Impact of a surgical checklist on safety culture, morbidity, and mortality

A stepped-wedge cluster randomised controlled trial

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Scientific environment

This PhD project gave rise to the Bergen Surgical Safety Checklist Study Group at the Department of Anaesthesia and Intensive Care and the Department of Research and Development, both at Haukeland University Hospital. The project is also affiliated with the Department of Clinical Science, Faculty of Medicine and Dentistry, the University of Bergen.

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I participate in the Postgraduate School of Clinical Medicine Program at the University of Bergen, Bergen, Norway; the Strategic Healthcare Research Program at the Centre for Clinical Research, Helse Bergen; the Research Network for Patient Safety, Norwegian Knowledge Centre for Health Services, Oslo, Norway; and the Western Regional Norwegian Health Authorities Network for Strategic Priority Area for Health Care Research, hosted by the Centre for Evidence-Based Practice, Bergen University College, Bergen, Norway.

This study was endorsed by the WHO Patient Safety Office, London, UK.

HELSE VEST HELSE BERGEN Haukeland universitetssjukehus

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Arvid Steinar Haugen

Abstract

Introduction

The incidence of in-hospital adverse events is estimated to occur in approximately 1 out of 10 patients. Events happening during surgical procedures contribute up to 60%, and of these, more than half are considered to be preventable. Communication breakdowns have been identified as an important contributor to errors. The introduction of surgical safety checklists that are intended to improve teamwork and communication decreases both morbidity and mortality. It has been hypothesised that improved patient outcomes result from changes in safety culture. Thus, randomised controlled studies are warranted in order to investigate whether the use of checklists are responsible for positive effects on patient outcomes.

Aims

1. In the study reported in Paper 1, we aimed to (1) validate the psychometric properties of the Hospital Survey on Patient Safety Culture (HSOPS) in a surgical environment, and (2) to compare results from its use on the safety culture in healthcare personnel in different countries.
2. In the study reported in Paper 2, we aimed to determine whether use of the World Health Organization (WHO) Surgical Safety Checklist (SSC) positively affects safety culture. We used the HSOPS to assess this.
3. In the study reported in Paper 3, we aimed to determine whether the use of the WHO SSC positively affects patient outcomes, reducing morbidity, mortality, and length of hospital stay.

Methods

In the first study, a cross-sectional survey using the HSOPS was conducted in 575 surgical personnel at Haukeland University Hospital in 2009. Surgeons, operating theatre nurses, anaesthetists, nurse anaesthetists, and ancillary personnel were included. We used explorative factor analysis to examine the applicability and the

internal consistency of the HSOPS factor structure in operating theatre settings. This survey constituted the baseline measure in the second study.

In the second study, the WHO SSC was introduced after the baseline survey was completed, along with an educational programme that provided the rationale for why and how the checklist was to be used. The implementation was carried out with a stepped-wedge cluster, randomised controlled design and was conducted in three surgical specialties (orthopaedic, cardiothoracic, and neurosurgery) at Haukeland University Hospital; the order of implementation for the three specialties was randomised. The control group comprised surgical personnel from ear, nose, and throat; maxillofacial; plastic; endocrine; urological; gastrointestinal; obstetric; and gynaecological surgical specialities. In this study, the controls did not receive the WHO SSC intervention during the study period. A total of 349 participants responded at baseline assessment, and 292 responded at post-intervention assessment. The primary outcome measure was the values of the twelve safety culture factors of the HSOPS, and the secondary outcome measure was the degree of WHO SSC compliance.

In the third study, the WHO SSC was implemented using a stepped-wedge cluster randomised controlled design in five surgical specialties. Three (orthopaedic, cardiothoracic, and neurosurgery) were from Haukeland University Hospital and two (urology and general surgery) were from Førde Central Hospital, with a total of 5,295 surgical procedures included. The intervention was randomised and conducted until all five specialties had received it. We examined whether using the WHO SSC affects in-hospital complications, as measured by ICD-10 codes, length of stay, and post-surgical mortality (up to 30 days).

Results

In the first study, the HSOPS was determined to be valid for measuring safety culture in an operating theatre setting, with internal consistency and Cronbach's alpha values ranging from 0.59 to 0.85. A twelve-factor structure of the survey instrument was supported.

In the second study, the WHO SSC intervention had a significant impact on two safety culture factors—'frequency of events (near misses) reported' and 'adequate staffing'—in the intervention group, with regression coefficients of -0.25 (95% CI, -0.47 to -0.07) and 0.21 (95% CI, 0.07 to 0.35), respectively. Between baseline and post-intervention assessments, there was a significant improvement in the factors 'hospital management promoting safety' and 'handoffs and transitions', with regression coefficients of 0.12 (95% CI, 0.04 to 0.20) and 0.08 (95% CI, 0.01 to 0.14), respectively.

In the third study, we observed a significant decrease in complications from 19.9% to 11.5% in 2,212 surgical procedures before and 2,263 after implementation of the WHO SSC ($P<0.001$). The absolute risk reduction (ARR) was 8.4 (95% CI, 6.3 to 10.5). Adjusted for possible confounding factors, the WHO SSC effect on complications remained significant, with an odds ratio of 1.95 (95% CI, 1.59 to 2.40). The checklist prevented one or more complications when used in twelve surgical procedures. Mean length of stay decreased by 0.8 days (95% CI, 0.11 to 1.43). Although in-hospital mortality decreased significantly from 1.9% to 0.2% in the central community hospital, the overall reduction of mortality (from 1.6% to 1.0%) across hospitals was not statistically significant.

Conclusions

The HSOPS was determined to be valid for use in this specific clinical setting. The WHO SSC intervention had a rather limited effect on the overall safety culture, but significantly changed perceptions of surgical professionals in the intervention group on two factors, 'frequency of events reported' and 'adequate staffing'. The stepped-wedge cluster randomised implementation of the WHO SSC was associated with robust reduction in morbidity and length of stay, and some reduction in mortality.

List of publications

Paper 1

Haugen AS, Søfteland E, Eide GE, Nortvedt MW, Aase K, Harthug S. Patient safety in surgical environments: Cross-countries comparison of psychometric properties and results of the Norwegian version of the Hospital Survey on Patient Safety. BMC Health Services Research. 2010, September; 10:279. doi:10.1186/1472-6963-10-279.

Paper 2

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. British Journal of Anaesthesia. 2013, May;110(5):807-815. doi:10.1093/bja/aet005.

Paper 3

Haugen AS, Søfteland E, Almeland S, Sevdalis N, Vonen B, Nortvedt MW, Eide GE, Harthug S. Effect of the World Health Organization Checklist on Patient Outcomes: A Stepped Wedge Cluster Randomized Controlled Trial. Annals of Surgery. 2014, May;00:1-8. doi:10.1097/ SLA.0000000000000716.

Abbreviations

AGFI = Adjusted Goodness of Fit Index

AHRQ = Agency for Healthcare Research and Quality in USA

ANOVA = Analysis of Variance

ARR = Absolute Risk Reduction

CDC = Centers for Disease Control

CFA = Confirmatory Factor Analysis

CI = Confidence Interval

GFI = Goodness of Fit Index

HRO = High Reliability Organisation

HSOPS = Hospital Survey on Patient Safety Culture

HUH = Haukeland University Hospital

ICD-10 = International Classification of Diseases 10^{th} version

IQR = Interquartile Range

MLM = Mixed Linear Model

NNT = Number Needed to Treat

OR = Odds Ratio

PACU = Post Anaesthetic Care Unit

RCT = Randomised Controlled Trial

RRR = Relative Risk Reduction

RSMEA = Root Mean Square Error of Approximation

SAQ = Safety Attitudes Questionnaire

SD = Standard Deviation

SSC = Surgical Safety Checklist

SSI = Surgical Site Infection

SSSL = Safe Surgery Saves Lives

SURPASS = Surgical Patient Safety System (checklists)

WHO = World Health Organization

WRNHA = Western Regional Norwegian Health Authority (Helse Vest RHF)

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1. INTRODUCTION

1.1 Background

To date, the World Health Organization (WHO) Surgical Safety Checklist (SSC) has been distributed to more than 3,000 hospitals globally, has become mandatory for use in more than 26 countries, and has been further endorsed by 300 organisations.[1] In the seven geographical regions of the WHO, 92 countries have participated in the Safe Surgery Saves Lives (SSSL) initiative.[2] Before 2009 and the subsequent vast distribution of the SSC, scientific evidence on how use of the WHO SSC affects morbidity and mortality was limited to a single study.[3] Thus, further research on the WHO SSC effects was critically needed.[4]

The present PhD project aimed to fill this need. The overall aim of this PhD research was to determine the WHO SSC's impact on safety culture, morbidity, and mortality in surgical specialties where reduction of in-hospital adverse events is critically needed.

Surgery is widely recognised to improve public health by treatment and alleviation of diseases and injuries. However, it is also associated with great technical complexity and potential hazards. In 2008, the global volume of surgical procedures was estimated to exceed 234.2 million (95% confidence interval [CI], 187.2 to 281.2 million) annually.[5] The global distribution of operating theatres ranges from 14 per 100,000 people in high-income regions to fewer than 2 per 100,000 in low-income regions.[2] The number of in-hospital surgical patients of health trusts in the Western Regional Norwegian Health Authority (WRNHA) has passed 67,000 per year.[6] In-hospital major surgical complications are estimated to occur in 3% to 17% of all admitted patients, with more than half of the complications considered to be preventable.[7, 8] The total number of complications attributable to surgery ranges from 48% to 62%.[9-11] The level of in-hospital mortality rates in European countries varies between 0.44% (95% CI, 0.19 to 1.05) and 6.92% (95% CI, 2.37 to 20.27), and 1.5% in Norway.[12]

1.2 Definitions

1.2.1 Patient Safety

Safety from a patient perspective has been defined as '*freedom from accidental injury*' *(page 18).*[13] Patient safety is, according to the Norwegian Knowledge Centre for Health Services, described as '*a process where no patients should experience harm as a result of the care provided, and the risk of unwanted harm should be mitigated to an acceptable level*'.[14]

1.2.2 Error

Error is defined as '*not completing the planned action with intended outcome or using the wrong plan to achieve its goal, when these failures are not attributed to chance*' (page 26).[15] Not all errors harm patients and cause complications.[13]

1.2.3 Adverse event and complication

In hospitalised patients, an adverse event is defined as '*a patient injury caused by medical management rather than the underlying disease, and that causes disability, prolonged hospital stay or death*'.[16, 17] Complications can be products of adverse events, caused by drugs, wound infections, and technical complications related to negligence, diagnostic mishaps, or management errors.[17] The Norwegian Knowledge Centre for Health Services has described complication as '*an unplanned or not wanted result following an intervention*',[14] including cases that occur due to underlying medical conditions.

1.2.4 What is a checklist?

A checklist is a '*formal list identifying items or a group of elements to be verified and consecutively checked and ticked off, enabling the user to omit human memory flaws'*.[18-20] As in aviation, the most common form of checklist used in surgery is a paper one. There are two primary checklist types and methods used to complete them: the *Do list,* in which a series of tasks are to be performed, much like with a 'cook book'; and the *Challenge-verification-response* method, in which the tasks are performed in advance and the checklist is used to verify that the items on the list have been accomplished.[19] The latter type of checklist and method corresponds with guidelines from the WHO SSSL campaign on how to perform multi-disciplinary team checklists.[21]

1.2.5 Organisational culture and organisational climate

The culture of an organisation is deeply rooted within the history of the organisation. Schein defined it as '*patterns of basic assumptions, developed within a given group and learned to cope with problems of external adaptations and internal integration, considered as valid perceptions and taught to new members of the group*' (page 109-111).[22] The concept of 'culture' is derived from sociology and social anthropology.[23]

Organisational climate is described as '*a surface manifestation of the organisational culture, not necessarily rendering its whole depth, thus found more applicable for research since the late 1960s, and further research can lead to a deeper understanding of the culture as a concept*' (page 109).[22] The concept of 'climate' relates to social psychology.[23]

1.2.6 Safety culture and safety climate

'Safety culture' is a term that began to be employed by the International Atomic Energy Agency (IAEA) after the catastrophic nuclear power plant accident in Chernobyl, Ukraine, in 1986.[24] The IAEA report from Safety Series No. 75-INSAG-4 (page 4 and 5) defines safety culture as '*an assembly of characteristics, values, attitudes, perceptions and pattern of behaviour in organisations and individuals with safety attention as an overriding priority*'.[25] The importance of measuring and monitoring safety culture is emphasised by the IAEA.[25] Safety culture is very similar to the organisational and human factor 'safety perspective' embedded in aviation, which subsequently has also become apparent in healthcare.[13, 19, 25-27]

Safety climate reflects and is a surface manifestation of the safety culture of values, beliefs, and underlying assumptions embodied by an organisation.[28] It is a temporal representation of the underlying safety culture and provides an operational construct for measuring that culture.[29]

1.3 Adverse events and complications

Preventable adverse events are a leading cause of death and injury in healthcare, with an estimated 44,000 to 98,000 medical-error–related deaths per 33.6 million admissions to U.S. hospitals in 1997.[13] These results have prompted great concern and awareness for the need to improve patient safety in modern healthcare.[26] Here, an adverse event is referred to as an unintended patient injury or complication resulting in death, disability, or prolonged in-hospital stay attributable to medical management and not confined to the patients' underlying condition.[10, 13, 16] A complication is referred to as an unplanned or unwanted result of an intervention.[14] In some cases, complications are inevitable due to underlying medical conditions.[14]

A systematic literature review of in-hospital adverse events, which included eight studies and a total of 74,485 patient records, reported that nearly 1 in 10 patients (9.2%; interquartile range [IQR], 4.6% to 12.4%) experience at least one adverse event, with the majority of events occurring in the operating theatre (41%; IQR, 39.5% to 45.8%).[10] Overall, 43.5% (IQR 39.4% to 49.6%) of adverse events are considered to be preventable.[10]

Consider some specific examples of this pattern. In Colorado and Utah, USA, iatrogenic injuries were estimated to occur in 2.9% and 3.7% of patients for medical and surgical hospital admissions, respectively. For this study, 48% of the events were related to surgery;[16, 17, 30] and of these, 48% to 58% were considered to be preventable.[16, 17, 31] In a Canadian study, adverse events were identified in 7.5% (CI 95%, 5.7 to 9.3) of all medical and surgical hospital admissions; and of these, 36.9% (95% CI, 7.8 to 33.8) were judged to be preventable.[9]

A similar pattern has been noted outside of North America. Nine per cent of hospital admissions (medical and surgical) in Denmark, for example, were associated with adverse events, amongst which 40.4% were found to be preventable.[32] Adverse events in this study prolonged hospital stays an average 7.0 days.[32] In a study of hospital admissions of medical and surgical patients in Sweden, adverse events were found in 12.3% (95% CI, 10.8 to 13.7) of patients, of which 70% were considered preventable.[33] In a national report from the Norwegian Knowledge Centre for Health Services, adverse events were identified to occur in 16% (minimum of 3.5% to maximum of 38%) of all hospital-admitted patients.[34]

In Australia, Europe, and the USA, complications and adverse effects related to anaesthesia that caused permanent damage were estimated to be 1 per 170-500 patients, with an overall mortality risk of less than 1 per 100,000 patients.[35] Even though anaesthesia-induced deaths are uncommon, rigorous studies have found minor anaesthesia-induced perioperative events to be quite frequent, occurring in 18% to 22% of patients.[36, 37]

Quality of care and prevention of adverse events are of paramount importance in healthcare and have been issues of global concern for decades. Safety prevention efforts have been integral in guidelines developed from reviews of well-designed scientific studies, and to a certain degree, on strong theoretical rationale in the absence of scientific evidence. Summarising US acute hospital data on infections, the Centers for Disease Control (CDC) produced the ‘Guideline for Prevention of

Surgical Site Infection, 1999'.[38] From 1986 to 1996, a consensus recommendation was derived from SSI surveillance of 593,344 operations. The surveillance revealed that SSIs accounted for 38% of all surgical nosocomial infections.[38] Despite improved operating theatre ventilation, equipment sterilization, surgical techniques, barriers, and availability of antimicrobial prophylaxis, SSIs remained a major contributor to morbidity and mortality amongst in-hospital surgical patients.[38]

In the practice of surgical anaesthesia, quality and safety have also been an important issue for decades.[39-41] The Helsinki Declaration on Patient Safety in Anaesthesiology was developed by the European Board of Anaesthesiologists and the European Society of Anaesthesiology to support improvements in patient safety and quality of care, endorsing use of the WHO SSC.[35, 39]

1.4 Checklists in surgery

The use of checklists has become an important approach amongst an array of strategies designed to combat medical errors in healthcare. Checklists are undertaken as preoperative briefings and debriefings after surgery,[42, 43] Time Out protocols,[44, 45] equipment checklists,[46] and surgical safety checklists.[3, 47] For example, in 108 Michigan hospital intensive care unit (ICUs), a number of different interventions have been used to decrease venous catheter-related bloodstream infections, including a checklist (daily sheet goals) to improve communication, a ventilator-associated pneumonia preventive intervention, and implementation of a patient safety culture programme.[48] The study followed for up to 18 months and found a significant decrease in infections per 1000 catheter days from 2.7 (0.6 to 4.8) at baseline assessment to zero 3-18 months after implementation ($P \leq 0.002$).[48]

In August 1998, the Joint Commission (JC), an independent organisation accrediting and certifying healthcare organisations in the USA, addressed surgical safety issues such as wrong site surgery, operating on the wrong patient, and performing wrong surgical procedures. In 2004, to prevent and mitigate such mishaps (also named ‘never events’), the JC issued a sentinel event alert recommending surgical teams use a preoperative verification process. This process involved marking the skin surface of the operative site and using a ‘Time Out’ protocol to verify the correct patient, site, and procedure.[49] Moreover, this verification was to be performed using active communication techniques.[49] Similarly, the Royal College of Surgeons of England recognised in 2007 that surgeons are obligated to use briefings to ensure safe team behaviour.[50]

At a global event in 2008, the WHO’s Patient Safety Alliance introduced the Surgical Safety Checklist, or WHO SSC.[51] Between October 2007 and September 2008, the WHO checklist was successfully piloted in eight hospitals in eight countries, comprising high and low income status.[1] For non-cardiac surgeries, 3,733 and 3,955 patients were consecutively enrolled, respectively, before and after introduction of the WHO SSC.[3] Complications dropped from 11% at baseline assessment to 7% after introduction of the checklist ($P<0.001$).[3] The rate of death declined from 1.5% to 0.8% ($P=0.003$).[3] This publication has become a seminal document in the surgical checklist literature.

Another important contributor to safety checklists in surgery is the comprehensive Surgical Patient Safety Checklist System (SURPASS), developed in the Netherlands concurrently with the WHO SSC.[52] The multidisciplinary SURPASS is a type of checklist that is completed by different healthcare professionals during each phase of a patient’s surgical pathway in the hospital.[52] This checklist system was developed after an exhaustive review of the literature on surgical errors and adverse events. It was tested in 171 high-risk procedures, in which 593 process deviations were observed. Of these, 96% corresponded to a checklist item.[52] In another study comparing 3,760 patients before and 3,820 patients after implementation of the SURPASS checklist, the proportion of patients with one or more complications decreased from 15.4% to 10.6% ($P<0.001$), and in-hospital mortality decreased from 1.5% (95% CI, 1.2 to 2.0) to 0.8 (95% CI, 0.6 to 1.1), respectively.[47] No changes were observed in control hospitals.

Both the WHO SSC and the SURPASS address overarching and generic patient safety issues in surgery, but some surgical specialties have developed more specific checklists better suited to their surgical clinical setting. One example is neurosurgical checklists that have elements of both the Time Out protocol and the WHO SSC. The Mayo Clinic in Arizona, USA, constructed an intraoperative neurosurgical checklist and have used it for over eight years.[53] It had a compliance of 99.5% during this period, with no incidents of wrong patient, wrong site, or wrong procedure.[53] Another checklist was piloted to detect and remediate procedural errors in movement disorder (deep brain) surgery.[54] In the context of vascular surgery, a preoperative team communication checklist used before patient arrival in the operating theatre was piloted in 18 surgical procedures. This checklist assessed perceived discussions of case-related information, confirmation of details, articulation of concerns, and team building and decision making.[55]

The use of equipment checklists is integral to anaesthesia guidelines.[56] In 2004, the Association of Anaesthetists of Great Britain and Ireland published a guideline for individual preoperative check of anaesthetic equipment.[57] This guideline was updated in 2012. In Norwegian anaesthesia clinical practices, electronic check of anaesthesia machines prior to use was established as the machines transitioned from being mechanical to electronically driven. This has been the case in Haukeland University Hospital since 1999. Since 2008, a locally developed pre-anaesthetic checklist has been used in some surgical sections at Haukeland University Hospital.[58]

Safe surgery has been a prime concern of the Western Regional Norwegian Health Authority (WRNHA–Helse Vest RHF). Thus, in December 2008, its board decided to join the WHO Safe Surgery Saves Lives initiative. The WRNHA mandated and supported a joint quality project from Helse Førde and Helse Bergen named ‘Trygg Kirurgi Vernar Liv’, which aimed to implement the SSC in all hospitals from 2009 to 2011.

1.4.1 Development of the WHO SSC

Challenged by what course to take in order to address the high incidences of adverse events in healthcare, WHO founded the World Alliance for Patient Safety in 2002.[59] The famous exhortation attributed to Hippocrates (470-360 B.C.), 'First, do no harm…', was the aim advanced by the new alliance.[60] With this motivation for patient safety, the alliance launched The Global Patient Safety Challenge programme, whose second campaign was named, 'Safe Surgery Saves Lives'.[1] In 2007, a technical working group was established to evaluate safety in the following surgical areas: *Clean Surgery, Safe Anaesthesia, Safe Surgical Teams, and Measurement.*[61] Evidence gathered in the first Global Patient Safety Challenge, 'Clean Care is Safer Care', showed that nosocomial infections were highly associated with SSIs and especially caused by invasive devices such as central lines, urinary catheters, and ventilators. Amongst adult patients in developed countries, SSIs were reported to occur in 1.2 to 23.6 per 100 surgical procedures and with a pooled incidence of 11.8%.[62] In a recent published systematic review, SSIs were found to be the leading cause of hospital infections, resulting in 5.6 infections per 100 surgical procedures.[63]

In their discussions of *clean surgery* and prevention of infections, the technical working group concurred, leading to the development of a SSI checklist. This checklist comprises employment of antimicrobial prophylaxis, use of aseptic techniques, decontamination of equipment, and proper tissue handling.[61] For *safe anaesthesia,* the group recommended that standards of care established by European anaesthetic societies and the World Federation of Societies of Anaesthesia should be revised and the revision circulated for broader international use.[61] Oximetry was recommended to be included as the standard of care.[61]

The topic of *safe surgical teams* was addressed by improving teamwork and communication. Communication failure in operating teams is a major contributor to medical mishaps and adverse events,[13] not only because information is sometimes inadequately transmitted but also because of hierarchical differences in communication styles; concerns amongst team members about upward social influence, interprofessional, and interpersonal power struggles; and conflicts.[64] Ineffective team communication occurs in 30% of team exchanges, and can be categorised in terms of poor timing, inaccurate information, unresolved issues, and exclusion of key individuals.[65] To ensure *safe surgical teams,* the technical working group suggested that a checklist would act as a tool to facilitate the team process, improve communication, and develop a patient safety culture.[61]

At the time the working group convened, *measurement* studies on the quality of surgeries worldwide was scarce and hampered by difficulties in collecting data, and few tools were available.[61] Thus, a set of suggestions was advanced to measure morbidity, mortality, surgical performance, and safety culture.[61, 66] During the technical working group's first meeting in Geneva in 2007, the concept of a common checklist for promoting safe surgical practices and teamwork globally was conceived.[61] Led by Dr. Atul Gawande, the 'Safe Surgery Saves Lives' campaign was introduced in 2008 to promote the use of the WHO SSC globally.[51]

WHO SSC development was driven by evidence accumulated from aviation experiences, checklist literature, and expert consensus. The development process was scheduled into five steps: *'content and format, timing, trial and feedback, formal testing and evaluation, and local modification'*.[20] Weiser and colleagues illustrated the development process in Figure 1.[20]

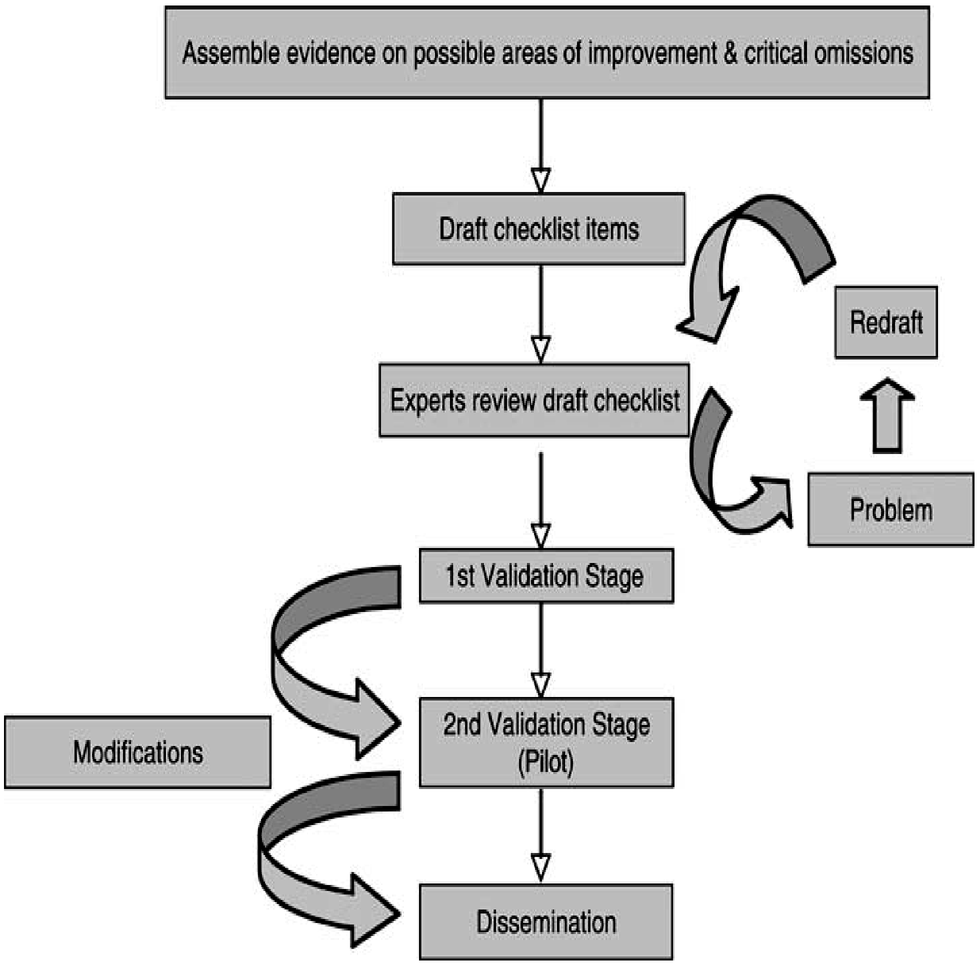


Figure 1 Development process of the WHO SSC

Source: Weiser TG et al. Int J Qual Health Care 2010;22:365-370. Reprinted with license (no. 3277510307283) from Oxford University Press.

