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. *Ann Surg* 2015; **261**: 821–828.
31 Lin WL, Yao G. Concurrent validity. In *Encyclopedia of Quality of Life and Well-Being Research*, Michalos AC (ed.). Springer Netherlands: Dordrecht, 2014; 1184–1185.
32 Streiner DL, Norman GR. *Validity* (4th edn). Oxford University Press: Oxford, 2008.
33 Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977; **33**: 159–174.
34 Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med* 2010; **363**: 2124–2134.
35 Mevik K, Griffin FA, Hansen TE, Deilkås ET, Vonen B. Does increasing the size of bi-weekly samples of records influence results when using the Global Trigger Tool? An observational study of retrospective record reviews of two different sample sizes. *BMJ Open* 2016; **6**: e010700.
36 Naessens JM, Campbell CR, Berg B, Williams AR, Culbertson R. Impact of diagnosis-timing indicators on measures of safety, comorbidity, and case mix groupings from administrative data sources. *Med Care* 2007; **45**: 781–788.
37 Office of the Auditor General of Norway. *Office of the Auditor General's Investigation of Medical Coding Practice within the Health Enterprises. Document 3:5 (2016–2017)*. https://www.riksrevisjonen.no/en/Reports/Documents/CodingPracticeHealthEnterprises.pdf [accessed 2 January 2018].
38 Jackson TJ, Michel JL, Roberts R, Shepheard J, Cheng D, Rust J *et al.* Development of a validation algorithm for 'present on admission' flagging. *BMC Med Inform Decis Mak* 2009; **9**: 48.
39 Flaatten H, Brattebø G, Alme B, Berge K, Rosland JH, Viste A *et al.* Adverse events and in-hospital mortality: an analysis of all deaths in a Norwegian health trust during 2011. *BMC Health Serv Res* 2017; **17**: 465.

Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.

NORDIC ECOLABEL 241 PRINTED MATTER 731

Graphic design: Communication Division, UiB / Print: Skipnes Kommunikasjon AS

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ISBN: 9788230848159 (print)
9788230852255 (PDF)