1.4.2 Objectives

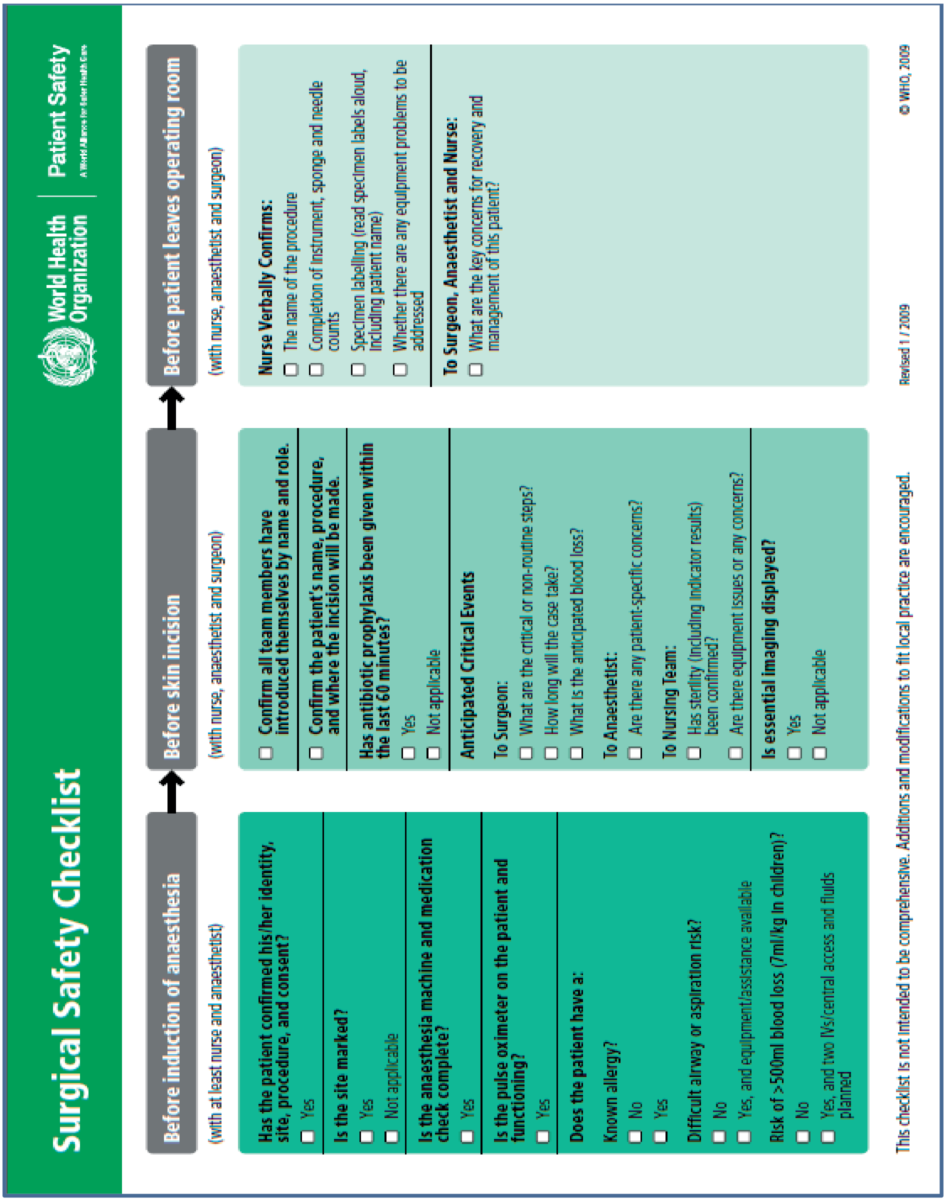
The WHO SSC development process had 10 objectives. Using the WHO SSC, the healthcare team will:

1) Operate on the correct patient at the correct site
2) Use methods known to prevent harm from the administration of anaesthetics, while protecting the patient from pain
3) Recognise and effectively prepare for life-threatening loss of airway or respiratory function
4) Recognise and effectively prepare for risk of high blood loss
5) Avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk
6) Consistently use methods known to minimise the risk for surgical site infection
7) Prevent inadvertent retention of instruments and sponges in surgical wounds
8) Secure and accurately identify all surgical specimens
9) Effectively communicate and exchange critical information for the safe conduct of the operation
10) Hospitals and public health systems to establish routine surveillance of surgical capacity, volume, and results

Source: WHO SSC Guidelines 2009, page 10.[67]

1.4.3 Checklist content

The checklist consists of 19 items, which are verified and completed at three critical steps of the surgical procedure: before the induction of anaesthesia, before the start of surgery, and before the patient leaves the operating theatre for recovery.


Surgical Safety Checklist

World Health Organization | Patient Safety — A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

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

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

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

Revised 1 / 2009

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Figure 2 WHO Surgical Safety Checklist 2009.[1]

Table 1 Basic elements of the WHO Surgical Safety Checklist[1]

Sign In (Before induction of anaesthesia)
Patient confirms identity, surgical site, and procedure, and consents
Site marked
Anaesthesia and medication checked
Monitoring equipment functioning and placed on patient
Prepared for difficult airway, aspiration, allergies, and high blood loss (intravenous access), and assistance available
Time Out (Before skin incision)
Team members introduce themselves by name and roles
The team confirm patient name, site, and procedure
Antibiotic prophylaxis administered if indicated
Surgeon reviews and explains patient risks, procedural risks, and steps
Anaesthesia risk review
Operating theatre nurse comments on sterility and availability of equipment
Essential images displayed
Sign Out (Before patient leaves theatre)
Procedure actually performed and correctly recorded
Instrument and sponge count completed and correct
Specimen labelled correctly
Equipment failure or issues to address
Review of key concerns and information handover to postoperative recovery

1.5 Safety culture and safety climate

In high-risk industries such as aviation, nuclear energy production, and military operations, assessing safety has been a central focus for many years.[27] In healthcare, the focus on safety paradigmatically changed after summary reports appeared from the US Institute of Medicine: 'To Err is Human' and 'Crossing the Quality Chasm'.[13, 26] Management of errors was then considered within a systems perspective, resulting in a shift in view of how to understand and approach errors in healthcare. The aim of this shift was to change from a culture in which blame/shame was of primary concern to one in which safety became a focus, a culture that promotes continuous learning for healthcare personnel and organisations.[13, 26]

Safety culture is considered to be part of the organisational culture.[68] In 1990, Schein categorised the concept of organisational culture into three levels: (a) basic underlying assumptions, (b) values and attitudes, and (c) observable artefacts.[22] The basic assumptions of the employers in an organisation occupy the core of the culture and are considered to be robust over time.[68] On the other hand, the safety climate can be understood to be a surface construct of the underlying culture.[28] Safety culture and safety climate are closely related terms, often used interchangeably in the literature.[23] Safety climate is used to describe workers' current state of perceptions, attitudes, and beliefs about safety and risk, while safety culture is considered to be a more enduring trait, reflecting fundamental safety values, norms, and assumptions.[23] In this PhD thesis, the concepts of safety culture and safety climate are used as overlapping and highly related concepts. There is an underlying presumption that positive changes in hospital workers' perceptions of safety culture or safety climate are associated with fewer medical errors and improved patient outcome.[69] Targeting practice and interventions to enhance patient safety climate is also considered to be a key strategy for improving patient safety and outcomes.[26, 70]

In the ensuing years after publication the US Institute of Medicine reports,[13, 26] safety culture and safety climate questionnaires were further developed and refined for use in healthcare. However, there is no consensus about which safety dimensions best capture the concept of safety climate.[29, 71, 72] In two systematic reviews of the most commonly used surveys measuring patient safety climate, nine and 12 surveys (see selection in Table 2)[29, 71] were found to cover essential safety dimensions such as leadership, safety systems, risk perceptions, policies and procedures, job demands, safety attitudes, staffing, teamwork, communication and reporting, and organisational factors. Colla and colleagues concluded that the surveys varied considerably in terms of psychometric properties and that few studies reported relationship to patient outcomes.[71]

The surveys' contribution to scientific knowledge on safety culture and safety climate depend on their psychometric qualities.[29] The Safety Attitudes Questionnaire, which was originally used in evaluating aviation safety, had sound psychometric properties, and was the only survey set validated for patient outcomes such as length of stay, medication errors, ventilator-associated pneumonia, and bloodstream infections.[73] Flin and colleagues found one study that comprehensively described the development and structure of the Hospital Survey on Patient Safety (HSOPS) for use in hospital settings.[29] In general, perceptions of safety culture/climate in hospitals vary between departments and professions.[69] Safety climate perceptions may also vary between hospitals[69] and within organisations and professions.[74]

In order to maximise response rates for safety climate surveys from hospital staff, questionnaires need to be simple and made available both on paper and electronically.[75] Safety climate surveys can be used to produce a precise picture of organisations' safety culture, to measure change after safety intervention programmes have been implemented, and to conduct internal or external benchmarking.[76]

Using structural equation modelling, Neal et al. investigated the validity of certain theoretical constructs of organisational climate with regard to safety climate and individual behaviour.[77] In an empirical test of their model, they discovered that the safety climate effects on actual safety performance were partially mediated by knowledge and motivation.[77] This finding has important implications, as it suggests that interventions aimed at improving safety behaviour will be more effective if education/knowledge are provided prior to any safety implementation and if healthcare professionals are given motivation to use this education/knowledge. It is also clear that any interventions need to be carried out in a positive organisational context in order to be successful.

Table 2 Safety climate surveys used in healthcare

CSS	Culture of Safety Survey	Neal et al.[77]
HSOPS	Hospital Survey on Patient Safety	Sorra & Nieva[78]
MSSA	Medication Self-Assessment	ISPM[79]
OMRAQ	Adjusted Operating Team Resource Management Survey	Itoh et al.[80]
PSCHO	Patient Safety Culture in Healthcare Organizations	Gaba et al.[81]
SAQ	Safety Attitudes Questionnaire	Sexton et al.[73, 82]
SLOAPS	Strategies for Leadership: An Organizational Approach to Patient Safety	Pronovost et al.[83]
Stanford/PSCI	Stanford/Patient Safety Center for Inquiry	Singer et al.[84]
ORMAQ	Operating Room Attitudes Questionnaire (from SAQ)	Flin et al.[85]

Safety climate is considered to reflect safety culture in the sense that safety culture at some level is captured in safety climate surveys. Possible relationships between the two concepts are pictured by an overall organisation culture,[68] with safety culture being part of the organisational culture. In addition to safety climate, knowledge and motivation also influence safety behaviour, compliance, and participation.[77]

1.5.1 Management

To improve patient safety culture of hospitals and to promote a non-punitive culture, leadership and management are encouraged to actively support and reward the reporting of adverse events and near misses.[76] One prospectively designed study found that executive leadership provided mediating and moderating effects on safety behaviour of group members.[86] Another study employing a cluster randomised controlled trial (RCT) design investigated the impact of leadership walk rounds on patient safety climate scores as reported by health workers involved.[87] Although the walk rounds did not affect safety climate scores of healthcare providers, in general, nurses who participated in the leadership walk rounds reported more positively and had higher safety climate scores than the control group (P=0.02). A recent PhD thesis (Deilkaas 2010, page 43) reported that significant variation exists in the mean perceptions of safety climate amongst staff, with managers (nurses) having a more positive perception than nurses (P=0.008) and junior physicians (P<0.001).[88] Assessment and monitoring of workers' perception of support by management with regard to patient safety is measured in safety climate surveys.[78, 82]

1.5.2 Event reporting

Openness and willingness to report errors are critical in order to accomplish true learning within organisations. Reporting major events causing patient harm and death is mandatory, yet this activity represents merely the 'tip' of the iceberg of the overall picture of healthcare errors.[13] Some errors do not actually cause patient harm but still should be considered incidents because of their potential for causing harm. Assessing these end-evaluating incidents as near misses is important for improving organisational learning. Such incidents actually represent the majority of events.[13] Reporting near misses is also more likely to occur, since there are fewer barriers and limited liabilities in reporting them in the first place. Secondly, they contribute to the overall picture of error patterns to be captured and used to enforce preventive efforts.[89, 90]

For example, in a survey of surgical team members' (N=427) perception of near misses and attitudes towards a Time Out protocol, we found that very high numbers of operating theatre personnel experienced near misses, specifically, those involving potential errors in correct patient (38%), correct site (81%), and correct procedures (60%).[91] The survey was conducted prior to WHO SSC implementation in Haukeland University Hospital in February 2009. A vast majority (96% [263/275]) believed that a Time Out protocol could have aided in preventing incorrect surgery, and 91% supported implementation of a protocol. Reports of errors that cause both harm or reports of near misses are dimensions included in safety climate surveys.[29]

1.5.3 Communication and information feedback

Communication and information feedback have been identified as important dimensions in safety climate surveys,[29, 71] and are recognised as important areas for producing improvements in healthcare[13] and in surgery.[60, 92] Feedback on errors reported include information features transmitted to both management and employers. This occurs in an organisational learning perspective regarding errors as well as the instant information feedback on errors communicated in multidisciplinary teams (i.e., operating theatre teams). Ineffectively communication increase cognitive load, interrupt routines, and cause tension in the operating theatre.[65] Interventions employing a checklist prototype aimed to promote interprofessional communication in the operating theatre seem to enhance information exchange and team cohesion.[55] Furthermore, standardising communication through the use of both the operating theatre WHO SSC and the more comprehensive SURPASS checklist system—starting at hospital admission to discharge—improve patient outcomes and prevent adverse events.[3, 47, 93]

1.5.4 Teamwork

Teamwork refers to human relations and communication amongst different professions within a given timeframe. Operating theatre team communication and teamwork are enhanced by implementing the WHO SSC.[94] Interdisciplinary operating team briefings, aided by the use of checklists, reduces communication failures and promotes collaborative team communication.[95] It also improves the timeliness of administering antimicrobial prophylaxis in surgery.[43] Teamwork within and between units and a positive teamwork climate are dimensions measured in safety climate surveys, as a part of an organisations' safety culture.[78, 82]

1.5.5 Handover and transition

Patient information handover and transition between healthcare personnel are important in surgery and take place several times during perioperative care. Communication breakdown during handovers is a leading cause of adverse events and is associated with increased death.[96, 97] A systematic review of information transfer and communication in surgery found that information handover failures are common and are distributed across the whole continuum of surgical care.[98] A review of research on patient handovers recommended systematic approaches to establish valid measures of handover quality and safety.[92]

Although the WHO SSC captures critical information for postoperative care in its Sign Out section, which is handed over to the post-anaesthetic care unit (PACU),[1] it does not contain a formal handover protocol. Handover and transition are also dimensions of safety culture measured in safety climate surveys.[72, 76]

1.6 Systematic review of checklist and safety culture

Inadequate communication and poor teamwork may result in errors and adverse events in surgery.[45, 65, 96] Driven by safety concerns noted in the reports from the US Institute of Medicine,[13, 26] and learning from error-reducing strategies in aviation industry,[19] the use of preoperative briefings[45, 99] and surgical safety checklists have increased both in clinical practice and in research.[1, 3, 47, 100, 101]

A preoperative briefing is a team meeting during which information is shared before surgery. The goals are to prevent wrong patient, wrong site, and wrong procedure errors.[99] In this way, it shares features with surgical safety checklists that are used during surgery. Following the increased use of surgical safety checklists, considerable research has been performed to determine how checklist use affects communication,[102-107] teamwork,[95, 102, 108-110] safety processes like timeliness of thrombotic and antibiotic prophylaxis,[3, 111-113] implementation,[114-116] compliance,[107, 113, 117, 118] postoperative outcomes,[3, 47, 119-126] and safety climate.[108, 127] Other patient safety interventions intended to reduce errors like the Safer Patient Initiative,[128-130] management safety walk rounds,[87, 131] and relation to morbidity and mortality[132-134] have been assessed by safety climate instruments.

In this PhD project, a systematic review of the literature was performed in order to assess the state of scientific knowledge on how use of the WHO SSC primarily affects (1) safety culture or climate, and (2) morbidity and mortality up to 30 days after surgery.

The literature search was built using search strings previously employed by the Norwegian Knowledge Centre for Health Services.[4] A research librarian at the University of Bergen assisted in the literature search. Databases searched included PubMed, Embase, Web of Science, Cochrane Central, and Database of Abstracts of Reviews of Effects (DARE). The search strategy combined MeSH terms and text terms like World Health Organisation, Surgical Safety Checklist; Safety Management; Safety Culture; Safety Climate (for a full description see Table A1 in the Appendices 9.1). The EndNote reference management software package (Carlsbad, CA, USA) was used to organise retrieved data.

The review comprised titles, abstracts, editorials/letters, and original articles of qualitative and quantitative design, reviews, and systematic reviews. Study participants in the reviewed literature included in-hospital healthcare personnel and both elective and emergency patients undergoing surgery. Operating theatre personnel were included in the safety culture or safety climate studies. Studies that did not use effect designs (randomised, cohort, before-after) were excluded. Primary interventions that were reviewed were effect studies on surgical safety checklists, with impact on safety culture, morbidity, and mortality. The studies reviewed were described as narratives.

The last search for this project was carried out on September 19, 2013.[i] The searches resulted in 2,984 titles and abstracts, of which 395 were determined to be relevant. Thus, the full text of the latter was read. The overall scheme of the literature search is illustrated in Figure 4, with a flow diagram. A total of 31 papers were included in the final review; 364 papers were excluded because they did not assess primary outcomes effects.

Of the identified papers, 14 were systematic reviews. Five of these reviews studied how using a surgical safety checklist affects morbidity and mortality;[135-139] six assessed teamwork, communication, and handover;[96, 140-144] two reviewed implementation;[145, 146] and one assessed equipment failure.[46] An additional 11 studies were found that studied how using checklists affects morbidity and mortality, and six studies measured the effects of preoperative briefings on safety climate (Table 3).

[i]An updated search was conducted the 5th of February 2014. The search identified two additional systematic reviews of WHO SSC effects on morbidity and mortality.[188,189]

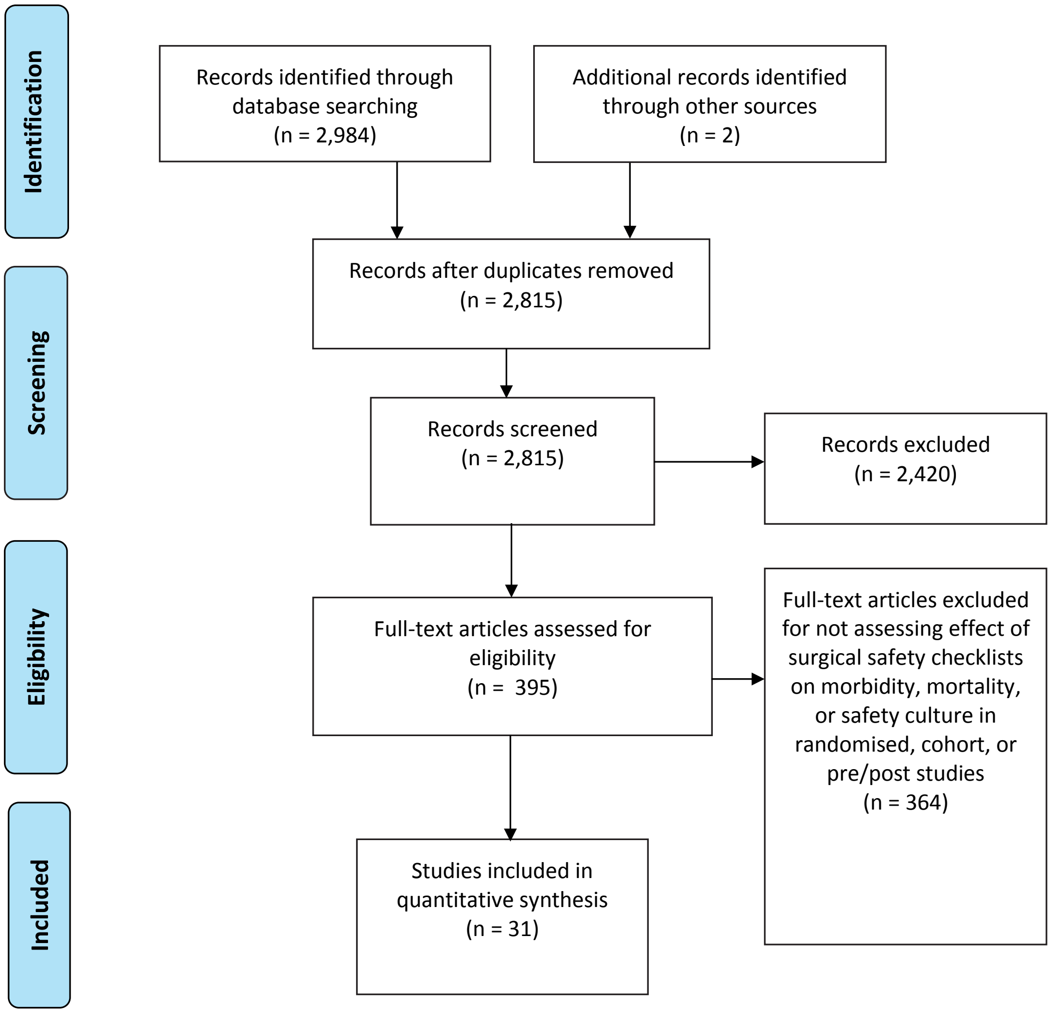

Figure 4 Prisma flow diagram of systematic literature review on surgical safety checklist effects on safety culture, morbidity, and mortality

Modified from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Plos Med, 2009; 6(6):e100097.

All studies examining effects on morbidity and mortality were conducted with pre- and post-intervention designs without controls. Exceptions were the studies of De Vries et al.,[47] who used control hospitals, and Van Klei et al.[148] and Bliss et al.,[120] who used historical cases at baseline for comparison. Eight studies were carried out in hospital settings in high-economic-status countries: the Netherlands (n=2), England (n=2), Switzerland (n=1), Canada (n=1), USA (n=2). One study was performed in Iran[126] and one in a hospital with severely limited resources in Moldova.[121] The two papers from the original WHO study included hospitals in eight countries with varying economic status.[3, 123]

Four WHO SSC studies that were conducted in high-income countries found that SSC implementation did not significantly improve overall complications,[122, 124, 125, 147] length of stay,[147] or mortality.[122, 124] Two WHO SSC studies that used historical baseline cases as controls and that were performed in high-income countries found significant decreases in morbidity[120] and risk-adjusted mortality.[148] Studies conducted in countries with diverse economic statuses reported significant decreases in both morbidity and mortality.[3, 121, 123] The comprehensive study employing the SURPASS checklist system and that used control hospitals in the Netherlands showed significant decreases in both morbidity and mortality, but not in length of stay.[47]

All studies examining how surgical briefings or surgical safety checklists affect patient safety culture/climate were conducted using longitudinal or pre- and post-intervention designs without controls. One study on the use of the WHO SSC reported weak or moderate changes for safety climate items (mean scores from 3.91 to 4.01, P=0.0127), but found a significant correlation with reduced complications (r=0.71).[108]

Table 3 Summary of a systematic literature review on the effects of surgical safety checklists on morbidity, mortality, and safety climate

Paper outcome: morbidity and/or mortality

Authors	Design	Aim	Population/Setting	Results
Askarian et al., 2011[126]	Pre- and post-study design	To encourage use of WHO SSC and measure effect on surgical outcomes.	144 patients before and 150 patients after WHO SSC intervention, in a 374-bed referral, educational hospital in Shiraz, Iran.	Incidence of complications was 22.9% before and 10% after (P=0.03).
Bliss et al., 2011[120]	Cohort with historical controls	To increase safety environment by adopting aviation industry teamwork principles with WHO SSC in the operating room.	2,079 historical patient cases, 246 cases without checklist, 73 cases with checklist. 600-bed tertiary hospital in USA.	WHO SSC compliance was 97.3%. 30-day morbidity decreased from 23.6% for historic cases and 15.9% in cases with only team training to 8.2% in cases with checklist use (P<0.001).
De Vries et al., 2010[47]	Pre- and post-study design with control hospitals	Evaluate effect of the Surgical Patient Safety Systems (SURPASS) checklist on morbidity and mortality.	3,760 patients before and 3,820 after checklist implementation; 2,592 vs. 2,664 in control hospitals. Six intervention and five control hospitals in the Netherlands.	Morbidity decreased from 15.4% to 10.4%, P<0.001. Adjusted for co-variables (regression analysis) rate ratio decrease was 9.7 (95% CI, 7.8 to 11.5). Mortality decreased from 1.5% (95% CI, 1.2 to 2.0) to 0.8% (95% CI, 0.6 to 1.1); P=0.003. Adjusted for co-variables (regression analysis) corrected rate ratio decrease was 0.54 (95% CI, 0.33 to 0.88). LOS decreased from 9.1 to 8.5 days, P=0.15. No change in control hospitals.
Haynes et al., 2009[3]	Pre- and post-study design	To reduce complications and deaths associated with surgery after implementing the WHO SSC.	3,733 patients before and 3,955 after implementation of the WHO SSC. 8 hospitals from 8 countries had various economic statuses.	Complications were reduced from 11% to 7%, P<0.001. Rate of death during hospitalisation (30 days after surgery) was reduced from 1.5% to 0.8%, P=0.003. Improved safety process measures improved P<0.001.

Authors	Design	Aim	Population/Setting	Results
Kwok et al., 2013[121]	Pre- and post-study design	To reduce complications in a severely resource-limited hospital by introducing the WHO SSC and pulse oximetry.	2,145 before and 2,212 after WHO SSC and pulse oximetry implementation. Government, university-affiliated, general, and trauma hospitals in Moldova.	Overall complications decreased from 21.5% to 8.8%, P<0.001. Safety processes increased from 0.0% to 66.9%. Hypoxic episodes lasting 2 minutes or longer per 100 hours of oximetry was reduced from 11.5 to 6.4 P<0.001.
Lübbeke et al., 2013[122]	Pre- and post-study design	To evaluate the effectiveness of the WHO SSC in a high-standard care environment on unplanned reoperations or admission to ICUs and in-hospital deaths within 30 days.	609 patients at baseline and 1,818 after (552, 558, and 708 in three periods). University hospital in Switzerland.	Unplanned return to operating room in 45/609 (7.4%) vs. 109/1818 (6.0%); reoperation for SSI in 18/609 (3.0%) vs. 109/1818 (1.7%); in-hospital death in 26 (4.3%) vs. 108/1818 (5.9%). Checklist prevented one reoperation for SSI in 77 procedures. No significant changes were found.
Morgan et al., 2013[147]	Pre- and post-study design	To evaluate whether postoperative pain, nausea/vomiting, LOS, and SAQ improved after WHO SSC implementation.	180 patients before and 195 after implementation. Ambulatory surgical setting in Canada.	Compliance on briefings 99.49%, timeout 97.95%, and debrief 96.92%. Median difference in pain scores was 0.5 (97.5% CI, 0-1; P=0.13). Median difference in post-discharge nausea/vomiting was -8.4% (97.5% CI, -17.9-1.1; P=0.06). LOS: hours median 3.1 [2.4-3.9] to 3.2 [2.6-3.9]; P=0.38. Safety attitudes were not significantly changed.

Authors	Design	Aim	Population/Setting	Results
Sewell et al., 2010[124]	Pre- and post-study design	To assess compliance, early complications, death, and staff perceptions after implementing WHO SSC.	480 patients before and 485 patients after SSC implementation. 100 operating room staff in trauma and orthopaedic hospital in UK.	Compliance changed from 7.9% to 96.9% (RR 12.2; 95% CI, 9.0-16.6). Early complications and mortality were not significantly changed, (RR 0.89; 95% CI, 0.58-1.37 and RR 0.88; 95% CI, 0.34-2.26, respectively); 77% of staff believed that the SSC improved team communication.
Tillman et al., 2013[125]	Pre- and post-study design	To determine whether WHO SSC improves patient outcomes for SSIs and care.	10,126 patients before and 9,676 patients after SSC implementation. 636-bed tertiary hospital in Texas, USA.	Antibiotic timing improved from 92.7% to 95.4%; $P<0.05$. Temperature management: 93.8% vs. 97.7%; $P<0.001$. Patients with postoperative temperature <98.6ºF dropped from 9.7% to 6.9%; $P<0.001$. Overall, no significant change in SSI rates, except for colorectal surgery subgroup: 24.1% to 11.5%; $P<0.05$.
Van Klei et al., 2012[148]	Cohort study with historical baseline cases	Evaluate effect of implementation of WHO SSC on mortality and compliance.	25,513 adult patients before and 11,151 after WHO SSC. A tertiary university hospital in the Netherlands.	After SSC implementation, mortality was reduced from 3.13% to 2.85%; P=0.19. Adjusted for baseline differences, mortality decreased significantly (odds ratio (OR) 0.85; 95% CI, 0.73-0.98). Strongly related to SSI compliance (all parts used) (OR 0.44; 95% CI, 0.28-0.70).
Weiser et al., 2010[123]	Pre- and post-study design	Assess whether WHO SSC reduces deaths and complications and improves compliance to basic standards of care in urgent surgical cases.	842 patients before and 908 patients after WHO SSC implementation. 8 hospitals in 8 countries of various economic statuses of the WHO trial (Haynes et al., 2009).	Complications decreased from 18.4% to 11.7%; P=0.0001. Death rates were 3.7% at baseline and 1.4% after; P=0.0067. Safety process steps improved from 18.6% to 50.7%; $P<0.0001$.

Paper outcome: patient safety culture/safety climate

Authors	Design	Aim	Population/Setting	Results
Allard et al., 2011[127]	Longitudinal study using three SAQ surveys	Evaluating relation between pre-surgical briefings and safety climate.	2003: 221 of 302 (73%) 2004: 224 of 332 (68%) 2006: 152 of 289 (53%) Operating theatre (OT) staff in two UK hospitals.	A positive correlation between the statement 'briefings are common in OT' and reports of a better 'safety climate' in OT practitioners (r=0.4).
Bleakley et al., 2012[149]	Longitudinal study using three SAQs over four years	Test whether a complex educational intervention (human factors, error report system, briefing and debriefing across surgical teams) improves attitudes and teamwork.	SAQ 1: 221/303 (73%) SAQ 2: 223/328 (68%) SAQ 3: 152/287 (53%) A UK Trust.	Practitioner's perception of 'teamwork climate' improved significantly and was sustained over time.
DeFontes et al., 2004[42]	Pre- and post-study design	To improve communication, collaboration, teamwork, and situational awareness with a team safety briefing using SAQ (2002/2003).	59 operating theatre staff and 60 surgeons in a US medical centre.	Teamwork climate perceptions improved from 'good' to 'outstanding'.

Authors	Design	Aim	Population/Setting	Results
Haynes et al., 2010[108]	Pre- and post-study design	To assess the relationship between changes in attitudes and changes in postoperative outcomes after WHO SSC implementation.	281 clinicians before and 257 responded after WHO SSC intervention in 8 hospitals in a WHO SSC trial.	Mean modified SAQ (6 items) score was 3.91 at baseline and 4.01 after (P=0.0127). Improvement of mean SAQ score correlated with a reduction in postoperative complication rate (r=0.71).
Makary et al., 2006[150]	Pre- and post-study design	To evaluate the impact of OT briefings on coordination of care and risk for wrong-site surgery (May 2005 to July 2005).	306 of 360 responded at baseline, and 116 of 154 after intervention. Academic medical centre in USA.	The briefing intervention significantly improved 5 of 6 modified SAQ items and reduced risk of wrong-site surgery.
Timmel al., 2010[151]	Pre- and post-study design	To improve patient safety culture with a comprehensive unit-based safety program (CUSP).	One surgical 18-bed unit in 2006, 2007, and 2008 Johns Hopkins Hospital, Baltimore, USA.	SAQ dimensions of safety climate, teamwork climate, and nurses' turnover rates were improved after implementing CUSP.

Abbreviations: SSC = Surgical Safety Checklist; SSI = Surgical Site Infection; CI = Confidence Interval; RR = Relative Risk; LOS = Length of Stay; OT = Operating Theatre; OR = Odds Ratio; CUSP = comprehensive unit-based safety program

Haynes and colleagues hypothesised that the mechanisms behind the SSC's effects on morbidity and mortality were related to a change in safety culture.[3] Does change in safety culture have to be achieved prior to implementation of a checklist or any patient safety intervention in order to make such interventions successful? Or do possible changes in safety culture come as a result of improved safety behaviour caused by the patient safety intervention itself?

Overall, the reviewed studies were heterogeneous with regard to study sites, countries, designs, and implementation methods applied. The main conclusions of the systematic reviews were that use of surgical safety checklists prevents errors, complications, and death, and improves safety culture. However, the recently published WHO SSC studies performed in high-income countries challenge these conclusions, as they failed to observe any significant reduction in morbidity and mortality.[122, 124, 125, 147]

The Norwegian Knowledge Centre for Health Services critically reviewed the Haynes study on use of the WHO SSC using group grades of evidence (GRADE) levels.[4] They concluded that the effect estimates of the Haynes study were of very low quality and had high uncertainty. They also rated the Haynes study to be medium quality in terms of how it was conducted. Two systematic reviews reported later that the published WHO SSC effect studies on morbidity and mortality generated high to moderate risk of bias.[137, 138]

In conclusion, new high-quality studies and RCTs are warranted in order to increase the level of evidence.

2. OBJECTIVES

The overall objective for this PhD project was to investigate the impact of the WHO SSC on safety culture, morbidity, and mortality. We hypothesised that a change in safety culture is a key mechanism through which checklist use produces positive effects on morbidity and mortality. The project included three studies with the specific aims listed below. These three studies were submitted for publication as three separate papers.

Study 1

This study determined the psychometric properties of the survey instrument HSOPS and placed the results in a national and an international clinical setting. Our aim was to validate the HSOPS in a surgical environment—and (2) to compare results from its use on the safety culture in healthcare personnel in different countries. The findings of this study were reported in Paper 1.

Study 2

This study determined the impact of using the WHO SSC on safety culture perceptions in operating theatre personnel using a prospective controlled cohort study design. Our aim was to determine—using the validated HSOPS—whether use of the WHO SSC enhances safety culture. The findings of this study were reported in Paper 2.

Study 3

This study determined whether using the WHO SSC positively affects complications, length of stay, and death up to 30 days postoperative using a stepped-wedge cohort RCT design. Our aim was to test the hypothesis that it will have a positive impact, reducing morbidity, mortality, and length of stay. The findings of this study were reported in Paper 3.

3. MATERIALS AND METHODS

3.1 Study design

Data from both healthcare personnel and patients contribute to the studies conducted for this thesis. Data on the caregivers' perceptions of safety climate are presented and discussed in Paper 1 and Paper 2. Patient data on complications and death are presented and discussed in Paper 3.

In study 1, a cross-sectional survey was conducted to assess the psychometric properties of the instrument in a surgical clinical setting and to place the results into a landscape across nations. In study 2, a controlled cohort study was performed to determine the impact of the SSC on safety culture. Study 3 was designed as a stepped-wedge cluster RCT to investigate the effects of the WHO SSC on morbidity and mortality.

3.2 Ethics

The studies proposed for this PhD project were reviewed by the Regional Committee for Medical and Health Research Ethics (Ref: 2009/561), which concluded that use of routinely collected, anonymous data represents clinical service improvement and therefore does not require patient consent or further committee approval. Hence, the study was presented to the hospital privacy ombudsman (Ref: 2010/413) and approved by local managers. Operating theatre personnel consented by responding to the surveys.

3.3 Clinical settings

The two surveys used in studies 1 and 2 were conducted at Haukeland University Hospital, and included frontline hospital personnel such as surgeons, anaesthetists, operating theatre nurses, nurse anaesthetists, and ancillary operating theatre personnel. Study 3, the investigation examining the effect of the WHO SSC on morbidity and mortality, was carried out in two hospitals in the Western Regional Norwegian Health Authorities (Helse Vest RHF): Førde Central Hospital, a 300-bed regional central community hospital; and Haukeland University Hospital, a 1,100-bed tertiary teaching hospital. In 2011, the annual surgical volume of the two hospitals was 9,733 and 28,578 (including outpatients), respectively.[6]

3.4 Participants

Participants in study 1 (N=349) and study 2 (N=292) included surgeons, anaesthesia personnel, operating theatre nurses, and ancillary personnel. Surgeons were from 10 surgical departments at Haukeland University Hospital: ear, nose, and throat, and maxillofacial; plastic; endocrine; urological; gastrointestinal; vascular; obstetric and gynaecological; orthopaedic; neuro; and cardiothoracic surgery. Anaesthesia personnel (physicians and nurses), operating theatre nurses, and ancillary personnel were all from the department of anaesthesia and intensive care.

In study 2, assessments were done over time. The intervention group consisted of surgeons, anaesthetists, nurse anaesthetists, and operating theatre nurses in orthopaedic, neuro, and cardiothoracic surgery. This group was assessed pre-intervention (N=146) and post-intervention (N=140). Participants in the control group included operating theatre personnel associated with ear, nose, and throat, and maxillofacial; plastic; endocrine; urological; gastrointestinal; vascular; and obstetric and gynaecological surgical specialties. This group was assessed at the same pre-intervention (N=203) and post-intervention (N=152) times as the intervention group.

In study 3, participants included patients from 5,295 surgical procedures in orthopaedic, cardiothoracic, neuro, urology, and general surgery in two hospitals. Patients from all age groups and both genders were included, as well as ones undergoing elective or emergency surgery; and a variety of comorbidities were included. However, surgical procedures that did not use the SSC (i.e., gamma knife treatment or donor surgery), and patients with incomplete data were excluded; further details are given in the CONSORT flow diagram in Figure 5.

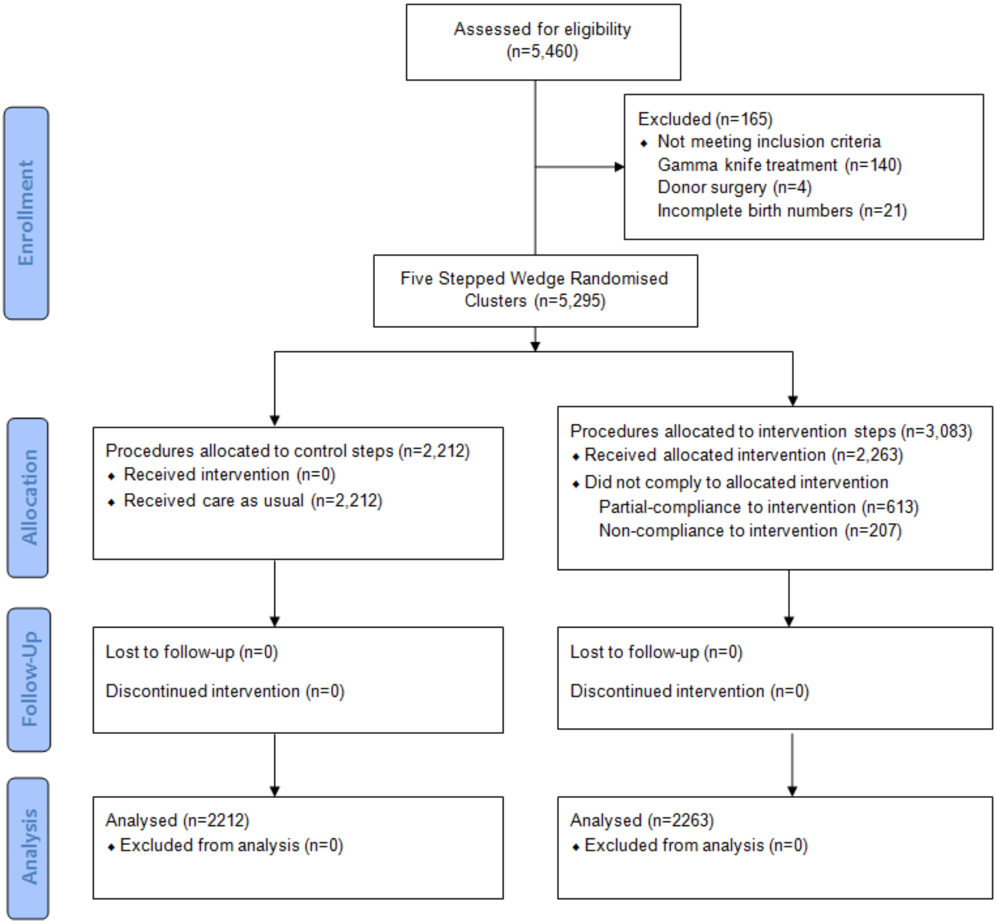

Figure 5 Flow diagram of the progress in the stepped-wedge cluster RCT

Based on: Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. Ann Intern Med 2001;134:657-62. Avaliable at: http://www.consort-statement.org/consort-statement/references0/#ref52.

3.5 Survey instrument HSOPS

Norwegian versions of the validated survey instruments for this study were the SAQ[152] and the HSOPS.[153, 154] The HSOPS was preferred, as it provides measures covering a broad concept of hospital safety culture. It also affords us the opportunity to compare results from a HSOPS pilot test conducted in another WRNHA university hospital.[72] In all, 1,919 hospital healthcare personnel were surveyed in 2006 (55% response rate) and 1,709 were re-surveyed in 2008 (49% response rate).[72] The US HSOPS comparative database provided the possibility for comparing our HSOPS results with those from other countries.[155]

3.5.1 Development of HSOPS

HSOPS was developed by Sorra and Nieva to assess the culture of patient safety in hospitals; its development was funded by the US Agency for Healthcare Research and Quality (AHRQ).[78] The developers reviewed literature on safety, accidents, medical error, error reporting, safety, and organisational culture and climate. In-depth interviews and telephone interviews of hospital staff were conducted before and after pre-test. The survey was pilot tested on 1,400 hospital employees from 21 hospitals in the USA in 2003. To investigate the structural concept and dimensionality of the survey itself, an explanatory and confirmatory factor analysis was performed. The HSOPS items were scored on a 5-point Likert scale using response scales of agreement (‘Strongly disagree’ to ‘Strongly agree’) or frequency (‘Never’ to ‘Always’). The explanatory factor analysis resulted in 42 items. Fourteen factors had eigenvalues higher than or equal to 1.0 and explained 64.5% of the total variance, with almost all items loading on only one factor ($\geq$0.40).[78]

The HSOPS is structured into 12 factors (each containing three to four items): (1) overall perceptions of safety; (2) frequency of events reported; (3) supervisors’ or managers’ expectations and actions promoting patient safety; (4)

organisational learning—continuous improvement; (5) teamwork within units; (6) communication openness; (7) feedback and communication about error; (8) non-punitive response to error; (9) adequate staffing; (10) management support for patient safety; (11) teamwork between units; (12) handoffs and transitions. In addition, there are two single-item outcome variables: 'patient safety grade' and 'number of events reported'.[72] Factors 3-9 are measured at the unit level, while factors 10-12 are measured at the hospital level.

The HSOPS was adapted, translated, and piloted with the intention of being used in Norwegian hospitals (Appendices 9.2). The survey instrument was also compared with safety climate perceptions in the petroleum industry.[72] Espen Olsen found six factors to be cross-industrial measurement concepts: (1) learning, feedback, and improvement; (2) teamwork within units; (3) supervisor/manager expectations and actions promoting safety; (4) transitions and teamwork across units; (5) organisational management for safety; and (6) stop working in dangerous situations.

3.5.2 Psychometric properties of the HSOPS

Validity

In psychometric theory, the measurement features of subjective states are dependent on valid and reliable scales. The concept of validity is understood to be to what extent an instrument measures what it is intended to measure.[156] Validity can be assessed through face validity, content validity, construct validity, and discriminant validity.[156] Face validity and content validity represent a subjective judgement on the measure, herein the HSOPS, by one or more experts.[156]

In the development of the HSOPS, the questionnaire was empirically evaluated by examining interviews of representative personnel before and after pre-test concerning its face, content, and scales.[78] The content validity of HSOPS is also achieved by the theoretical construct of its measurement. Construct validity refers to the underlying hypothetical constructs of the measurement that explains the relationships to other variables, i.e., attitudes.[156] Developers of the HSOPS addressed this matter by assessing the literature, so that the survey would be based on the theoretical dimensions of hospital safety culture.

Discriminant validity refers to correlations between different factors/measures when they are expected to measure different constructs of a concept, with low or moderate correlations preferred as evidence. HSOPS factors are described as being low to moderately correlated.[153] Validation is a cumulative process whereby validating measures used in one clinical setting need to be validated in different organisations and cultures.[72] As safety culture perceptions can vary at the national level, the dimensional structure needs to be replicated in various organisational settings.[157] This underlines the necessity for assessing the psychometric properties, as performed in study 1 and reported in Paper 1.

Reliability

The concept of reliability is manifested by obtaining evidence that demonstrates that a scale measure is reproducible and consistent.[156] Items that are used to assess an underlying construct or concept should correlate with each other. Inherently, the items should form a scale that needs to have internal consistency.[158] Internal consistency is measured with intraclass correlation coefficients, of which Cronbach's alpha is commonly used.[159] Correlation coefficients are expressed as numbers ranging from 0.0 to 1.0. A coefficient of 0.0 reflects no association between two or more measures (indicating no reliability), while a coefficient of 1.0 indicates a perfect relationship. There is no consensus on the cut-off value for reliability. A value of 0.6 is commonly accepted,[160] although values greater than 0.7 are preferred.[158] For scales used to compare groups, α may be less than that used in clinical situations.[158]

The internal consistency of the factors in the Norwegian version of HSOPS was found to be satisfactory when using the HSOPS in Norwegian hospitals. In a pilot study of healthcare personnel (N=1,919) in a WRNHA hospital, Cronbach's alpha scores varied from 0.64 to 0.82 in 11 of 12 factors, with one exception: The factor 'organisational learning – continuous improvement' had an alpha of 0.51.[72]

Confirmatory factor analysis

In the above-mentioned Norwegian study of the HSOPS by Espen Olsen, confirmatory factor analysis was performed to assess whether the cultural and contextual difference between healthcare systems in the USA and Norway would influence reproducibility of the factor structure. Goodness-of-fit indices suggested that the factor structure acceptably fit the data, with Root Mean Square Error of Approximation (RMSEA) below 0.05 (RMSEA=0.044) and comparative fit index (CFI) of 0.97, goodness of fit (GFI) of 0.91, and adjusted goodness of fit (AGFI) of 0.90.[72]

3.6 WHO SSC intervention

The WHO SSC was translated and adapted to the Norwegian flow of care in collaboration with the research group from Haukeland University Hospital, Førde Central Hospital, and researchers at the Norwegian Knowledge Centre for Health Services. Each item in the checklist had a check box that could be ticked off when completed. Minor modifications were made to the original WHO checklist, such as removing the items 'patient consent (legal issues)' and 'use of pulse oximetry' (the latter was already a standard of care). The item 'is essential imaging displayed' was moved from the Time Out phase to the Sign In phase to avoid inducing anaesthesia in patients before it was verified that appropriate medical images were on hand. For cardiothoracic surgery, we added an item on critical events for cardiopulmonary bypass. The item 'prophylaxis for thrombosis administered if indicated' was incorporated in the Time Out. Further were checks of 'patient warming' and 'blood glucose level' added at the end of the Time Out. The final version is shown in Table A2 (Appendices 9.3). Version 2.1 can be found at the WHO website for surgical safety checklists.[161]

Our WHO SSC intervention was based on recommendations provided by the WHO implementation guidelines for the checklist.[21] A standardised educational programme was developed for the intervention in the two study hospitals (see section 3.3). This included a presentation that provided knowledge of the rationale (why and how) behind using the checklist. Motivation was encouraged by presenting two videos on '*how TO use*' and '*how NOT to use*' the checklist, as provided by surgeon Amit Vats at St. Mary's Hospital, Imperial College London, and the National Health Services, UK.[162] Informational material was translated and made available in the specific operating theatres for caregivers to read.[163]

3.7 Implementation

The WHO SSC was implemented by using a stepped-wedge randomisation of the surgical specialties included (see section 3.4). The intervention was carried out at one site at a time until all had received the checklist. The research group in the two hospitals conducted the implementation by first introducing the intervention to the managers, then to the healthcare personnel involved. As the intervention unfolded, the research team provided direct guidance to operating theatre staff for a period of two weeks before evaluative meetings were carried out.

3.8 Outcomes

3.8.1 Safety culture/climate

In study 1, the primary outcome measure was internal reliability (Cronbach's alpha) of the 12 safety culture/climate factors and the two single-item outcome variables of the HSOPS. A composite score of the positive responses was calculated for comparison to the US HSOPS comparative database, data from the pilot study in another WRNHA university hospital, and data from hospitals in the Netherlands. In study 2, primary outcome measures were changes in mean scores of the 12 HSOPS safety culture/climate factors after implementation of the WHO SSC intervention.

3.8.2 Morbidity and mortality

Primary outcome measures in study 3 were rate of complications and mortality up to 30 days after surgery, as recorded in patients' medical journals by ward doctors and surgeons after patients underwent in-hospital surgical treatment. These adhered to the International Classification of Diseases version 10 (ICD-10) for complication codes. The ICD was endorsed by the 43rd World Health Assembly in May 1990 and was incorporated by WHO member states starting in 1994. WHO describes the ICD as '*the standard diagnostic tool for epidemiology, health management and clinical purposes',*[164] which has been applied in epidemiologic and clinical research in Norway[165] and Denmark.[166] All major complications included in the American College of Surgeons' National Surgical Quality Program[167] (i.e., pneumonia, pulmonary embolism, myocardial infarction, cardiac arrest requiring resuscitation, acute renal failure, bleeding, stroke, deep vein thrombosis, major wound disruption, infections of surgical sites, sepsis, septic shock and systematic inflammatory response syndrome, unplanned returned to operating theatre, unplanned intubation, graft failure, and death) and all minor complications reported in the SURPASS study (i.e., arrhythmia, congestive heart failure, angina pectoris, urinary tract infections, nervous system complications such as delirium and somnolence, meningitis, peri- and endocarditis, gastroenteritis, abdominal complications, asthma, pleural effusion, and dyspnoea), in addition to anaesthesia-related complications were all identified through ICD-10 codes recorded.

Mortality was recorded for patients for up to 30 days after surgery and was electronically assessed from the Norwegian Mortality Register.

Secondary outcome measures in study 3 were total length of stay in the hospital and in the operating theatre. The outcome data were based on time points recorded in the patient administrative systems of the two participating hospitals.

3.9 Data handling

Data handling and survey quality assurance are described in Papers 1 and 2. Electronic survey data was directly transferred to SPSS by the software Corporator Surveyor®. Data captured by paper were entered manually by a research assistant, with data quality verified by the principal researcher.

In study 3, data were routinely recorded by healthcare personnel (i.e., surgeons, ward doctors, operating theatre nurses, nurse anaesthetists, anaesthesiologists, post-anaesthetic care unit nurses, and ward nurses). This was done with care, according to the established clinical routine (i.e., in the patient summary at the end of stay). Trained medical officers who were not informed of our ongoing study performed an additional quality check of the recorded ICD-10 codes used through routine screening.

Compliance data on the use of the WHO SSC were also recorded from the proforma checklist used in the operating theatres. The paper checklist data were entered by a research assistant and quality checked by the principal researcher. When there was a discrepancy between paper checklist data and the electronically recorded data (in the patient administrative system), the latter was used.

All identified complication data were quality checked against the patients' medical records. Confirmed complications were coded using the number one and unconfirmed cases were coded using zero. Data on mortality were retrieved from the Norwegian Mortality Register as hospital routine. In-hospital death up to 30 days after surgery was coded as one, and patients alive at discharge or after 30 days (but still in hospital) were coded as zero. All data were made anonymous after a final quality check.

3.10 Statistics

Statistical analyses were performed with SPSS versions 17, 20, and 21, respectively (SPSS, Chicago, IL, USA), for data analysed in studies 1, 2, and 3.[168] Sample size was calculated with Sample Power 2 in SPSS. Confirmatory factor analysis was calculated in Amos SPSS version 20. The goodness-of-fit indices are described in the Appendices 9.4.

In study 1, descriptive statistics were used to assess sample characteristics. One-way analysis of variance (ANOVA) scores was conducted to test the null hypothesis, assuming equality in mean perceptions of safety climate amongst the professions. Principal component analysis with Varimax rotation was used to explore the factors of HSOPS. Internal consistency was measured by Cronbach's alpha for comparisons of reliability. Correlations between the factors were estimated with Pearson's correlation coefficients to investigate the construct validity of the HSOSP in an operating theatre personnel population.

In study 2, sample characteristics and WHO SSC compliance data were quantified by using descriptive statistics. Variation between the intervention and control group was assessed with Pearson exact chi-squared test. Intervention and control group mean scores were compared using ANOVA. Hierarchical multiple regression analysis with mixed linear model (MLM) was used to investigate the effects of the WHO SSC on safety culture (HSOPS), following individual subjects at two time points.

In study 3, patient characteristics were descriptively listed. All analyses in the stepped-wedge cohort RCT involved comparisons between all data in the steps before WHO SSC intervention (controls) with the steps after WHO SSC intervention. Categorical data were compared with exact Pearson's chi-squared test with Bonferroni corrections for multiple comparisons, and numerical data were compared with independent samples t-tests. Effect was measured with absolute risk reduction (ARR),[ii] relative risk reduction (RRR), and number needed to treat (NNT).[169] Effect

[ii] Calculations were quality checked using Stats Calculator. http://ktclearinghouse.ca/cebm/practise/ca/calculators/statscalc

sizes were calculated with parametric eta squared. For all three studies, a two-sided $P<0.05$ value was considered to be statistically significant.

4. SUMMARY OF RESULTS

4.1 Patient safety in surgical environments

In study 1, we investigated the psychometric properties of the survey instrument HSOPS in Norwegian hospitals. Our aim was to validate the HSOPS in an environment not previously studied—the surgical environment—and (2) to compare results from its use on the safety culture in healthcare personnel in different countries. The findings of this study were fully reported in Paper 1.

Of surgical personnel 62% (358/575) responded to the survey: surgeons, 56% (126/225); anaesthetists, 62% (47/76); operating theatre nurses, 61% (62/84); nurse anaesthetists, 84% (62/74); and ancillary personnel, 63% (39/62). The internal consistency measured with Cronbach's alpha ranged from 0.64 to 0.85, except for the factor 'adequate staffing'. This had an alpha of 0.59. Safety culture factors correlated moderately, with Pearson's correlation coefficients ranging from 0.26 to 0.62 ($P<0.001$).

The 12 safety culture factors were explored using principal component analysis with Varimax rotation. The solution converged after eleven iterations. Ten factors explained 60% of the total variance. The positive composite scores calculated for the factors varied from 22% to 77%. Except for the factor 'non-punitive response to error', factor scores were lower than those obtained in US hospitals. Although HSOPS was considered to be valid for use in operating theatre personnel, its external validation is required.

4.2 Impact of WHO SSC on safety culture

In study 2, we investigated the impact of using the WHO SSC on patient safety culture perceptions of operating theatre personnel. Our aim was to determine whether its use would positively affect safety culture. We used the HSOPS to assess this. The findings of this study were fully reported in Paper 2.

Of operating theatre personnel, 61% (349/575) responded at baseline and 51% (292/569) responded post-intervention. WHO SSC compliance in surgical procedures was 85% (2,015/2,367) for the Sign In phase, 84% (1,981/2,367) for the Time Out phase, and 77% (1,832/2,367) for the Sign Out phase. Compliance for utilizing all three parts was 75% (1,767/2,367). There were significant changes in the intervention group for the safety culture factors ‘frequency of events reported’ and ‘adequate staffing’, with regression coefficients at -0.25 (95% CI, -0.47 to -0.07) and 0.21 (95% CI, 0.07 to 0.35), respectively (illustrated in Figure 6).

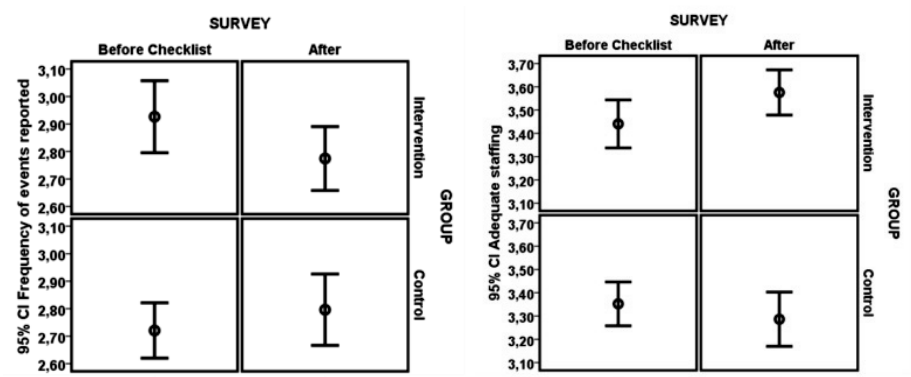

Figure 6 Impact of the WHO SSC on two of the safety culture factors in HSOPS

The intervention group scored significantly higher on several of the safety culture factors compared to the control group, as shown in Table 4 in Paper 2. However, implementation of the WHO SSC had limited impact on the overall safety culture.

4.3 Effect of WHO SSC on patient outcomes

In study 3, changes in morbidity and mortality after implementing the WHO SSC were investigated. Our aim was to determine whether use of the WHO SSC positively affects patient outcomes, reducing morbidity, mortality, and length of hospital stay. The findings of this study were fully reported in Paper 3.

The overall complication rate during the entire study period was 15.6% (824/5,295). Complications for all surgical procedures decreased from 19.9% (440/2,212) before WHO SSC implementation to 12.4% (384/3,083) after implementation (P<0.001). ARR was 7.5 (95% CI, 5.5 to 9.5). When all three parts of the WHO SSC were used, complications decreased from 19.9% to 11.5% (260/2,263), P<0.001. ARR was then 8.4 (95% CI, 6.3 to 10.5) (see Figure 7). A large effect size of 0.14 was found, as demonstrated by parametric eta-squared test. In order to prevent one or more complications to occur, the NNT with the WHO SSC was 12 (95% CI, 9 to 16).

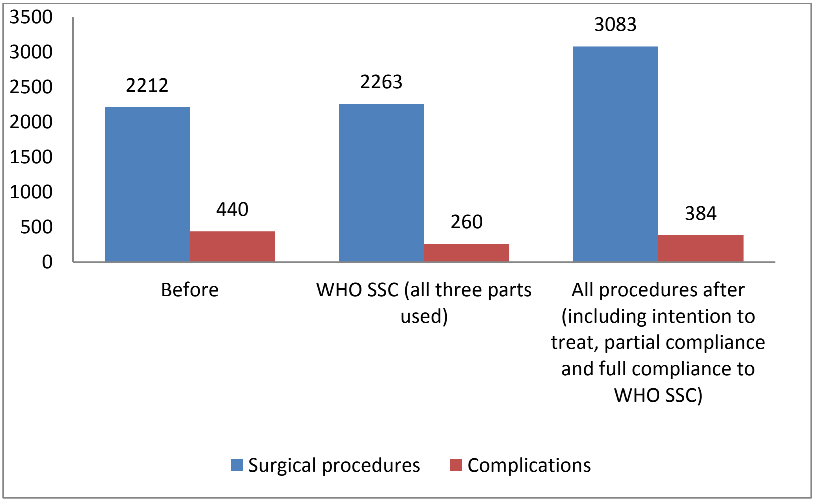

Figure 7 Effect of the WHO SSC on complications in the stepped-wedge cluster RCT 2009-2010

The effect of using the WHO SSC on complications were adjusted for possible confounding variables, including age, gender, comorbidity, surgical specialty, urgency of surgery, type of anaesthesia, and time (study period) by using logistic regression. The decrease in complications remained significant after adjusting for these variables, with an OR of 1.95 (95% CI, 1.59 to 2.40) in the final regression model.

Mean length of stay in the operating theatre was significantly changed. Across the two hospitals, the average in-hospital length of stay was reduced from 7.8 days to 7.0 days after the WHO SSC implementation, with a mean difference of -0.8 days, t=2.30, (95% CI, 0.11 to 1.43).

The effect of using the WHO SSC on in-hospital mortality up to 30 days after surgery was analysed in unique patients. The overall mortality rate for the entire study period was 1.3% (49/3,811). We observed a decrease from 1.6% (28/1,778) before WHO SSC intervention to 1.0% (20/2,033) after the intervention ($P<0.151$). This decrease remained non-significant after adjusting for age, gender, comorbidity, surgical specialty, urgency of surgery, type of anaesthesia, and time (study period). However, post hoc analysis of mortality by individual hospitals revealed a significant decrease from 1.9% to 0.2% ($P=0.020$) in the central community hospital.

5. DISCUSSION

5.1 Discussion of methodological issues

5.1.1 Study design

Study 1 was conducted using a cross-sectional design, study 2 was a prospective cohort study with controls, and study 3 was a stepped-wedge cluster randomised trial.

Cross-sectional surveys, as was used in study 1, are appropriate when investigating a phenomenon or relationships between variables at one time point.[170] Here, results of cross-sectional surveys must be interpreted with caution, as the design is not suitable for causational conclusions for variables being measured at one time point.[170] Our intentions with study 1 were, however, not to investigate causality but to validate the survey instrument for use in a surgical environment and to describe the phenomenon of safety culture in an operating theatre environment.

Prospectively designed studies with control and intervention groups at two time points are considered to be more appropriate for investigating the effects of an intervention.[170, 171] In study 2, the design used included a control and an intervention group, whereby the same healthcare personnel were assessed before and after the WHO SSC intervention. In the intervention group, the order of implementation of the WHO SSC in the clusters of surgical specialties was randomised.

To our knowledge, the present study is the first to employ this robust design. In our systematic review, we found no studies that used similar controlled designs to assess the effects of surgical safety checklists, Time Out protocol, or briefings on safety culture in operating theatres. The most commonly used previous designs were longitudinal or prospective before and after designs, lacking separate control subjects and lacking a following of the same individuals over time. This limitation of previous studies thereby increases risk of bias.[172]

To investigate the relationship between an intervention and an outcome, RCTs are considered to be the most robust design. In patient safety research, the use of individual randomisation can be inappropriate, or impossible to achieve, when an intervention does not target individuals but instead targets teams or clusters .[173] Thus, cluster RCTs are increasingly being used in healthcare settings, with stepped-wedge cluster randomised designs considered to be especially suitable for addressing issues in patient safety research.[173-176] We used the stepped-wedge cluster randomisation in study 3, because it was the best option amongst possible RCT designs for our type of intervention.

5.1.2 Validity

To validate an instrument's ability to measure what we intend to measure, internal and external validity must be assessed. Internal consistency, construct validity, and discriminant validity all refer to internal validity, while representativeness and criterion validity refer to external validity.

In studies 1 and 2, the HSOPS was used to investigate the perceptions of healthcare personnel on safety culture in an operating theatre setting. Internal consistency was assessed in both studies with Cronbach's alpha. In study 1, analysis showed that internal consistency for the factor 'adequate staffing' was 0.59. Although we explored whether this factor could be combined with another factor to improve reliability, we failed to find a theoretical rationale for combining the concept 'adequate staffing' with another factor.

The factor 'organisational learning and continuous improvement' scored 0.64 on internal consistency. As the recommended cut-off value for internal consistency is at least 0.60, preferably 0.7 or higher,[158] we explored whether combining two closely related factors could improve internal consistency. We combined the items 'organisational learning and continuous improvement' and 'feedback and communication about error' into one factor with six items. This improved internal consistency to 0.78. In order to establish which factor structure would fit the data best, confirmatory factor analysis was performed on the data sets from studies 1 and 2 (see Appendices 9.4). This was also suggested in a critical comment posted post-publication of Paper 1.[177] The results of the confirmatory factor analysis supported the twelve-factor structure of the HSOPS and confirmed previously reported findings.[72] For these reasons, we did not alter the factor structure of the HSOPS for use in study 2, when assessing possible changes in the safety culture.

In study 1, internal validation of the HSOPS factors was tested with correlations amongst the 12 factors and the two single outcome measures. Low to moderate correlations were preferred, as very high correlations between the factors would mean that they measured the same concept and predicted each other (i.e., were redundant). The significant factor correlations found in study 1 ranged from 0.20 to 0.61 for unit-level factors and from 0.26 to 0.62 for hospital-level factors. This supported both discriminant and construct validity of the HSOSP.

Concern as to the external validity of Paper 1 and Paper 2 is what to degree this study population did indeed represent a broader operating theatre population. Surgeons, operating theatre nurses, anaesthetists and nurse anaesthetists, and ancillary personnel constitute the core of operating theatre personnel in hospitals. The HSOSP was previously used in a smaller WRNHA university hospital resulting in very similar findings,[72] indicating that the survey instrument has stability and certain external validity.

Another aspect of external validity is criterion validity, which measures to what extent a survey instrument is correlated with another instrument/measure; i.e., a possible change in patient outcomes, as conducted for the SAQ.[73] The HSOPS has been compared to another safety climate instrument across industries, as previously mentioned,[72] but correlations to patient outcomes remain to be explored for the HSOPS.

Systematic or random errors may affect the internal validity of a study. Validity in study 3 refers to what degree we were able to measure what we intended to measure, i.e., complications associated with a surgical procedure. In this study, it was not feasible to objectively determine to what extent the identified complications or deaths were due to underlying diseases or whether they were caused entirely or at all by healthcare management. The complications were electronically identified through ICD-10 codes and registered by a surgeon or a ward physician for each patient in the patient administrative system, which is routine and required. All ICD-10 codes in the patients' medical records are routinely quality checked at discharge by a medical officer. Such follow-up routines minimise systematic and random errors in the coding.

The next step of quality checks was to assess whether any given complication was associated with the actual surgical procedure performed. In all, 1200 cases were identified using an electronic match control with the predetermined ICD-10 complication codes to be recognised. The research team reviewed the patients' medical records to verify whether in fact the codes were accurately associated with a complication. This review was performed in order to increase the internal validity of study 3. Some ICD-10 codes represented conditions that did not result from the actual surgical procedure, but were actually causes leading to surgery, such as in-hospital infections.

In studies 2 and 3, the implementation of the WHO SSC could be subject to information bias between the intervention and control groups, vis-à-vis information provided about the intervention. While we took measures to avoid this possibility, this information could have been transmitted amongst the different personnel groups, either unintentionally or intentionally. Blinding healthcare providers is difficult to achieve and is often glossed over in reports of RCTs involving nonpharmacological treatments.[178] To minimise such biases, the research team ensured that the staff educational programme was conducted in closed sessions for all healthcare personnel involved.

In study 3, the study population was representative of patients seen at a tertiary teaching hospital and a central community hospital. They came from combining heterogeneous surgical specialties of the two hospitals. Including patients from such a large range of surgical specialties and different levels of treatment in the sample likely increases the external validity of the study. Hence, our results on the effects of using the WHO SSC on complications, death, and length of stay can be generalised to other Norwegian hospitals with similar characteristics and surgical specialties.

5.1.3 Reliability

Reliability refers to the repeatability and stability of measures when repeatedly used.[156] In studies 1 and 2, the internal consistency proved to be stable over time, with only small variations in Cronbach's alpha values from baseline to post-intervention. Although the Cronbach's alpha scores for the factors 'adequate staffing' and 'non-punitive response to error' increased and decreased, respectively, at the post-intervention assessment, these small changes were considered acceptably reliable.[160] Stability of the HSOPS over time indicates that it has high reliability and reproducibility.

The reliability of surveys can further be affected by respondents' ability and availability to make a response. Such a situation would be present if the participants were expected to complete the questionnaire in a busy operating theatre environment, for example. To take this into account, the research team asked managers to arrange for time for the healthcare personnel to complete the surveys during educational hours or when the operation programme allowed it.

Reporting a RCT requires transparency about how it was conducted, analysed, and interpreted in order for the readers of the final report to properly assess the reliability of the findings.[179] In study 3, we were diligent in following as close as possible the steps outlined in the Consort flow diagram (Figure 5) and the Consort checklist of information for reporting a cluster RCT (Appendices 9.5). However, not all items in the Consort checklist were adapted to report the relatively new and innovative study design, the stepped-wedge cohort RCT.[179]

5.2 Discussion of results

5.2.1 Safety culture

In study 1, variability in the perceptions of safety culture varied amongst the ‘sharp end’ professions, with anaesthesia personnel scoring highest on most of the 12 safety culture factors (mean scores). This variability could reflect the fact that healthcare personnel are organised in different departments and units. Thus, there was more agreement between the professions on certain factors at the hospital level, like ‘teamwork across units’, compared to other factors at the unit level, like ‘handoffs and transitions’, for which all professions had relatively low scores.

The kind of variability we observed in safety culture perceptions between healthcare professions is in agreement with findings from other Norwegian studies. Conclusions from these studies suggest that there is multilevel partitioning of variance in patient safety culture.[88, 180] In study 1, there was also variability in perception of safety culture amongst different countries, specifically the average sum score of the positive responses of the 12 HSOPS factors. Hence, the overall variation was limited when comparing our operating theatre personnel with healthcare personnel in the previously reported HSOPS study in a Norwegian university hospital.[72]

Taken together, in the Norwegian HSOPS studies participants scored very high on their perception of ‘non-punitive response to error’ compared to other countries. This indicates that a safety culture exists in which errors are being treated more as system errors than like individual errors. This perspective was highly desired and recommended as a goal in the reports from the US Institute of Medicine.[13, 26] On the extreme regarding this, concern could be raised that hospital managers find it difficult to address such safety issues. The emphasis on ‘organisational learning – continuous improvement' and 'feedback and communication about error' could support this assumption. In a study of hospital safety climate using the SAQ, subordinate leaders were found to perceive the safety climate significantly more positively than the frontline staff.[88] Hence, hospital managers should routinely monitor safety culture perceptions in 'sharp end' professions.

5.2.2 Impact of using the WHO SSC on safety culture

In study 2, we found a significant change in 2 of 12 safety culture factors after implementing the WHO SSC. The factor 'adequate staffing' was reported more positively, having a regression coefficient increase to 0.21 (95% CI, 0.07 to 0.35) in the intervention group. This factor contains four items. The 'adequately staffed to handle workload' item contributed mostly to the change of scores.

In study 1, 'adequate staffing' was related to 'overall patient safety', 'non-punitive response to errors', and 'teamwork within units'. We found moderate correlations of 0.49, 0.45, and 0.41, respectively, ($P<0.01$). This implies a relationship between patient safety, error response, teamwork, and being adequately staffed. Although we did not observe changes in the factor 'teamwork within units', it may be possible that the WHO SSC intervention had an impact on the teams' perception of being better able to handle the workload. This notion is supported by findings in other studies that investigated effects of using the WHO SSC. These reported improved communication,[107, 139, 181] preparedness,[103] and teamwork.[102, 109]

The factor 'frequency of events reported' on near misses was reported less positively. The regression coefficient decrease was -0.25 (95% CI, -0.47 to 0.07) in the intervention group. More openness and willingness to report errors and near misses are encouraged in order to create learning organisations, implying that an increase in scores on this factor would be desired.[13, 26] On the other hand, in light of the content of the items in this factor, we interpret this finding to correspond with mitigation of complications after the WHO SSC intervention, as presented in study 3. This is supported in other studies of surgical safety checklists.[3, 47]

It is likely that a reduction in complications is associated also with a reduction of near misses in the operating theatre. In one study using the SURPASS checklist, items caught incidents that could have led to near misses or actual patient harm if not corrected (2562 checklists; 40.3%).[182] In line with this, another study (conducted in 2009) that investigated experiences of near misses and incorrect surgery (wrong patient, wrong procedure, and wrong site) at Haukeland University Hospital found that most of the operating theatre personnel supported introduction of a Time Out protocol (91%, 250/275), and 96% (263/275) believed it could prevent errors.[91] The surgical team members reported that they were very familiar with near misses of incorrect surgery, with 38% responding that they had been uncertain about patient identity, 81% responding that they had been uncertain about surgical site or side, and 60% responding that they had prepared for the wrong procedure.[91]

Thus, we hypothesise that mitigation of near misses found in study 2 by improving standard of care explains the decrease in ‘frequency of events (near misses) reported’ scores. This was reported in Paper 2.

Our systematic review of the literature identified two studies that used a validated safety culture/climate instrument to investigate the effects of using the WHO SSC on safety culture in the operating theatre. The first was a study by Haynes and colleagues that used a modified SAQ instrument.[108] They investigated subset items of the patient safety culture with additional questions on utilisation of the WHO SSC. The six items selected were related to teamwork climate and safety climate domains, which resulted in an internal consistency of 0.60. Interestingly, the improvement in mean SAQ scores after implementing the WHO SSC was significantly correlated with a decrease in relative risk of patient complications (r=0.71, P=0.038).[108]

The second study did not find any changes in SAQ scores after implementing the WHO SSC.[147] A very recent study that was published after completing our systematic review found an increase in two dimensions of the SAQ after WHO SSC implementation in the operating theatre. The total mean score changed from 3.39 to 3.57 ($P<0.05$).[183]

The systematic review, however, did identify studies that reported positive SAQ changes after implementation of pre-surgical briefings and debriefings.[42, 110, 127, 149, 151] For most of the surveys, the common denominator was that one or two dimensions of the instruments had been applied. Whether the interventions would have affected all domains/dimensions of safety culture remains an open question.

Safety culture is difficult to measure as a concept. However, safety climate instruments could provide an initial picture of the safety culture of an organisation. When only parts of safety climate instruments are used, it is of course difficult to argue that the entire safety culture has been changed. Applying all dimensions (12 factors) of the HSOSP in study 2, we failed to find an overall change of the safety culture. This suggests that using the WHO SSC and other similar instruments can influence only parts of the safety culture. To evaluate quality improvement interventions and safety culture, and to obtain a broader picture of changes in care processes and team function, other tools like audits, observational studies, and interviews of healthcare staff may be needed.[3, 172, 184]

The use of an interdisciplinary- and team-based checklist does indeed imply a change in behaviour in order to be successful.[108] According to Conley et al., in order to reduce morbidity and mortality by using the surgical safety checklist, the implementation process itself must be carried out effectively. Leaders need to persuasively explain the rationale and benefits of using the checklist and then effectively show how to use it.[115] Our implementation of the WHO SSC is in accordance with this guideline. On the other hand, poorly implemented checklists can cause professional divisiveness, increase tensions, and mask knowledge gaps and/or safety gaps, especially when individuals in the team hinder the process with uncooperative behaviour.[18, 185] A recently published systematic review of the impact of using surgical safety checklists in the operating theatre provided evidence that enhanced quality of teamwork and communication is achieved by establishing an open platform for communication at the start of the procedure.[186] The review also discussed evidence of a negative impact on team function when individuals were not tightly integrated into the checklist implementation process, or when use of the checklist itself was suboptimally implemented.[186]

In study 2 (reported in Paper 2), we found that introduction of the WHO SSC influenced some aspects of safety culture but did not influence the overall safety culture, as measured by the HSOSP. Hospital safety theory provides support for the construct model that safety climate, knowledge, and motivation mediate safety performance regarding compliance and participation.[77] The changes in safety culture we found could be driven by change in knowledge and motivation prior to the intervention and the change in safety behaviour of team members produced by the intervention itself. The question of whether the overall safety culture will in fact change over time is of great interest, requiring further monitoring with the HSOPS to answer.

5.2.3 Effect of WHO SSC on patient outcomes

The WHO SSC intervention resulted in a decrease of one or more surgical procedure complications, from a baseline of 19.9% down to 11.5% ($P<0.001$). Also in study 3 (reported in Paper 3), we found significant decreases in all types of complications (respiratory, cardiac, infections, bleeding, surgical wound rupture, mechanical implant, and other complications) after WHO SSC implementation.

Our results are comparable to findings of a WHO SSC implementation study conducted in eight countries for both elective and emergency surgery.[3, 123] Only 1 of 5 high-income country studies of WHO SSC effects on complications showed an overall decrease in complications from 23.6% for historic cases and 15.9% for cases with only team training. When the WHO SSC was used the percentage was 8.2% ($P<0.001$).[120] However, the studies on use of the comprehensive checklist system SURPASS in the Netherlands by de Vries and colleagues reported similar results. They found a reduction in total complications from 15.4% to 10.4% ($P<0.001$).[47]

Our study investigated both elective and emergency surgical procedures covering five surgical specialties, including the highly specialised procedures of cardiothoracic surgery and neurosurgery. Other studies confirmed that improvement is possible in similar settings. A prospective audit study in a UK hospital on the use of a surgical Time Out checklist and human factor training found a substantial reduction of venous thromboembolism prophylaxis errors over time in thoracic surgical patients.[113] Implementation of the WHO SSC in a general surgical setting and in the specialties of cardiothoracic, orthopaedic, general, and gynaecological surgery resulted in improvements in antibiotic administration timeliness from 92.7% to 95.4% ($P<0.05$), and in temperature management from 93.8% to 97.7% ($P<0.001$).[125] This study of process outcomes was conducted in a tertiary hospital in Texas, USA.

In previous studies, the quality of the effect size measure has been low.[4] A large effect size reflects more confidence in the findings.[187] In statistics, the effect size is a measure of the strength of a phenomenon, in our case, the strength of the change in an outcome after the checklist intervention. The calculation conveys the estimated magnitude of a relationship. This statistic indicates the proportion of variance in the complications variable that is explained by the checklist intervention. In our study, we found a large effect size (0.14) based on the parametric eta-squared test on the reduction in complications associated with surgical procedures after the WHO SSC intervention. We confidently interpret this to mean that use of the checklist reduced complications.

Another way to assess the effect size of a treatment is by determining the number of subjects needed to treat in order to see the effect.[169] A smaller number means the effect size is larger, or in other words, the intervention is so robust that very few subjects are needed to demonstrate its efficacy. In our study, the number needed to treat to prevent one or more complications in a surgical procedure was 12, a relatively small number of subjects.

One study conducted in a high-income setting on the use of the WHO SSC in orthopaedic surgery failed to find a significant decrease in complications. Hence, the number needed to treat was reported to be 77, a relatively large number in order to demonstrate a reduction in complications in surgical procedures.[122] By contrast, we found a 65% reduction of unplanned returns to the operating theatre, with a decrease from 1.7% to 0.6% ($P<0.001$) across all specialties. This finding corresponds well to the WHO SSC intervention study by Haynes and colleagues, which reported a decrease in unplanned returns from 2.4% to 1.8% ($P=0.047$).[3] Using the WHO SSC reduces risk of harm by surgical care itself and contributes to improvement of patient safety by preventing major and minor complications.

In our study, we were able to adjust for the possible effects of certain confounding factors on outcomes. Using logistic regression, we adjusted for the possible confounding effects of age, gender, comorbidity, surgical specialty, elective or emergency surgery, type of anaesthesia, and time (study period) on reducing complications. In the final model, age, comorbidity, surgical specialty, elective/emergency surgery, and type of anaesthesia were all controlled for, but these factors did not influence the effect that the WHO SSC intervention had on decreasing complications. This provides a strong indication of the robustness of the WHO SSC intervention on decreasing complications.

As with all multivariate studies, unknown confounding variables in our study could have influenced the particular outcomes we assessed. One possibility is that another unidentified quality improvement project was being concurrently conducted with ours. To our knowledge, there were no other such projects being carried out in this time period that could have confounded our results.

Another possible confounding factor to consider is the placebo-like Hawthorn effect, which is thought to affect people's behaviour and to obscure the effect of interest.[187] By using a stepped-wedge randomised design, this effect would be minimised, since any 'contagious' enthusiasm would affect both intervention and control groups equally. One of the strengths of the stepped-wedge design is that possible confounding factors influence all clusters in both intervention and control phases of the study, thus minimising possible confounding effects on the outcomes.

A reduction of in-hospital complications should theoretically be followed by a measurable reduction in length of stay. In study 3, we found a significant reduction in length of stay of 0.8 days (19 hours) (P=0.022). We found no other studies in our systematic review of the literature that reported similar findings regarding the effect of surgical safety checklists on length of stay. The SURPASS study of de Vries et al. reported a reduction in length of stay from 9.1 to 8.5 days that was not significant (P=0.15).[47] The reduction in length of stay we observed further bolsters the notion that a decrease in complications resulted from use of the WHO SSC.

Using all three parts of the checklist—Sign In, Time Out, and Sign Out—appears to be critically important. In study 3, we found a decrease in complications for all surgical procedures after implementing the WHO SSC. This was the case also when including procedures that not used the checklist (intention to treat) and those that only used one or two parts of the checklist. For this case, the ARR was 7.5 (95% CI, 5.5 to 9.5). The greatest reduction in complications was produced when all three parts of the WHO SSC were used. For this case, the ARR was 8.4 (6.3 to 10.5). This finding is similar to that of another study that provided evidence for a strong relationship between decrease in mortality and full checklist compliance.[148] The study reported an OR of 0.44 (95% CI, 0.20 to 0.70), when all three parts were used, compared to ORs of 1.09 (95% CI, 0.78 to 1.52) and 1.16 (95% CI, 0.86 to 1.56) for partial use or for noncompliance, respectively.[148]

In study 3, results on in-hospital mortality up to 30 days after surgery were based on unique patients and procedures, in which all three parts of the checklist were used. We found a non-significant decrease in mortality from 1.6% to 1.0% (P=0.151). The ARR was 0.5 (95% CI, -0.2 to 1.3). When adjusting for possible confounding factors, the effect of using the WHO SSC was still not significant, with an OR of 1.48 (95% CI, 0.80 to 2.78) in the final model. Generally, the mortality risk increased with higher comorbidity (ASA classification system) and emergency surgery. Still, when analysing this variable at the hospital level, we found a significant difference in mortality in the central community hospital, Førde Central Hospital. At this hospital, mortality decreased from 1.9% to 0.2% (P=0.020) after implementation of the WHO SSC. The ARR was 1.7 (95% CI, 0.4 to 3.0). However, this finding was not strong enough to significantly decrease the overall mortality in the adjusted model.

A significant reduction in mortality has been very difficult to achieve in WHO SSC studies conducted in high-income countries. The systematic review identified only one WHO SSC study from the Netherlands that reported a significantly decreased mortality, with an OR of 0.85 (95% CI, 0.73 to 0.98) when adjusted for baseline differences.[148] In the first WHO SSC study, Haynes and colleagues found a total reduction in mortality from 1.5% to 0.8% (P=0.003) after use of the checklist. However, they did not find a significant decrease in mortality for high-income countries, decreasing from only 0.9% to 0.6% (P=0.18). By contrast, for study sites in low-income countries, they reported a decrease from 2.1% to 1.0% (P=0.006).[3] These findings are at variance with others, however.[121, 123]

In the study of the comprehensive checklist system of SURPASS used in the Netherlands, a significant reduction in mortality was demonstrated after implementation of the checklists. This study showed a reduction from 1.5% to 0.8% and an ARR of 0.7 percentage points (95% CI, 0.2 to 1.2).[47] There are a number of confounding factors that influence mortality results, including small sample sizes, implementation deficiencies, quality of checklist performance, and resistance to utilisation.[18] Other factors such as new treatments, drugs, or equipment could further obscure the outcome results.

We cannot exclude the possibility that some unknown explanatory factors could have affected the outcomes in our study. In our favour, however, is the fact that we used a randomised stepped-wedge cluster design, which certainly reduces the introduction of biases that otherwise are difficult to control for in non-randomised studies. Two very recent systematic reviews supported the WHO SSC effects on morbidity and mortality,[188, 189] though evidence from randomised studies was wanted.[189]

6. CONCLUSIONS

1. The internal validity of the 12 safety culture factors in the HSOPS measured at two time points was determined to be acceptable for the instrument to be used in our surgical environment. A twelve-factor structure was supported by confirmatory factor analysis. The 12 factors correlated moderately and supported construct validity. The Norwegian version of the HSOPS needs further external validation to assess its criterion validity.

2. Compared to hospital healthcare personnel of other high-income countries, our Norwegian surgical environment scored lower on all the safety culture factors of the HSOPS, except for the ‘non-punitive response to error’. Thus, additional patient safety interventions are required to improve the level of safety culture in our clinical setting. This is especially the case, since addressing errors in a system perspective is warranted in healthcare.

3. Some of the surgical healthcare personnel’s perceptions of safety culture were influenced by checklist implementation. Introduction of the WHO SSC had an impact on two safety culture factors: ‘frequency of events (near misses) reported’ and ‘adequate staffing’. With a possible reduction of adverse events and improved team recognition, these findings correspond well to improvements found in patient outcomes after WHO SSC implementation.

4. Although the implementation of the WHO SSC was successful, it did not change the overall level of safety culture, as measured with the HSOPS. It is possible that more targeted and or a larger number of patient safety interventions are required to address the continuum of safety culture.

5. Using a stepped-wedge cluster randomised trial design, we found that use of the WHO SSC significantly reduced overall surgical procedure complications,

from 19.9% at baseline assessment to 11.5% post-intervention (P<0.001). We observed a reduction in respiratory and cardiac complications, infections, bleeding, surgical wound ruptures, mechanical implant complications, and other complications, and unplanned returns to the operating theatre.

6. Controlling for the possible confounding factors of age, gender, comorbidity, surgical specialty, elective/emergency surgery, type of anaesthesia, and time (study period), the reduction in complications resulting from the WHO SSC implementation remained significant.

7. All three parts of the WHO SSC should always be used. We observed a smaller reduction in complications when only one part, or two parts were used, or when non-compliance prevailed. The greatest effect was found in cases in which all three parts of the WHO SSC were used.

8. We found that use of the WHO SSC prevented complications in surgical procedures. With use of the WHO SSC, the number of subjects needed to treat was 12, when the target was preventing one or more complications in a surgical procedure (95% CI, 9 to 16).

9. Use of the WHO SSC significantly reduced hospital length of stay by a mean of 0.8 days, t=2.30 (95% CI, 0.11 to 1.43) across the two hospitals. However, a non-significant decrease in length of time spent in the operating theatre was observed. The decrease in in-hospital length of stay supports the notion that reduction in number of complications leads to earlier discharge.

10. Sub-analyses revealed that the WHO SSC intervention reduced mortality in the central community hospital, from 1.9% at baseline assessment to 0.2% post-intervention (P=0.020). However, the intervention did not significantly reduce mortality across all participating hospitals and all five surgical

specialties. At this level of analysis, the values were 1.6% to 1.0% (P=0.151). Adjusted for possible confounding factors, the effect on mortality remained non-significant.

11. In summary, we find that the change we measured in safety culture was driven by implementing the WHO SSC. It is important to use all three parts of the WHO SSC in order to improve patient safety and to prevent harm due to healthcare management.

7. SUGGESTIONS FOR FURTHER RESEARCH

1. The external validity of the HSOPS remains to be tested for criterion validity. We suggest that further studies should be conducted to explore the relationship between safety culture (HSOPS) and patient outcomes in surgery.
2. Further research is needed in a more longitudinal perspective to determine whether the WHO SSC affects the broader safety culture.
3. The WHO SSC items should be investigated in detail to better understand the relationship between complications and the items included in the checklist.
4. As errors can occur throughout the entire surgical care pathway, introduction of checklists, like the comprehensive checklist system SURPASS, should be a topic for further research.
5. The systematic literature review failed to find any research on the effect of the WHO SSC on post-discharge morbidity or mortality. This represents a prominent void in existing knowledge that needs to be filled.

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9. APPENDICES

9.1 Search strategy for systematic literature review

Table A1 Search strategy

Search dated 1.25.2013

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Full search history:

1 ((WHO or "WHO's" or world health organi#ation or surgical or safety or safe surgery or operat$) adj6 (checklist$ or check list$)).tw. (786)

2 World Health Organization/ or Safety Management/ or Surgical Procedures, Operative/ or Operating Rooms/ (96966)

3 (checklist$ or check list$).tw. (18765)

4 2 and 3 (451)

5 1 or 4 (1022)

6 exp Organizational Culture/ and exp Safety Management/ (1163)

7 (safety adj2 (culture or climate or attitude*)).tw. (1333)

8 exp Hospitals/ (188635)

9 6 or 7 (2105)

10 8 and 9 (292)

11 Operating Rooms/ (9968)

12 (operating adj2 (room* or theatre*)).tw. (18351)

13 11 or 12 (24079)

14 9 and 13 (84)

15 10 not 14 (275)

16 5 and 15 (2)

17 5 and 9 (38)

18 (safety adj4 (culture or climate or attitude*)).tw. (1727)

19 6 or 18 (2454)

20 5 and 19 (40)

21 20 not 14 (28)

Search dated 9.18.2013

Database: Ovid Embase <1974 to 2013 September 17>

Full search history:

1 ((WHO or "WHO's" or world health organi#ation or surgical or safety or safe surgery or operat$) adj6 (checklist$ or check list$)).tw. (1274)

2 *patient safety/ or *surgery/ or *operating room/ or *world health organization/ (112987)

3 *checklist/ (1052)

4 (checklist$ or check list$).tw. (27229)

5 3 or 4 (27357)

6 2 and 5 (417)

7 surgical safety checklist/ (29)

8 1 or 6 or 7 (1427)

9 limit 8 to yr="2012 -Current" (424)

9.2 Hospital Survey on Patient Safety Culture

Spørreskjema til helsepersonell ved Haukeland Universitetssykehus

RIV AV DENNE SIDEN VED INNLEVERING

Veiledning

Hensikten med dette spørreskjemaet er å få ditt syn på pasientsikkerheten på denne arbeidsplassen. Undersøkelsen er helt anonym og svarene analyseres av prosjektgruppen for Safe Surgery, i samarbeid med Universitetet i Stavanger. Besvarelsen tar ca. 15 minutter.

Det er svært viktig at så mange som mulig svarer på undersøkelse.
Vær oppmerksom på at spørsmålene både er positivt og negativt ladet, så svaret ”uenig” er noen ganger positivt ment, og andre ganger negativt. Ferdig utfylt spørreskjema legges i den vedlagte konvolutten og sendes i internposten eller i postkasse ved ekspedisjonen SOP.

For mer informasjon om undersøkelsen kontakt Arvid S. Haugen eller Eirik Søfteland

Terminologi

En uønsket hendelse er en utilsiktet hendelse som følge av medisinsk undersøkelse og/eller behandling. Den har ikke alltid uønskede følger, men ofte har den uønskede følger som: forverring av symptomer og plager, forlenging av sykdom og behandlingstid, invaliditet eller død.

Nærhendelse er en hendelse som ikke førte til skade, fordi den ble oppdaget eller korrigert i forkant.

Med uttrykket ”hos oss” og ”ledelsen” refereres fortrinnsvis til avdelingen hvor du arbeider, og til lederne i din avdeling.

Instruks

Bruk blå eller svart penn.

Sett kryss i rutene slik: ☒
Dersom du krysser i feil rute, stryk ut feil slik: ■

1. GENERELT OM ARBEIDET OG PASIENTSIKKERHET

Sett ett kryss for hver linje

Hvor enig eller uenig er du i følgende uttalelser? Tenk på din avdeling.	**Helt uenig**	**Uenig**	**Både/og**	**Enig**	**Helt enig**
I vår seksjon/avdeling støtter vi hverandre	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vi er tilstrekkelig personell til å håndtere arbeidsmengden	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Når det er mange oppgaver som skal gjøres raskt arbeider vi sammen som et team for å løse oppgavene	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I vår avdeling behandler vi hverandre med respekt	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I vår avdeling jobber vi lengre vakter enn hva som er best for pasientene	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vi jobber aktivt for å forbedre pasientsikkerheten	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vi bruker flere vikarer enn det som er til det beste for pasientbehandlingen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ansatte føler at feil blir brukt mot dem	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Feil (og uønskede hendelser) er blitt brukt for å få til positive forandringer her	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Det er kun en tilfeldighet at det ikke skjer flere alvorlige feil her i avdelingen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Når ett område i seksjonen/avdelingen er overbelastet hjelper andre i seksjonen/avdelingen til	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Når en uheldig hendelse blir rapportert, føles det som om personen og ikke problemet, kommer i sentrum	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Når vi har gjennomført endringer for å forbedre pasientsikkerheten, evaluerer vi effekten	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vi arbeider i "krisemodus" hvor vi forsøker å gjøre for mye, alt for raskt	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pasientsikkerhet blir aldri nedprioritert for å få unna mer arbeid	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ansatte er bekymret for at feilene de gjør blir registrert i deres personalmapper	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vi har problemer med pasientsikkerheten i vår avdeling	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Våre prosedyrer og systemer fungerer godt for å forhindre uønskede hendelser	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Jeg ber mine kolleger stanse arbeid som jeg mener blir utført på en risikabel måte	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Jeg melder fra dersom jeg ser farlige situasjoner	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. OM SIKKERHETEN TIL DE ANSATTE

Sett ett kryss for hver linje

Hvor enig eller uenig er du i følgende uttalelser? Tenk på din avdeling.	**Helt uenig**	**Uenig**	**Både/og**	**Enig**	**Helt enig**
Mine kolleger stopper meg dersom jeg arbeider på en usikker måte	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Jeg stopper å arbeide dersom jeg mener at det kan være farlig for meg eller andre å fortsette	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. DIN NÆRMESTE LEDER

Sett ett kryss for hver linje

Er du enig eller uenig i følgende uttalelser om din nærmeste overordnede eller den person, du refererer til?	**Helt uenig**	**Uenig**	**Både/og**	**Enig**	**Helt enig**
Lederen min uttrykker seg positivt når han/hun ser arbeidet blir utført i overensstemmelse med våre prosedyrer for å ivareta pasientenes sikkerhet	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Lederen min vurderer personalets forslag om forbedringer av pasientsikkerheten	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Når arbeidspresset øker, ønsker vår leder at vi arbeider raskere selv om det kan bety at man må ta "snarveier"	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Lederen min overser problemer med hensyn til pasientenes sikkerhet selv om en hendelse skjer gang på gang	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. KOMMUNIKASJON

Sett ett kryss for hver linje

Hvor ofte skjer følgende innenfor ditt arbeidsområde/fagområde? Tenk på din avdeling.	**Aldri**	**Sjeldent**	**Av og til**	**Ofte**	**Alltid**
Vi får tilbakemeldinger om endringer som blir igangsatt basert på rapporterte uønskede hendelser (Synergirapporter)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ansatte snakker åpent ut hvis de ser noe som kan påvirke pasientbehandlingen i negativ retning	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vi blir informert om uønskede hendelser som skjer i vår avdeling	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ansatte kan fritt stille spørsmål vedrørende beslutninger og handlinger tatt av personer med mer autoritet	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I denne enheten diskuterer vi hvordan vi kan forebygge at de samme uønskede hendelsene gjentas	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ansatte er redde for å stille spørsmål når det er noe som virker feil	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. VURDERING AV PASIENTSIKKERHETEN

Sett ett kryss

	Fremragende	**Meget god**	**Akseptabel**	**Dårlig**	**Meget dårlig**
Gi en generell vurdering av pasientsikkerheten i din avdeling.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. HYPPIGHET AV RAPPORTERTE UØNSKEDE HENDELSER

Sett ett kryss for hver linje

Hvor ofte blir nærhendelser rapportert (det vil si hendelser som blir oppdaget og avverget før de rekker å skade pasienten). Tenk på din avdeling.	**Aldri**	**Sjeldent**	**Av og til**	**Ofte**	**Alltid**
Hvor ofte blir nærhendelser rapportert - det vil si hendelser som blir oppdaget og avverget så pasienten ikke rekker å bli skadet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Hvor ofte blir feil som på ingen måte kan skade en pasient rapportert	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Hvor ofte blir potensielt skadevoldende feil rapportert - det vil si feil som kunne skade pasienten, men som ikke gjorde det?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. ANTALL UØNSKEDE HENDELSER SOM BLIR RAPPORTERT

Sett ett kryss

Hvor mange rapporter om uønskede hendelser (SYNERGI) har du utfylt og videresendt innenfor de seneste 12 månedene?	Ingen rapporter	1-2 rapporter	3-5 rapporter	6-10 rapporter	11-20 rapporter	21 rapporter eller flere
	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. OM SYKEHUSET

Sett ett kryss for hver linje

Er du enig eller uenig i følgende uttalelser om Haukeland Universitetssjukehus (HUS)? Tenk på sykehuset som helhet.	Helt uenig	Uenig	Både/og	Enig	Helt enig
Sykehusledelsen tilrettelegger for et arbeidsklima som fremmer pasientsikkerheten	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Avdelingene ved sykehuset er ikke er ikke flinke til å koordinere seg med hverandre	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ting "faller mellom to stoler" når pasienter blir overflyttet fra en avdeling til en annen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Samarbeidet fungerer godt mellom avdelinger som har behov for å jobbe sammen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Informasjon som er viktig i pasientbehandlingen går ofte tapt ved vaktskifte	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Det er ofte vanskelig å arbeide sammen med personale fra andre avdelinger/klinikker	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Det oppstår ofte problemer i forbindelse med utveksling av informasjon mellom avdelinger	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Toppledelsens handlinger viser at pasientsikkerheten har topp prioritet	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sykehusledelsen virker kun interessert i pasientsikkerhet etter at en uønsket hendelse har skjedd	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sykehusets avdelinger arbeider godt sammen for å sikre at pasienten får den beste behandlingen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Vaktskifte er problematisk for pasientene på sykehuset	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. SYSTEMER OG TILTAK

Sett ett kryss for hver linje

Denne delen omhandler systemer og tiltak.	**Helt uenig**	**Uenig**	**Både/og**	**Enig**	**Helt enig**	**Vet ikke**
Etableringen av rapporteringssystemet SYNERGI har påvirket pasientsikkerhetsarbeidet ved HUS i positiv retning	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6
Det siste året har jeg fått tilstrekkelig opplæring og trening til å ivareta pasientsikkerhet i jobben min	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6
I seksjonen/avdelingen jeg jobber har vi gjennomført tiltak for å forbedre pasientsikkerheten det siste året	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6
Rapporteringssystemet SYNERGI fungerer godt for å rapportere hendelser	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6
Rapporteringssystemet SYNERGI fungerer godt for å lære av hendelser	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6
HUS har gode systemer og tiltak for å ivareta pasientsikkerheten	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6
I min avdeling er systemer og tiltak for pasientsikkerhet bedre tilrettelagt nå enn for 2 år siden	□ 1	□ 2	□ 3	□ 4	□ 5	□ 6

10. Hva er ditt primære arbeidsområde/fagområde?

Sett ett kryss

Kirurgi	☐ 1
Gynekologi/obstetrikk	☐ 2
Akuttmedisin	☐ 5
Intensiv behandling	☐ 4
Anestesi	☐ 5
Operasjon	☐ 6
Flere forskjellige områder	☐ 7

12. Er din stilling forbundet med direkte kontakt med pasienter? Sett ett kryss

JA, jeg har direkte kontakt med pasienter	☐ 1
NEI, jeg har ikke direkte kontakt med pasienter	☐ 2

11. Hvilken faggruppe tilhører du? Marker det svaret som best beskriver din stilling.

Sett ett kryss

Seksjonsleder	☐ 1
Fagsykepleier/fagutviklingssykepleier	☐ 2
Operasjonssykepleier	☐ 3
Anestesisykepleier	☐ 4
Intensivsykepleier	☐ 5
Overlege (avd. overlege, seksjonsoverlege)	☐ 6
Assistentlege > 2 års praksis	☐ 7
Assistentlege	☐ 8
Turnuslege	☐ 9
Portør	☐ 10
Merkantilt personell	☐ 11
Administrasjon (avdelings-/klinikkledelse)	☐ 12
Annen	☐ 13

13. Hvor mange timer i uken arbeider du gjennomsnittlig på dette sykehuset?

Sett ett kryss

Mindre enn 20 timer i uken	☐ 1
20-37 timer i uken	☐ 2
Mer enn 37 timer i uken	☐ 3

14. Hvor lang tid har du arbeidet på dette sykehuset?

Sett ett kryss

Mindre enn 1 år	☐ 1
1-5 år	☐ 2
6-10 år	☐ 3
11-15 år	☐ 4
16-20 år	☐ 5
21 år eller mer	☐ 6

15. Hvor lang tid har du arbeidet med din nåværende spesialitet eller fag?

	Sett ett kryss
Mindre enn 1 år	☐ 1
1-5 år	☐ 2
6-10 år	☐ 3
11-15 år	☐ 4
16-20 år	☐ 5
21 år eller mer	☐ 6

16. Her kan du fritt skrive dine kommentarer til pasientsikkerhet, feil, rapportering på sykehuset og lignende

____

____

____

____

____

____

9.3 Modified Norwegian WHO SSC: Sjekkliste for Trygg Kirurgi

Table A2

Forberedelse
før innledning av anestesi

Har pasienten bekreftet?
- ☐ Identitet
- ☐ Operasjonsfelt
- ☐ Type inngrep

Er operasjonsfelt merket?
- ☐ Ja
- ☐ Ikke aktuelt

Er anestesisjekk utført og medikamenter kontrollert?
- ☐ Ja

Har pasienten:

Kjent allergi?
- ☐ Ja
- ☐ Nei

Vanskelig luftvei / risiko for aspirasjon?
- ☐ Ja, og utstyr / assistanse er tilgjengelig
- ☐ Nei

Risiko for >500 ml blodtap? (>7 ml / kg hos barn)
- ☐ Ja, og adekvat intravenøs tilgang og væske er tilgjengelig
- ☐ Nei

Risiko for hypotermi?
- ☐ Ja, og tiltak er planlagt eller iverksatt
- ☐ Nei

Er nødvendig billedinformasjon tilgjengelig?
- ☐ Ja
- ☐ Ikke aktuelt

Sjekkliste for trygg kirurgi

Time-out
før operasjonsstart

Er alle i teamet presentert for hverandre med navn og funksjon?
- ☐ Ja

Kirurg, operasjonssykepleier, anestesilege og anestesisykepleier bekrefter muntlig:
- ☐ Hva er pasientens navn og identitet?
- ☐ Hva er planlagt prosedyre, operasjonsfelt og -side?
- ☐ Er pasienten i rett leie?

Gjennomgang av potensielt risikofylte hendelser

Kirurg:
- ☐ Hva er forventet blodtap?
- ☐ Er det noen risikofaktorer teamet bør kjenne til?
- ☐ Er det behov for spesielt utstyr eller ekstra undersøkelser?
- ☐ Hva er forventet varighet av operasjonen?

Anestesilege og anestesisykepleier:
- ☐ Hva er pasientens ASA-klassifikasjon?
- ☐ Er det særlige risikofaktorer ved anestesien som teamet bør kjenne til?

Operasjonssykepleier:
- ☐ Er steriliteten på instrumentene bekreftet (inkludert indikatorer)?
- ☐ Er det utfordringer knyttet til bruken av utstyret?

Perfusjonist (når aktuelt):
- ☐ Er det noen risikofaktorer teamet bør kjenne til?
- ☐ Er det behov for spesielt utstyr?

Infeksjonsforebyggende tiltak
- ☐ Ikke aktuelt
- ☐ Er antibiotikaprofylakse fullført i løpet av de siste 60 minuttene?
- ☐ Er pasientoppvarming iverksatt?
- ☐ For pasienter med diabetes: Er blodsukkeret innenfor normalområdet?

Er tromboseprofylakse aktuelt? ☐ Ja ☐ Nei

Avslutning
før hovedoperatør forlater operasjonsfeltet

Teamet gjennomgår muntlig:
- ☐ Hvilke inngrep er gjennomført?
- ☐ Stemmer antall instrumenter, kompresser/duker og nåler (eller ikke aktuelt)?
- ☐ Er prøvematerialet riktig merket, inklusive pasientens identitet?
- ☐ Har det vært problemer med utstyret som det skal varsles om?
- ☐ Hva er viktig for postoperativ behandling av denne pasienten?

Merknader / funn:

Dato og pasientidentifikasjon:

Modifisert HUS versjon 1.1 / 11 12 2009

Table A2 (continued)

kunnskapssenteret PASIENTSIKKERHET
Nasjonal enhet for pasientsikkerhet

HELSE BERGEN
Haukeland universitetssjukehus

Helse Førde

Sjekkliste for trygg kirurgi

Denne norske sjekklisten er laget med utgangspunkt i Verden helseorganisasjons (WHO) "Surgical safety checklist" http://www.who.int/patientsafety/safesurgery/en/ og den tilretteleggingen som er laget for England og Wales http://www.npsa.nhs.uk/nrls/

Nasjonal enhet for pasientsikkerhet har stått for oversettelsen i samarbeid med **Helse Bergen og Helse Førde.** Sjekklisten sendes til høring hos regionale fagdirektører, i det norske fagmiljøet og til FFO.

Sjekklisten er ikke uttømmende og lokale tilrettelegginger kan gjøres. Det advares mot å gjøre listen for omfattende og å stryke mange punkt.

Sjekkliste for trygg kirurgi

Modifisert HUS versjon 1.1 / 11 12 2009

9.4 Confirmatory factor analysis

To test the hypothesis concerning the twelve-factor structure of the HSOSP, we performed confirmatory factor analysis (CFA) on the survey's combined data set obtained at baseline and after implementation of the WHO SSC. We used goodness-of-fit indices to investigate whether the twelve factor structure would fit the data. The statistical analysis was conducted in Amos version 20 (SPSS, Chicago, Il, US). Fit indices included the following: subjective chi-square/degree of freedom ratio of <2.0; the root mean square error of approximation (RMSEA) adjusted for the error approximation in the population and to take into account the complexity of the model with values <0.05, indicating good model fit; baseline comparison fit index (CFI) should be at least 0.90; and a parsimony-adjusted index exceeding 0.50.[iii] Amos also provided a closeness of fit P_{close} test, with a recommended value of >0.50.[iv] Hoelter's criterion (0.05 indices), with a sample size value above 200, indicates that the model adequately represents the sampled data.[v]

The analysis resulted in satisfactory CFA scores for the twelve-factor structure of the HSOPS used in studies 1 and 2 (reported in Papers 1 and 2). The chi-square/degree of freedom ratio was 1.831; CFI was 0.89; the parsimony-adjusted index was 0.74; RMSEA was 0.048 (90% CI, 0.44-0.52), with a P_{close} of 0.760; and Hoelter's criterion was 212. For the eleven-factor structure model suggested in study 1 and described in Paper 1, the CFA scores showed that the data did not satisfy the fit indices values, as

[iii] Byrne BM. Structural Equation Modelling With AMOS: Basic Concepts, Applications, and Programming Multivariate applications series. New York: Routledge, Taylor and Francis Group, 2010.

[iv] Hu L-T, Bentler PM. Cut-off criteria for fit indices in covariance structure analysis: Conventional criteria versus new alternatives. *Psychol Methods* 1999; 3:424-453.

[v] Hu L-T, Bentler PM. Evaluating model fit. In: Hoyle RH, ed. Structural equation modelling: Concepts, issues, and applications. Thousand Oaks, CA: Sage, 1995; pp. 76-99.

mentioned above. The findings supported the original twelve-factor structure and provided no incentive to change the factor structure of the HSOSP.

9.5 Consort 2010 report for a cluster RCT (Paper 3)

Section/Topic	Item No	Standard checklist item	Extension for cluster designs	Page No *
Title and abstract		**Effect of the WHO Checklist on Patient Outcomes: A Stepped-Wedge Cluster RCT**		1
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1,1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[vi,vii]	See Table 2	2,3
Introduction				4
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level, or both	5
Methods				5
Trial design	3a	Description of trial design (such as parallel, factorial), including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with		-

vi Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomized trials in journal and conference abstracts. *Lancet* 2008; 371:281-283.

vii Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 2008; 5(1): e20.

		reasons		
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6, 5
	4b	Settings and locations where the data were collected		5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level, or both	5,6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level, or both	6,6
	6b	Any changes to trial outcomes after the trial commenced, with reasons		-
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	8/-
	7b	When applicable, explanation of any interim analyses and stopping guidelines		-
Randomisation:				6
Sequence generation	8a	Method used to generate the random allocation sequence		6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching, if used	-
Allocation concealment	9	Mechanism used to implement the random	Specification that allocation was based on clusters rather than	-,5

mechanism		allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace with 10a, 10b, and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	-
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both) and whether consent was sought before or after randomisation	14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		**7**
	11b	If relevant, description of the similarity of interventions		**-**
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	8
	12b	Methods for additional analyses, such as subgroup		8

		analyses and adjusted analyses		
Results				8
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Supplement
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	Supplement
Recruitment	14a	Dates defining the periods of recruitment and follow-up		6,23
	14b	Why the trial ended or was stopped		-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	18-19
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	18-19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intra-cluster correlation (ICC or k) for each primary outcome	9,20-21
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		20-21
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified		20 +supplement

		from exploratory		
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[viii])		-
Discussion				10
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		11
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	Generalizability to clusters and/or individual participants (as relevant)	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		10-13
Other information				-
Registration	23	Registration number and name of trial registry		YES/NA
Protocol	24	Where the full trial protocol can be accessed, if available		Supplement
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		14

Source: Cluster Trials 2012. Available at: http://www.consort-statement.org/extensions/designs/cluster-trials/. Accessed 20 February 2014.

[viii] Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

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RESEARCH ARTICLE Open Access

Patient safety in surgical environments: Cross-countries comparison of psychometric properties and results of the Norwegian version of the Hospital Survey on Patient Safety

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Abstract

Background: How hospital health care personnel perceive safety climate has been assessed in several countries by using the Hospital Survey on Patient Safety (HSOPS). Few studies have examined safety climate factors in surgical departments per se. This study examined the psychometric properties of a Norwegian translation of the HSOPS and also compared safety climate factors from a surgical setting to hospitals in the United States, the Netherlands and Norway.

Methods: This survey included 575 surgical personnel in Haukeland University Hospital in Bergen, an 1100-bed tertiary hospital in western Norway: surgeons, operating theatre nurses, anaesthesiologists, nurse anaesthetists and ancillary personnel. Of these, 358 returned the HSOPS, resulting in a 62% response rate. We used factor analysis to examine the applicability of the HSOPS factor structure in operating theatre settings. We also performed psychometric analysis for internal consistency and construct validity. In addition, we compared the percent of average positive responds of the patient safety climate factors with results of the US HSOPS 2010 comparative data base report.

Results: The professions differed in their perception of patient safety climate, with anaesthesia personnel having the highest mean scores. Factor analysis using the original 12-factor model of the HSOPS resulted in low reliability scores (r = 0.6) for two factors: "adequate staffing" and "organizational learning and continuous improvement". For the remaining factors, reliability was ≥ 0.7. Reliability scores improved to r = 0.8 by combining the factors "organizational learning and continuous improvement" and "feedback and communication about error" into one six-item factor, supporting an 11-factor model. The inter-item correlations were found satisfactory.

Conclusions: The psychometric properties of the questionnaire need further investigations to be regarded as reliable in surgical environments. The operating theatre personnel perceived their hospital's patient safety climate far more negatively than the health care personnel in hospitals in the United States and with perceptions more comparable to those of health care personnel in hospitals in the Netherlands. In fact, the surgical personnel in our hospital may perceive that patient safety climate is less focused in our hospital, at least compared with the results from hospitals in the United States.

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Background

Patient safety climate in hospitals has recently gained greater attention. The Hospital Survey on Patient Safety (HSOPS) has been used widely to measure the safety culture in hospitals in the United States since it was introduced in 2004 [1,2]. The HSOPS is translated to 17 languages and used in 30 countries [3]. The psychometric properties of the HSOPS have been assessed in the US, the Netherlands, United Kingdom and Norway in large-scale studies on safety attitudes among health care providers in hospitals with varying results [1,4-6]. The results from UK and the Netherlands suggest deviations from the 12 factor structure of the questionnaire and the reliability tests vary between the factors; ranging from r = 0.49 to r = 0.83 [4,5]. The previous psychometric evaluation of the Norwegian version of HSOPS presented a 12 factor structure of which one had very low reliability "organizational learning - continuous improving" (r = 0.51) and also five other factors had lower reliability (r < 0.7) than recommended [6]. Further, other results indicate that the outcome variable "number of events reported" is probably not useful as an outcome measure [5,7]. Except for these limitations, the validity of the Norwegian HSOPS version was satisfactory regarding the confirmative factor analysis and construct validity [6,8]. The study was performed at one teaching hospital and concluded that further studies of the questionnaires psychometric properties is required, subsequently in Norwegian university hospitals to gain more knowledge of these properties [6].

The HSOPS can be regarded as measuring the patient safety climate giving a picture of the safety culture at a specific time point. The developers of the survey recommend not using the word "culture" as it tends to be confused with ethnicity or race [2]. Studies focusing on safety climate in the fields of surgery or anaesthesia have previously been performed using tools like the Safety Attitudes Questionnaire; however, for the HSOPS, the safety climate of operating theatre personnel has not been focused as one environment [1,2,4-11].

Operating theatres can be described as being units of high complexity and hazard with high potentials for patient harm and adverse events. Adverse events occur in 2.9-16.6% of admitted hospital patients, many of these (37-51%) probably being preventable [12-20]. More than half of all adverse event cases (51-62%) are associated with surgical services [19,21,22]. De Vries *et al.* categorize the types of adverse events as operation- or drug- related and majority of these events are located at the operating theatres [21]. Safety attitude instruments presents relationship to patient outcomes as correlations to fewer medical errors [23,24]. Promoting high reliability care in the surgical environment as the operating theatre needs a strong patient safety climate [25,26].

The objective of this study was to examine psychometric properties of the Norwegian HSOPS and compare our results to comparative database results from hospitals in the United States and to results from the Netherlands and Norway.

Methods

Design

This study was a cross-sectional survey examining perceptions of patient safety climate in operating theatre personnel using the validated Norwegian version of the HSOPS [1,5,6]. The Norwegian version of the HSOPS has previously been validated for paper distribution [7]. The questionnaire was translated into Norwegian before it was retranslated back to English, processed by two independent researchers. A pilot test was performed using health care personnel, to ensure that the concepts were correctly worded and conceptualized [8]. We performed the survey using a mixed distribution method, with a web and a paper version of the HSOPS. Before we distributed the survey, eight health care workers and research personnel pilot tested the readability and functionality of the web-based version. This pilot test resulted in splitting the first section of the HSOPS into two separate sections to improve readability. The Norwegian version has not previous been validated using a mixed distribution method.

Sample

The sample consisted of operating theatre personnel at Haukeland University Hospital, Bergen, Norway: surgeons, anaesthesiologists, operating theatre nurses, nurse anaesthetists and ancillary personnel (unit assistants, clerks and cleaning assistants) present at work during a four week study period in October and November 2009. The hospital is one of the largest in Norway with 1,100 beds and about 10,000 employees, serving a population of 950,000 as a referral hospital and 500,000 as an emergency hospital. The annual number of surgical procedures exceeds 24,000. The following surgical departments were included in the survey: orthopaedic; thoracic; neuro-; ear, nose and throat; maxillofacial; plastic; endocrine; urinary; gastrointestinal; and obstetric surgery. Of the eligible personnel 575 individuals were invited to participate. Thirty-one enlisted personnel were absent during the study period due to vacation, illness, working other places, education or specialist training and were not included.

Selection of the clinical setting of this sample presents a large number of physicians; surgeons and anaesthesiologists, compared to specialist nurses contrasting other patient safety climate studies which included all health care personnel of the hospitals [5-7,10,11]. The operating theatre personnel are located at three separate locations: the largest of them are the central operating unit with 19 operating theatres, the women's clinic with 5 operating theatres in a separate building, and the day surgical unit with 2 operating theatres being physical connected to the central operating unit.

Data collection

We distributed the web-based questionnaire to the operating theatre personnel through the hospital e-mail system. A paper version was sent to the personnel not responding to e-mail reminders. Physicians received two e-mail reminders before being sent the paper version. The operating theatre nurses, nurse anaesthetists and ancillary personnel received the paper version after one reminder. Some of the operating theatre personnel had logistical and technical difficulties in responding to the web-based questionnaire, such as being unable to gain access to the web version when using common log-on procedures and not having enough time in between daily routines. Identification numbers were assigned to or printed on each questionnaire to identify the working area or unit. We preserved the anonymity of data collection for the paper version by having respondents use closed envelopes addressed to the primary investigator (ASH) through the hospital's internal mail system. A consultant at the hospital research and development department administered the web-based questionnaire.

Data screening

We examined data and checked for errors. Respondent who answered less than half the questionnaire items were excluded. Five respondents had chosen two options in one item, and we allocated these to the most positive or negative value of the categories [27]. The highest number of missing values was in the factor "frequency of events reported", which had missing values in 5.3% of the items. In the remaining factors, missing values were present in 0.3% to 3.1% of the cases. We did not exclude any items based on these few missing values and replaced them by the mean scores of the item.

Questionnaire

Westat developed the HSOPS for the United States Agency for Healthcare Research and Quality as a safety culture assessment tool. Patient safety culture factors were selected based on a literature review of research pertaining to safety, error and accidents and an examination of previously existing safety culture assessment tools [27]. During the development of the HSOPS, hospital employees and administrators were interviewed to identify key issues related to patient safety and error reporting. The factors and items finally included in the HSOPS were selected to reveal information on relevant safety topics and to ensure satisfactory psychometric properties [6,24,26,27]. The HSOPS displays the perceptions of patient safety climate in 12 factors (Table 1). The patient safety climate factors contain three or four items each (a total of 42 items) and are all measured on a Likert scale, with a score from 1 to 5 on level of agreement: strongly disagree (1), disagree (2), neutral (3), agree (4) and strongly agree (5) [2]. The HSOPS also comprises two single-item outcome measures:

- the patient safety grade, scored from 1 to 5; failing (1), poor (2), acceptable (3), very good (4) or excellent (5); and
- the number of adverse events reported by the respondent during the last year, scored from 1 to 6; no events (1), 1-2 events (2), 3-5 events (3), 6-10 events (4), 11-20 events (5) and ≥ 21 events (6).

Sample characteristics are included such as profession, clinical experience, working hours during the week and working area or unit. Results are compared with data from 885 United States hospitals, the Hospital Survey on Patient Safety: 2010 User Comparative Database Report, as well as data from three hospitals in the Netherlands and one university hospital in Norway [2,5,6,8]. The results are presented as percent of average positive response (agree or strongly agree) in each item and factor, the highest percentage being the most positive. Sorra et al. [2] describe the method of calculation. In the previous psychometric evaluation study of the Norwegian version of the HSOPS, the twelve factors were classified as outcome variables (factor 1 and 2),

Table 1 Patient safety climate factors of the HSOPS used in the HSOPS study at Haukeland University Hospital, Bergen, Norway in October-November 2009

Patient safety climate factors of the HSOPS	Items
1. Overall perception of safety	4
2. Frequency of events reported	3
3. Supervisor or manager expectations and actions promoting patient safety	4
4. Organizational learning - continuous improvement	3
5. Teamwork within units	4
6. Communication openness	3
7. Feedback and communication about error	3
8. Non-punitive response to error	3
9. Adequate staffing	4
10. Hospital management support for patient safety	3
11. Teamwork across hospital units	4
12. Hospital handoffs and transitions	4

measures at hospital unit level (factor 3-9) and at an overall hospital level (factor 10-12) [6].

Statistical analysis

Descriptive statistics was used to display the frequencies of sample characteristics and patient safety climate factors. Negatively worded items were reversed to ensure that positive answers indicated a high score. For the 12 factors of the HSOPS questionnaire inferential statistics were used. To analyse differences in the means of explanatory variables according to profession and surgical departments' one-way analysis of variance was used. To investigate whether the HSOPS would fit with the data from a surgical environment sample in Norway we performed factor analysis using Varimax rotation [28]. Bartlett's test was used to examine if the inter-item correlations were sufficient. The chi-square distribution should correspond with the significance level of $P = 0.05$ [29]. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy, with value range from 0 to 1, should exceed 0.5 to meet Kaiser's criterion [30]. The internal consistency of the factors was assessed by intra-class correlations and by Cronbach's alpha. For the factors to be consistent the alphas should exceed 0.7 [31]. We measured correlations by Pearson's correlation coefficient and internal consistency by Cronbach's alpha. We used SPSS (version 17.0) for Windows for data analysis [32].

Ethics

The study was performed according to the ethical standards of the Helsinki Declaration [33]. The hospital research manager and the unit management leaders approved the study. The Committee for Medical Research Ethics of Western Norway reviewed the study and responded that approval was not necessary according to Norwegian law, since the study did not involve patients. The data privacy unit at Haukeland University Hospital consented to the project.

Results

Sample

The final sample included 575 operating theatre personnel. The overall response rate ($n = 358$) for the survey was 62% (358/575) and, for each profession: surgeons 56% (126/225), anaesthetists 62% (47/76), operating theatre nurses 61% (84/138), nurse anaesthetists 84% (62/74) and ancillary personnel 63% (39/62). Physicians represented 48% of the respondents, nurses 41% and ancillary personnel 11%. Ninety-four percent of the personnel had been in direct contact with patients. Among the operating theatre personnel, 54% worked more than 37 hours, 41% worked 20-37 hours and 4% worked less then 20 hours per week. Forty-two percent of the respondents were male and 58% female. The participants responded using the web version in 59% of the cases, and 41% used the paper version as their final entry. Table 2 lists the sample characteristics.

Background variables

Two of the 12 patient safety culture factors were considered outcome variables: "overall perception of safety" and "frequency of events reported". Seven of the remaining 10 factors were classified to be measured at the hospital unit level and the last three at the hospital level. The means of these factors were compared according to the background variables using one-way analysis of

Table 2 Characteristics of 358 respondents to the HSOPS in Haukeland University Hospital, Bergen, Norway, October-November 2009

Characteristics (*n*)	Category	*n*	(%)
Professions ($n = 358$)	Senior physician[a]	96	(26.6)
	Physician[a] > 2 years experience	52	(14.6)
	Physician[a] < 2 years experience	18	(5.0)
	Operating theatre nurse	68	(19.1)
	Nurse anaesthetist	74	(20.8)
	Ancillary personnel[b]	26	(7.2)
	Administration, unit level	24	(6.7)
	Missing	1	
Years at this hospital ($n = 352$)	< 1 year	17	(4.7)
	1-5 years	84	(23.5)
	6-10 years	67	(18.7)
	11-15 years	67	(18.7)
	16-20 years	43	(12.0)
	≥ 21 years	74	(20.7)
	Missing	6	
Years in profession ($n = 349$)	< 1 year	10	(2.9)
	1-5 years	99	(28.4)
	6-10 years	105	(30.1)
	11-15 years	41	(11.7)
	16-20 years	27	(7.7)
	≥21 years	67	(19.2)
	Missing	9	
Hours per week ($n = 355$)	< 20 hours	16	(4.5)
	20-37 hours	145	(40.8)
	> 37 hours	194	(54.7)
	Missing	3	
Sex ($n = 358$)	Male	150	(41.9)
	Female	208	(58.1)

[a]Physician: surgeons and anaesthesiologists.

[b]Ancillary personnel: unit assistants, clerks and cleaning assistants.

variance (ANOVA). Additional file 1: Table S1 presents the results for the various professions; the mean factor scores ranged from 2.80 to 3.55 between the five professional groups (ANOVA: $P < 0.01$). The mean factor scores of the two outcome variables differed between the professions ($P < 0.01$). In addition the mean factor scores differed within the variable "surgical departments" (ANOVA: $P < 0.05$) except for the factors "frequency of events reported" and "non-punitive response to error".

Reliability and validity

The internal consistency of the patient safety climate factors was confirmed when measured using Cronbach's alpha, ranging from 0.64 to 0.85, except for the factor "adequate staffing", the internal consistency was 0.59. The correlations found supported discriminate and construct validity. The unit-level factors had mutual correlations ranging from 0.20 to 0.61 ($P < 0.01$). The hospital-level factors had correlations varying from 0.26 to 0.62 ($P < 0.01$). The correlation between the outcome variables "patient safety grade" and "overall perception of safety" was 0.59 ($P < 0.01$). Additional file 2: Table S2 lists all correlations.

Factor analysis

Bartlett's test of the 42 patient safety climate items demonstrated a sufficient inter-item correlation: χ^2 = 6149; df = 946, $P < 0.001$. Further, the Kaiser-Meyer-Olkin measure of sampling adequacy was satisfactory, with a value of 0.91. Explorative factor analysis was performed using principal component analysis with Varimax rotation. Rotation converged after 11 iterations. Ten factors explained 60% of the total response variance. We compared the internal consistency measured by Cronbach's alpha with psychometric properties of the 2004 comparative database results from hospitals within the United States and the previous mentioned studies of the Netherlands and Norway (Table 3). For 10 of 12 factors, the Cronbach's alpha of our study was lower than those of the original factors from the United States data. Comparing the outcome variable "adequate staffing" resulted in unsatisfactory values on Cronbach's alpha ranging from 0.49 to 0.65. Combining the two factors "organizational learning and continuous improvement" with "feedback and communication about error" resulted in one factor with 6 items and an alpha value of 0.78.

Comparative results

The percent of average positive responses (agree, strongly agree) varied between 22% and 72% across the twelve patient safety climate factors of the HSOPS. The total average percent of the average positive responses in all the patient safety climate factors was 47% in our sample. Table 4 compares these results to comparative database results from hospitals in the United States and results from the Netherlands and Norway. Figure 1 illustrates the variation between the percent average positive responses in the twelve patient safety climate factors of this study compared with the results from the United States.

Discussion

Variation in safety climate perception

The variation in the perception of patient safety climate factors between different surgical departments and between different professions was in accordance with previous HSOPS studies in Norway, which found significant differences ($P < 0.001$) both between clinical departments and professions [6,8]. Here we found significant variations ($P < 0.05$) in mean scores between different surgical departments regarding the patient safety climate at the outcome and unit factor levels. Between the different professions, the variation found was significant ($P < 0.001$) for the patient safety climate at the outcome and unit factor levels. The anaesthesiologists and nurse anaesthetists had higher mean scores than the surgeons and operating theatre nurses, both in outcome variables and unit-level factors. The ancillary personnel had the lowest mean scores here. The group with less education and being most distant to the patients, the ancillary personnel, reports most negative as to the patient safety climate. This might imply that perceptions of the safety climate may vary between operating theatre personnel groups. However, this needs further investigation to be validated.

The HSOPS is assumed to measure patient safety climate within hospitals and hospital units [2]. This is supported by our results and by findings in hospitals in the Netherlands, with clustering of responses within hospitals and hospital units rather than between individuals [34]. Our results may indicate variation in safety climate perceptions within surgical units and between operating theatre professions. The findings of our study may also reflect a perception of distance between the management at the unit and hospital levels regarding involvement in patient safety issues. Involvement and support from hospital management are strongly associated with the success of patient safety initiatives [35,36].

Factor analysis

We used explorative factor analysis to investigate differences between our results and the comparative database results in the United States and results from the Netherlands and Norway [5,7,37]. The internal consistency of our data on operating theatre personnel was in-between

Table 3 Cross-countries comparison of internal consistency of explorative factor analysis of the HSOPS

			Explorative factor analysis			
Patient safety culture factors of the HSOPS[a]		**Items**	**United States [35] (n = 1437) Hospital environment Cronbach's α**	**Netherlands [5] (n = 3585) Hospital environment Cronbach's α**	**Norway [8] (n = 1919) Hospital environment Cronbach's α**	**Norway (n = 358) Operating environment Cronbach's α**
Outcome variables						
1.	Overall safety	4	0.74	0.62	0.76	0.78
2.	Frequency of events	3	0.84	0.79	0.82	0.82
Unit-level factors						
3.	Leader's expectations	4	0.75	0.70	0.79	0.85
4.	Continuous improvement	3	0.76	0.57	0.51	0.64
5.	Teamwork within units	4	0.83	0.66	0.77	0.75
6.	Open communication	3	0.72	0.72	0.68	0.67
7.	Error feedback	3	0.78	0.75	0.70	0.73
8.	Non-punitive	3	0.79	0.69	0.64	0.68
9.	Adequate staffing	4	0.63	0.49	0.65	0.59
Hospital-level factors						
10.	Management support	3	0.83	0.68	0.79	0.80
11.	Teamwork across units	4	0.80	0.68	0.65	0.73
12.	Handoffs and transitions	4	0.80	0.59	0.65	0.68

[a] Complete labels: 1: overall perceptions of safety; 2: frequency of events reported; 3; supervisors' or managers' expectations and actions promoting patient safety; 4: organizational learning - continuous improvement; 5: teamwork within units; 6: communication openness; 7: feedback and communication about error; 8: non-punitive response to error; 9: adequate staffing; 10: hospital management support for patient safety; 11: teamwork across hospital units; 12: hospital handoffs and transitions.

those of the comparative studies, but the factor "organizational learning - continuous improvement" (α = 0.64) was more satisfactory in this study than in previous studies in the Netherlands and Norway [5-7]. Combining the factor "organizational learning - continuous improvement" with "feedback and communication about error" into an 11-factor structure produced internal consistency (Cronbach's α = 0.78) that was as satisfactory as for the study in the Netherlands [5]. In the psychometric evaluation of the HSOPS within a large acute National Health Service trust in the United Kingdom, more than half the factors failed to achieve satisfactory internal consistency (α < 0.7). Their factor analysis with split-half sample validation was converted into nine dimensions [4]. The results from the United Kingdom are interesting when considering this necessary psychometric evaluation of the questionnaire. They contrast somewhat with our findings in Norway. The correlations and patterns in our study seem more consistent in the construct validity of the patient safety climate factors compared with the previously mentioned studies [4-7]. The Norwegian version of the HSOPS cannot be regarded as externally validated until more Norwegian surgical environments and hospitals have been surveyed and the results compared and validated against patient outcomes.

Comparative results

The health care personnel in United States hospitals generally seem to have a more positive perception of their hospitals' patient safety climate than operating theatre personnel in Norway. The largest difference in patient safety climate factors was found for the factor "hospital management support for patient safety", with a maximum 50 percentage-point difference in responses. These results, with the United States hospital personnel responding more positively, can be explained by cultural and organizational differences. Previous studies from Norway support our findings [6,8]. One explanation of the excessive variation could be that the owners of hospitals in Norway measure hospital managers not as much on patient safety as on financial results. Another major deviation from the United States 2010 User Comparative Database Report results in our study is for the factor "non-punitive response to error". The difference in positive responses is 28 percentage points, this time with the operating theatre personnel in Norway responding more positively. According to the Institute of Medicine of the United States National Academies, achieving a patient safety climate in which individuals are not blamed for errors (a non-punitive climate) may accomplish an important goal towards a safer health system [38]. Our

Table 4 Cross-countries comparison of percent of average positive responses in patient safety climate factors of the HSOPS to responses from operating theatre personnel at Haukeland University Hospital in October-November 2009

		United States [2]	Netherlands[a]	Norway [8]	Norway
Patient safety climate factors of the HSOPS[b]		Hospital environment *n* = 338,607	Hospital environment *n* = 3,779	Hospital environment *n* = 1,919	Operating environment *n* = 358
		%	%	%	%
	Outcome variables				
1.	Overall safety	65	52	-	57
2.	Frequency of events	62	38	28	31
	Unit-level factors				
3.	Leaders' expectations	75	62	72	65
4.	Continuous improvement	72	47	50	46
5.	Teamwork within units	80	84	68	57
6.	Open communication	62	69	64	58
7.	Error feedback	63	49	40	37
8.	Non-punitive	44	67	72	72
9.	Adequate staffing	56	62	49	52
	Hospital-level factors				
10.	Management support	72	32	25	22
11.	Teamwork across units	58	28	31	32
12.	Handoffs and transitions	44	40	39	31
Total average sum score		63	53	49	47

[a] Source: Wagner C, Smits M. *Patient safety culture. Differences between professions and countries* http://internationalforum.bmj.com/2010-forum/presentation-slides/wednesday/A7%20Wagner,%20Smits.pdf

[b] Complete labels: 1: overall perceptions of safety; 2: frequency of events reported; 3; supervisors' or managers' expectations and actions promoting patient safety; 4: organizational learning - continuous improvement; 5: teamwork within units; 6: communication openness; 7: feedback and communication about error; 8: non-punitive response to error; 9: adequate staffing; 10: hospital management support for patient safety; 11: teamwork across hospital units; 12: hospital handoffs and transitions.

results suggest that the surgical environment in our hospital seems to have a more non-punitive climate, although the "frequency of events reported" is 31 percentage points lower than in United States hospitals compared. The patient safety climate factor that correlated most strongly with this factor was "feedback and communication about error". We interpret that this may indicate that health care personnel experiencing feedback and communication about the errors reported would benefit the patient safety climate, giving incentives to the health care personnel to report events more frequently.

Our hospital has been using an electronic error reporting system for a relatively short time (3 years), and altering systems of error reporting may influence the frequency of reports. The difference in events reported between the hospitals in the United States and the HSOPS studies in Norway could also indicate a difference in cultural patterns. Our findings of low scores on "hospital management support in patient safety issues" may indicate that such tools as event reports and feedback on such reports should be used more extensively to motivate reports even further.

The perception of patient safety climate of our surgical environment and the hospitals in the studies previously mentioned seem to differ from those of the hospitals in the United States. Although there are minor differences in the factor structure, the variation in average positive responses of the twelve HSOPS factors, indicate differences in perceptions of the climate [4-6]. In fact, the surgical personnel in our hospital may perceive that this particular surgical environment has a lenient attitude towards patient safety climate. Low hospital management support results in low reporting of errors and a subsequent low frequency of feedback to the surgical units and personnel. This, together with few or no punitive measures, may create a low standard of patient safety as a final result.

Limitations of the study

Several questionnaires are used worldwide to measure patient safety culture or climate, including the "Patient Safety Climate in Healthcare Organizations" [39], the "Culture of Safety Survey" [40], the "Safety Attitudes Questionnaire" [41] and the Hospital Survey of Patient

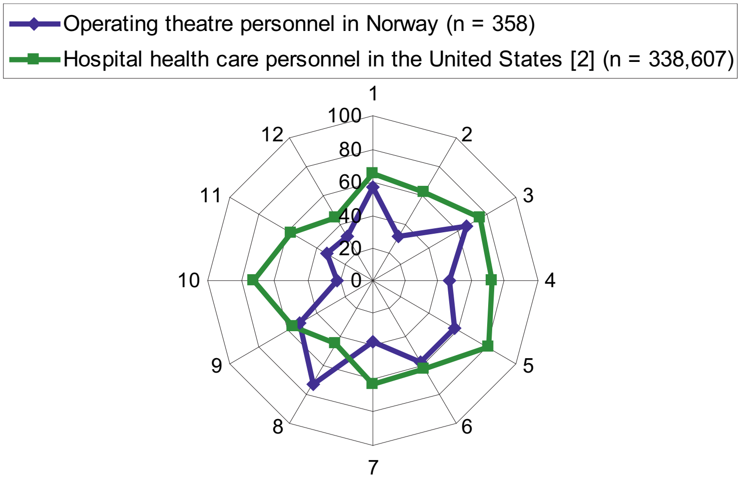

Figure 1 Comparison of percent average positive responses of the HSOPS's patient safety climate factors between operating theatre personnel in Haukeland University Hospital in Norway October-November 2009 and hospital health care personnel in the United States (HSOPS 2010 user comparative database report). *Outcome variables*. 1. Overall perceptions of safety. 2. Frequency of events reported. *Unit-level factors*. 3. Supervisors' or managers' expectations and actions promoting patient safety. 4. Organizational learning - continuous improvement. 5. Teamwork within units. 6. Communication openness. 7. Feedback and communication about error. 8. Non-punitive response to error. 9. Adequate staffing. *Hospital-level factors*. 10. Hospital management support for patient safety. 11. Teamwork across hospital units. 12. Hospital handoffs and transitions

Safety [1,2]. Evaluation of the psychometric properties of safety culture instruments have been performed in various ways [24,26]. Generally, these instruments measure abstract phenomena termed factors or dimensions from self reported perceptions of safety culture or safety attitudes. Such factors are by Byrne defined as indicators of the underlying construct they are presumed to represent. The use of sound psychometric instruments is then even more critical when the items measured are presumed to represent an underlying construct or factor [42]. When interpreting patient safety climate surveys one should have this limitation in mind.

This study is carried out in a single hospital, which limits the external validity of it even though the results are quite similar to the previous Norwegian studies [6,7]. The largest respondent group was the surgeons, who also had the lowest overall response rate (56%). Although the investigators persisted in informing the personnel about the survey, several respondents may have missed out on the information. We have not performed an analysis on nonresponders and cannot rule out the possibility of bias of variations in the mean scores between the professions. The average numbers of respondents in the studies compared varied from 37% to 56%; our overall response rate was 62%, however a response rate exceeding 70% would have been favourable [2,4,6,7].

Conclusions

The psychometric properties of the Norwegian version of the HSOPS needs further investigation in surgical environments to be regarded as an appropriate instrument for assessing the patient safety climate among operating theatre personnel in large hospitals in Norway. The factor structures of the HSOPS questionnaire used in the United States, the Netherlands and Norway have minor differences. All originally defined items could be used, and internal consistency became more acceptable with the two factors "organizational learning - continuous improvement" and "feedback about and learning from error" combined into one six-item factor, supporting an 11-factor model. We found that professions and surgical departments differed in the perception of patient safety culture, but mainly the health care personnel in the United States and the surgical environments in Haukeland university hospital, differed regarding the patterns of patient safety climate. In fact, the operating theatre personnel in our hospital may perceive that patient safety climate is less focused in our hospital, at least compared with the results from hospitals in the United States.

Additional material

Additional file 1: Table S1: Patient safety climate factors according to profession in a large operating theatre environment at Haukeland University Hospital in October-November 2009: one-way analysis of variance of means. Table S1 presents the results of one-way analysis of variance of means according to profession and patient safety climate factors.

Additional file 2: Table S2: Descriptive statistics[a], intra-class correlations[b] and correlations[c] for outcome variables and sub dimensions of the HSOPS from the operating theatre personnel (*n* = 358) at Haukeland University Hospital in October-November 2009. Table S2 presents the results of correlations between the patient safety climate factors.

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Authors' contributions

All authors contributed to the design and execution of the study. ASH, ES and SH conceived of and designed the study. ASH performed the data collection and drafted the manuscript. ASH and GEE performed the data analysis and all the authors contributed to the interpretation. ES, GEE, MWN, KA and SH contributed to and revised the manuscript critically for intellectual content. All authors read and approved the final draft.

Competing interests

The authors declare that they have no competing interests.

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Additional file 1

Table S1: Patient safety climate factors according to profession in a large operating theatre environment at Haukeland University Hospital in October–November 2009: one-way analysis of variance of means

Patient safety climate factors[a]	All $n = 358$	Anaesthetists $n = 47$		Operating theatre nurses $n = 84$		Surgeons $n = 126$		Nurse anaesthetists $n = 62$		Ancillary personnel $n = 39$		Total $n = 358$
	Mean	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	*P*
Outcome variables												
1 Overall safety	3.55	3.63	3.45–3.81	3.48	3.35–3.62	3.62	3.50–3.73	3.65	3.53–3.77	3.24	3.01–3.46	0.007
2 Frequency of events	2.80	3.22	3.01–3.44	2.66	2.49–2.83	2.61	2.48–2.74	3.12	2.93–3.32	2.64	2.72–2.88	<0.0001
Unit-level factors												
3 Leader's expectations	3.64	3.77	3.54–4.01	3.58	3.41–3.75	3.73	3.59–3.86	3.85	3.68–4.03	2.96	2.66–3.26	<0.0001
4 Continuous improvement	3.34	3.54	3.37–3.72	3.37	3.24–3.50	3.23	3.12–3.34	3.53	3.36–3.70	3.07	2.78–3.36	0.001
5 Teamwork within units	3.59	3.80	3.64–3.96	3.44	3.32–3.55	3.66	3.54–3.78	3.73	3.58–3.88	3.21	3.05–3.37	<0.0001
6 Open communication	3.58	3.66	3.52–3.80	3.60	3.47–3.73	3.63	3.50–3.75	3.75	3.60–3.90	3.00	2.78–3.22	<0.0001
7 Error feedbacks	3.17	3.21	3.09–3.37	3.20	3.03–3.37	3.11	3.00–3.23	3.48	3.28–3.69	2.72	2.49–2.95	<0.0001
8 Non-punitive	3.74	4.05	3.88–4.23	3.75	3.62–3.88	3.77	3.63–3.89	4.00	3.87–4.12	3.00	2.73–3.28	<0.0001
9 Adequate staffing	3.38	3.55	2.77–3.22	3.31	3.17–3.45	3.45	3.32–3.63	3.49	3.34–3.63	2.98	2.78–3.18	<0.0001
Hospital-level factors												
10 Management support	2.81	2.99	2.77–3.22	2.74	2.61–2.87	2.93	2.79–3.08	2.68	2.51–2.85	2.62	2.29–2.94	0.03
11 Teamwork across units	3.12	3.08	2.93–3.23	3.09	2.98–3.20	3.22	3.11–3.32	3.06	2.95–3.16	3.08	2.92–3.24	0.20
12 Handoffs and transitions	3.04	2.93	2.74–3.12	3.00	2.88–3.12	3.11	2.99–3.23	3.09	2.97–3.21	2.89	2.71–3.06	0.20

[a] Complete labels: 1: overall perceptions of safety; 2: frequency of events reported; 3: supervisors' or managers' expectations and actions promoting patient safety; 4: organizational learning – continuous improvement; 5: teamwork within units; 6: communication openness; 7: feedback and communication about error; 8: non-punitive response to error; 9: adequate staffing; 10: hospital management support for patient safety; 11: teamwork across hospital units; 12: hospital handoffs and transitions. CI: confidence interval.

Additional file 2

Table S2: Descriptive statistics[a], intra-class correlations[b] and correlations[c] for outcome variables and sub dimensions of the HSOPS from the operating theatre personnel (n = 358) at Haukeland University Hospital in October–November 2009

	Items	Mean	SD	α	PSG	AE	1	2	3	4	5	6	7	8	9	10	11
Outcome variables																	
Patient safety grade	1	3.56	0.58	–													
Adverse events	1	1.84	1.04	–	0.09												
1 Overall safety	3	3.55	0.62	0.78	0.59*	0.08											
2 Frequency of events	3	2.80	0.78	0.82	0.28**	0.30**	0.28*										
Unit-level factors																	
3 Leaders' expectations	4	3.64	0.80	0.85	0.45**	0.16**	0.53**	0.36**									
4 Continuous improvement	3	3.34	0.66	0.64	0.39**	0.13*	0.45**	0.41**	0.48**								
5 Teamwork within units	4	3.59	0.61	0.75	0.43**	0.16**	0.53**	0.30**	0.56**	0.49**							
6 Open communication	3	3.58	0.65	0.67	0.36**	0.14**	0.51**	0.37**	0.57**	0.40**	0.49**						
7 Error feedback	3	3.17	0.73	0.72	0.36**	0.25**	0.42**	0.50**	0.56**	0.51**	0.43**	0.61**					
8 Non-punitive	3	3.74	0.69	0.67	0.28**	0.18**	0.56**	0.23**	0.41**	0.22**	0.45**	0.49**	0.28**				
9 Adequate staffing	4	3.38	0.65	0.59	0.45**	0.03	0.49**	0.20**	0.40**	0.26**	0.41**	0.32**	0.28**	0.45**			
Hospital-level factors																	
10 Management support	3	2.81	0.74	0.80	0.44**	-0.05	0.46**	0.22**	0.39**	0.36**	0.30**	0.31**	0.33**	0.23**	0.38**		
11 Teamwork across units	3	3.12	0.52	0.68	0.35**	0.01	0.37**	0.10	0.27**	0.28**	0.32**	0.27**	0.18**	0.16**	0.26**	0.53**	
12 Handoffs and transitions	4	3.04	0.60	0.73	0.37**	0.02	0.44**	0.19**	0.31**	0.26**	0.31**	0.28**	0.20**	0.31**	0.39**	0.45**	0.62**

*$P < 0.05$ (2-tailed); **$P < 0.01$ (2-tailed).

[a]Mean, standard deviation = SD. [b]Intraclass correlation by Cronbach's alpha. [c]Pearson correlation.

PSG: patient safety grade; AE: adverse events reported on the past 12 months; 1: overall perceptions of safety; 2: frequency of events reported; 3: supervisors' or managers' expectations and actions promoting patient safety; 4: organizational learning – continuous improvement; 5: teamwork within units; 6: communication openness; 7: feedback and communication about error; 8: non-punitive response to error; 9: adequate staffing; 10: hospital management support for patient safety; 11: teamwork across hospital units; 12: hospital handoffs and transitions.

II

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BJA

QUALITY AND PATIENT SAFETY

Impact of the World Health Organization's Surgical Safety Checklist on safety culture in the operating theatre: a controlled intervention study

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Editor's key points

- The World Health Organization's Surgical Safety Checklist was introduced to improve perioperative morbidity, mortality, and adherence to clinical protocols.
- The role of changes in safety culture in the positive effects of this checklist was assessed in a prospective controlled intervention survey in operating theatre personnel.
- Successful checklist implementation had limited impact on patient safety culture in this single-site study, for unclear reasons that require further study.

Background. Positive changes in safety culture have been hypothesized to be one of the mechanisms behind the reduction in mortality and morbidity after the introduction of the World Health Organization's Surgical Safety Checklist (SSC). We aimed to study the checklist effects on safety culture perceptions in operating theatre personnel using a prospective controlled intervention design at a single Norwegian university hospital.

Methods. We conducted a study with pre- and post-intervention surveys using the intervention and control groups. The primary outcome was the effects of the Norwegian version of the SSC on safety culture perceptions. Safety culture was measured using the validated Norwegian version of the Hospital Survey on Patient Safety Culture. Descriptive characteristics of operating theatre personnel and checklist compliance data were also recorded. A mixed linear regression model was used to assess changes in safety culture.

Results. The response rate was 61% (349/575) at baseline and 51% (292/569) post-intervention. Checklist compliance ranged from 77% to 85%. We found significant positive changes in the checklist intervention group for the culture factors 'frequency of events reported' and 'adequate staffing' with regression coefficients at −0.25 [95% confidence interval (CI), −0.47 to −0.07] and 0.21 (95% CI, 0.07–0.35), respectively. Overall, the intervention group reported significantly more positive culture scores—including at baseline.

Conclusions. Implementation of the SSC had rather limited impact on the safety culture within this hospital.

Keywords: checklist; safety; safety climate; safety culture; surgery

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An estimated 234 million major surgical operations are performed annually worldwide.[1] As volume and importance of surgery in global healthcare increase, patient safety and quality in surgical care gain more attention.[2 3] Nearly one in 10 in-hospital patients experience iatrogenic events and more than half of them occur within perioperative care.[4]

In 2008, the World Health Organization (WHO) launched the Safe Surgery Saves Lives campaign and produced the 'Surgical Safety Checklist' (SSC) designed to reduce complications and deaths associated with surgery.[5] In an international pilot study, the SSC intervention resulted in a decrease in mortality (1.5–0.8%) and morbidity (17–11%).[6] Similar effects were found after implementing the more comprehensive Surgical Patient Safety System (SURPASS) checklist on patient outcomes in the Netherlands.[7] An important purpose of introducing the WHO SSC was to improve basic clinical processes as shown by the increase in appropriate antibiotic use from 56% to 83%, correct site marking from

54% to 92%, and overall clinical safety processes from 34% to 57%, suggesting improved reliability in clinical care.[6]

Within the healthcare and other industries, checklists are more than a simple intervention. At a basic level, they function as reminders, which ensure basic care processes are adhered to (assuming whichever checklist is in place is used correctly). At a broader level, checklists and their usage have implications for team working, team cohesion, and safety culture. Checklists require people to change their work routines—for example, the Time Out phase of the WHO SSC requires the entire operating theatre team to gather and pause for a few seconds before proceeding with a procedure. Given that the healthcare industry was rarely using such interventions until recently, it has been argued that checklists are not a panacea that will fix every safety problem—rather they are likely to interact with the team and safety culture of the local team and wider organization.[8] If significant wider problems exist within an organization, the likely outcome is that a checklist will not have a positive benefit, and indeed, it may be reduced to a tick box exercise.[9]

Along these lines, checklist-driven improvements have been hypothesized to impact positively on team and safety culture and, in turn, to drive decreases in patient mortality and morbidity.[6] Safety culture relates to personnel's attitudes, common thoughts, and behaviours within an organization.[10] Although not easy to measure, a number of surveys that assess safety culture have been published[11]—alongside studies that investigate culture via ethnographic approaches and observation.[12 13] Survey instruments typically investigate a range of facets of culture, including team working,[14 15] communication,[16 17] and attitudes to safety.[18] Studies to date have linked occurrence of patient safety incidents with safety culture and hence tools to monitor culture within hospitals have been implemented.[11 19]

To date, the effects of the WHO SSC have been evaluated regarding compliance,[20] communication,[21 22] staff attitudes, and partly safety culture.[18 22 23] Published studies are typically pre-/post-implementation designs without control groups. The primary aim of this study was to measure the effects of the WHO SSC on operating theatre personnel perceptions of safety culture using a controlled study design. We hypothesize that implementation of the SSC is associated with positive changes in safety culture.

Methods

The study was reviewed by the Regional Committee for Medical and Health Research Ethics (Ref: 2009/561) and the hospital privacy Ombudsman, who approved it (Ref: 2010/413). Written informed patient consent was waived. Operating theatre personnel gave consent by responding to the surveys.

Study design

This was a prospective controlled intervention study using pre- and post-intervention surveys with the intervention and control groups. The primary outcome was the changes of safety culture perceptions in operating theatre personnel after implementation of the Norwegian version of the WHO Surgical Safety Checklist, introduced after WHO guidelines.[5] A randomized stepped wedge design[24] was utilized to determine the order of intervention introduction across three surgical specialities (orthopaedic, thoracic, and neurosurgery—see the following section for details) in the intervention site of the hospital. Compliance with checklist usage was the secondary outcome.

Study population

The study took place in Haukeland University Hospital, a 1100-bed tertiary university hospital in the western part of Norway. The perioperative setting comprised 10 surgical departments and the accompanying departments of anaesthesia and intensive care administering anaesthesia and perioperative care. The target population of perioperative personnel included all eligible surgeons, anaesthetists, operating theatre nurses, nurse anaesthetists, and ancillary personnel (unit assistants, clerks, and cleaning assistants) located at two separate sites. The intervention group comprised personnel from orthopaedic surgery, thoracic surgery, and neurosurgery placed at the central hospital site. The control group comprised personnel from ear, nose, and throat; maxillofacial; plastic; endocrine; urology; gastrointestinal; obstetric; and gynaecological surgery specialities located at the peripheral hospital site. Within the hospital, operating theatre clinical and other personnel work in the separate sites without rotation, except for a few anaesthetists. Inclusion was based on work list information. A census approach was taken for recruitment—with the entire target population (as described above) invited to take part in the study. A total of 349 participants responded at baseline and 292 responded at post-intervention.

Study procedure

The study was carried out over 9 months from October 2009 to July 2010. Baseline and post-Checklist intervention survey data were collected during two 4 week periods in October 2009 and June 2010 (Fig. 1). The surveys were forwarded to the operating theatre personnel using both hospital electronic mail and the internal mail system (i.e. hardcopies). Identification numbers were assigned to or printed on each questionnaire to match individuals for the pre- and post-intervention surveys. Compliance with the Checklist was prospectively recorded (i.e. Checklist 'used' or 'not used') via the computer-based operating planning system within the operating theatres of the hospital. Nurse anaesthetists and theatre nurses also checked manually whether the paper versions of the Checklist had been completed for every case.

Checklist intervention

The Norwegian version of the SSC was introduced using a randomized sequential roll-out of the intervention.[24] In a joint venture between the Norwegian National Unit for Patient Safety, the Health Trust of Førde, and the Surgical

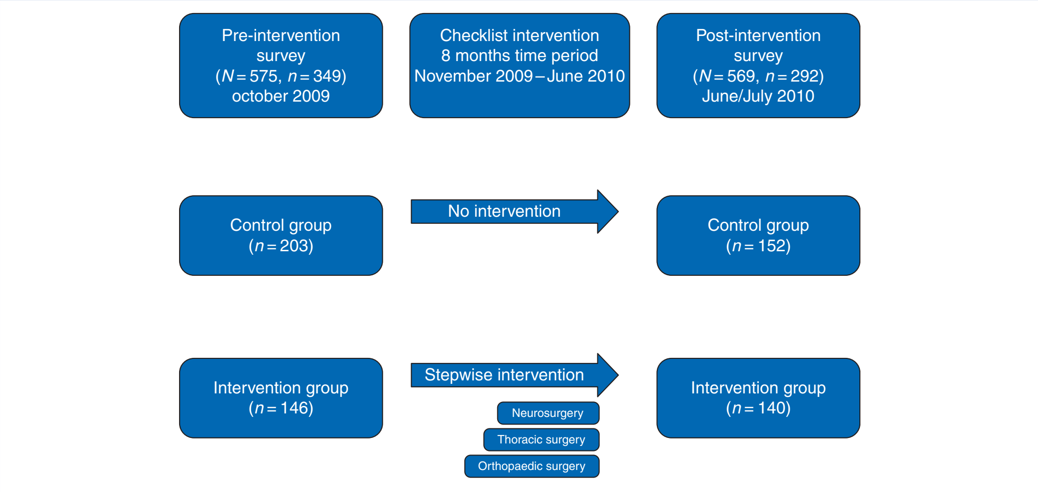

Fig 1 Study procedure for the SSC intervention and the pre-intervention and post-intervention surveys at Haukeland University Hospital, Bergen, Norway, in 2009–2010. *N*, subjects included; *n*, subjects responded.

Safety Study Group of Bergen, the Checklist was translated and adapted to meet Norwegian surgical flow of care. The Checklist consisted of 20 items orally confirmed by operating theatre personnel aimed at ensuring patient safety during anaesthesia and surgery. It was performed at three critical junctures in care: before induction of anaesthesia (Sign In), immediately before incision or start of treatment (Time Out), and before the leading surgeon left the operating theatre after surgery (Sign Out).[5] The Sign In part before anaesthesia induction was led by the nurse anaesthetist. The Time Out and Sign Out parts were led by the circulating nurse. A completed checklist form was included into the patient's notes.

With management leaders support, the Surgical Safety Study Group of Bergen introduced the SSC to all specialities/professional groups in the intervention group, using an educational programme consisting of lectures, the NHS (UK) videos on how to perform and not to perform the checklist,[25] information disseminated via e-mails, and WHO guideline material[5] translated into Norwegian. The SSC was piloted during the two first weeks of implementation resulting in a few minor adjustments—including that the Sign In should be led by the nurse anaesthetist with anaesthetist and operating theatre nurse present before induction, and the Time Out should be performed by the operating theatre nurse as the surgeon was ready to start the operation—pausing the whole team. Further feedback was received by end-users 2 weeks and also 2 months post-initial implementation. The randomized stepped wedge implementation started with orthopaedic surgery followed by thoracic and neurosurgery at 4 week intervals in the intervention site of the hospital.

Outcome measures

The primary outcome was post-implementation changes in safety culture measured by the Norwegian version of the Healthcare Research and Quality *Hospital Survey on Patient Safety Culture* (Hospital SOPS).[19 26–28] The survey instrument measures hospital staff perceptions of safety culture using 42 items that cover 12 factors, or elements of culture: 'overall patient safety', 'frequency of events reported' (including near misses in theatres), 'unit manager/leader promoting safety', 'organizational learning—continuous improvement', 'teamwork within units', 'communication openness', 'feedback on error reported', 'non-punitive response to errors', 'adequate staffing' (to handle difficult situations in theatre), 'hospital manager/leader promoting safety', 'teamwork across units', and 'quality of information handoffs and transitions of care'.[28] The first nine factors address culture at clinical unit level, whereas the last three factors address culture at the wider hospital level. Items are scored on five-point agreement scales (1, strongly disagree, to 5, strongly agree) or frequency scales (1, never, to 5, always) as appropriate.[19 28] The Hospital SOPS instrument had previously not been used within this hospital. The instrument was selected based on its very good psychometric properties[27–29] and also because we could compare our findings with previous findings from similar populations assessed using the same tool.[27 28]

Statistical analyses

Statistical analyses were carried out using SPSS version 20 (SPSS, Chicago, IL, USA). The reliability of the Norwegian Hospital SOPS instrument in the form of internal consistency was assessed using Cronbach's α coefficients. Descriptive statistics quantified sample characteristics and compliance data. Each of the 12 patient safety culture factors was based on three or four items, which were aggregated to produce a mean score for the factor. Negatively worded items were reversed to ensure that higher scores overall indicate better safety culture. A mean sum score was calculated across all 12 factors. The intervention and control groups were compared using analysis of variance (ANOVA). We used a hierarchical mixed linear model (MLM) based on multiple regression analysis to calculate effects of the SSC intervention. Following subjects responding both at baseline and post-intervention, the MLM test allows for inclusion of subjects responding only at baseline or post-intervention.[30] The regression model is detailed in the Appendix. Variations between responders and non-responders were assessed with the Pearson χ^2 test. Statistical significance was set at two-tailed $P \leq 0.05$.

Results

Sample characteristics

A total of 641 participants took part in the study. Overall response rates for the two phases of the study were 61% (349/575) at the baseline/pre-intervention survey and 51% (292/569) at the post-intervention survey. Subjects responding in both surveys represented 67% (432/641) of the respondents. Detailed sample characteristics are displayed in Table 1. We performed a χ^2 analysis of non-responders to establish possible differences with responders regarding gender, groups, and profession and found a significant variation ($P<0.01$) for professions in both surveys, with fewer non-responding nurse anaesthetists in the pre- and post-intervention surveys and more surgeons and ancillary personnel as non-responders in the post-intervention survey. Checklist compliance for the study period was 85% of all cases (elective and emergency surgery) for the Sign In, 84% for the Time Out, and 77% for the Sign Out (Table 2).

Norwegian 'Hospital SOPS' reliability

Reliability was assessed at baseline ($n=349$) with lowest Cronbach's α of 0.60 and 0.64 for 'adequate staffing' and 'organizational learning and continuous improvement' and with the α ranging between 0.67 and 0.85 for the remaining factors. At post-intervention ($n=292$), the lowest α was 0.60 for 'non-punitive response' and ranged from 0.66 to 0.85 for the other factors. Overall, these are acceptable to very good levels of reliability for research purposes.

Checklist intervention effects on safety culture

Detailed descriptive analyses across the two groups (control *vs* intervention) and the two time-points (pre-intervention *vs* post-intervention) are presented in Table 3.

Table 1 Characteristics of the intervention (WHO SSC) and control groups ($n=641$)

	Pre-intervention survey						Post-intervention survey					
	Checklist		Control		Total	*P*-value	Checklist		Control		Total	*P*-value
	n	%	*n*	%	*n*		*n*	%	*n*	%	*n*	
Occasion and groups	146	41.8	203	58.2	349	–	140	47.9	152	52.1	292	0.21
Gender												
Male	64	43.8	80	39.4	144	0.44	65	46.4	52	34.2	117	0.04
Female	82	56.2	123	60.6	205		75	53.6	100	65.8	175	
Profession						<0.01						<0.01
Surgeon	44	30.1	83	40.9	127		32	22.9	60	39.5	92	
Operating theatre nurse	35	24.0	42	20.7	77		36	25.7	35	23.0	71	
Anaesthetist	24	16.4	20	9.9	44		31	22.1	10	6.6	41	
Nurse anaesthetist	43	29.5	33	16.3	76		41	29.3	30	19.7	71	
Ancillary personnel	—	—	25	12.3	25		—	—	17	11.2	17	
Patient contact						0.02						0.21
Yes	140	98.6	182	90.5	322		128	96.2	140	92.2	269	
No	2	1.4	19	9.5	21		5	3.8	12	7.8	17	
Weekly working hours												
<20	2	1.4	15	7.5	17		1	0.7	5	3.3	6	
20–37	59	40.7	80	39.8	139		53	38.4	63	41.9	116	
>37	84	57.9	106	52.7	190		84	60.9	83	55.0	167	
Hospital experience (yr)						0.97						0.43
<1	7	4.8	9	4.5	16		9	6.5	7	4.7	16	
1–5	34	23.4	50	25.3	84		25	18.1	42	28.2	67	
6–10	28	19.3	36	18.2	64		28	20.3	28	18.8	56	
11–15	28	19.3	38	19.2	66		26	18.8	21	14.1	47	
16–20	20	13.8	22	11.1	42		19	13.8	17	11.4	36	
21–40	28	19.3	43	21.7	71		31	22.5	34	22.8	65	

Table 2 Compliance with the WHO SSC in orthopaedic, thoracic, and neurosurgical operations (N=2367) at Haukeland University Hospital, Bergen, Norway, in 2009–2010

Surgery	Use of SSC								
	N	Sign In		Time Out		Sign Out		All parts	
		n	%	*n*	%	*n*	%	*n*	%
Orthopaedic	1579	1414	90	1386	88	1307	83	1264	80
Thoracic	393	337	86	338	86	300	76	287	73
Neuro	395	264	67	257	65	225	57	216	55
All	2367	2015	85	1981	84	1832	77	1767	75
P-value		<0.01		<0.01		<0.01		<0.01	

The multivariate analysis with MLM demonstrated a significant effect (P<0.01) of the SSC intervention on the two factors 'frequency of events (near misses) reported' and 'adequate staffing' (Fig. 2). The effect is described by regression coefficients for the interaction as −0.25 [95% confidence interval (CI), −0.47 to −0.07] and 0.21 (95% CI, 0.07–0.35), respectively (Table 4). For instance, for 'frequency of events reported', there was an increase of 0.11 from pre to post in the control group, but a decrease in the Checklist group (0.11−0.25=−0.14). For 'adequate staffing', there is hardly any change (b_2=−0.07) in the control, but an increase in the Checklist group (−0.07+0.21=0.14). For the safety culture measured on the overall hospital level, the MLM analysis also showed a significant effect of the Checklist intervention for the factors 'hospital management promotes safety' and 'quality of information handoffs and transitions of care' in both groups. The regression coefficients for the differences were 0.12 (95% CI, 0.04–0.20) and 0.08 (95% CI, 0.02–0.14), respectively. The same pattern was obtained when we adjusted the analyses using profession, gender, level of patient contact, and work experience as covariates. Subgroup analyses with covariates did not change the results.

Across both baseline and post-intervention, we found significant group differences between the Checklist intervention group and the control group, in favour of the intervention group, for the factors 'overall patient safety', 'frequency of events reported', 'manager promoting safety', 'organizational learning-continuous learning', 'teamwork within units', 'feedback/communication about errors', 'non-punitive response to error', and the 'sum score' (i.e. overall safety culture scale mean score)—details of these differences are presented as regression coefficients with 95% CI in Table 4.

Discussion

In this prospective controlled intervention study of the WHO SSC in Norway, the introduction of the Checklist was associated with rather small impact on patient safety culture (measured by the 'Hospital SOPS' scale). Overall, the intervention group scored higher on a number of baseline culture factors—but even taking this into account, we only found positive effects on two dimensions of patient safety culture: a significant decrease in 'frequency of events reported' and a significant improvement in perceptions of 'adequate staffing' in the Checklist intervention group. The decrease in events reported could be associated with a real mitigation of near misses or errors after the introduction of the WHO Checklist in the intervention group. The SSC effects change in theatre routines, such that team members may eventually be better prepared for anaesthesia and surgery, hence leading to fewer near misses. Improved safety processes in the operating theatre have been seen after SSC implementation, such as raised awareness in the operating team and foreseeing any errors or problems.[6 31] In fact, the SURPASS study quantified incidence of errors caught to 40.6% (2562/6313) of checklists, supporting the assumption that checklists prevent near misses and errors.[32] Direct observational evidence would be required to further validate this finding.

The improvement in perceptions of having adequate staffing to handle difficult situations in theatre is more difficult to account for. During the study period, there was no objective increase in staffing as an explanatory variable. According to data from the hospital personnel system, the number of active health personnel was constant during the study period and even the numbers on sick leave were not significantly different. It is possible that this effect is entirely subjective—staff's perceptions of teamwork have been shown to be associated with measures of safety and quality in patient care,[33] and Bõhmer and colleagues[22] found that the team introductions during the Time Out contributed to improved staff satisfaction. The use of the SSC, including team introductions, might have enhanced team cohesion and thus affected subjective perceptions of staffing. This finding clearly requires further investigation.

Checklist and safety culture

Is it possible for operating theatre teams to adopt a practice which seems important to them but without broader improvements in their attitudes to and perceptions of safety? The safety culture factors that did not improve post-implementation of the SSC in this study are somewhat different from findings in other studies, especially regarding teamwork[15 16] and communication.[21 22 34]

For checklist implementation to be effective, a concurrent cultural change within organizations has been suggested to be crucial[6 35 36]—indeed, it has been argued

Table 3 Descriptive statistics analyses in the intervention (checklist) compared with control groups for the pre-intervention (n=349) and post-intervention (n=292) phases of the study. SE, standard error; CI, confidence interval

Safety factors (scale 1–5)	Pre-intervention			Post-intervention		
	Mean	SE	95% CI	Mean	SE	95% CI
Overall patient safety						
Intervention	3.63	0.05	3.53, 3.73	3.69	0.04	3.60, 3.77
Control	3.51	0.04	3.42, 3.60	3.57	0.05	3.48, 3.66
Frequency of events reported						
Intervention	2.93	0.07	2.80, 3.06	2.77	0.06	2.66, 2.89
Control	2.72	0.05	2.62, 2.82	2.80	0.07	2.67, 2.93
Unit manager promoting safety						
Intervention	3.78	0.06	3.66, 3.90	3.70	0.06	3.56, 3.82
Control	3.56	0.06	3.44, 3.67	3.52	0.07	3.38, 3.65
Organizational learning						
Intervention	3.43	0.05	3.34, 3.53	3.50	0.05	3.41, 3.60
Control	3.27	0.05	3.18, 3.37	3.33	0.06	3.22, 3.45
Teamwork within units						
Intervention	3.66	0.05	3.55, 3.76	3.72	0.05	3.62, 3.81
Control	3.55	0.04	3.46, 3.63	3.54	0.05	3.44, 3.64
Communication openness						
Intervention	3.67	0.05	3.56, 3.78	3.61	0.06	3.50, 3.72
Control	3.52	0.04	3.43, 3.61	3.57	0.06	3.46, 3.68
Feedback/communication on error						
Intervention	3.33	0.06	3.20, 3.45	3.21	0.06	3.08, 3.33
Control	3.07	0.05	2.98, 3.17	2.98	0.06	2.85, 3.10
Non-punitive response to error						
Intervention	3.88	0.05	3.78, 3.98	3.89	0.04	3.80, 3.98
Control	3.68	0.05	3.57, 3.78	3.70	0.06	3.59, 3.82
Adequate staffing						
Intervention	3.44	0.05	3.34, 3.54	3.58	0.05	3.48, 3.67
Control	3.35	0.05	3.26, 3.45	3.29	0.06	3.17, 3.40
Hospital management promoting safety						
Intervention	2.80	0.06	2.69, 2.93	2.90	0.06	2.78, 3.02
Control	2.86	0.05	2.76, 2.96	2.95	0.06	2.83, 3.07
Teamwork across units						
Intervention	3.06	0.04	2.97, 3.14	3.03	0.04	2.94, 3.11
Control	3.08	0.04	3.00, 3.15	3.13	0.04	3.05, 3.21
Quality of handoffs and transitions						
Intervention	3.03	0.05	2.93, 3.12	3.05	0.05	2.96, 3.15
Control	3.05	0.04	2.97, 3.13	3.17	0.05	3.08, 3.26
Sum mean score (12 factors)						
Intervention	3.39	0.03	3.32, 3.45	3.39	0.03	3.32, 3.45
Control	3.27	0.03	3.20, 3.33	3.29	0.04	3.22, 3.36

that poor organizational culture and deeper-running problems can undermine the effectiveness of interventions like checklists.[9] Interestingly, the compliance rates with the SSC in this study were rather high (85%, 84%, and 77% for the Sign In, Time Out, and Sign out phases, respectively) which indicate fairly successful early implementation. Anecdotal evidence observed by and also relayed to the research team also concurred that there were no major problems. This compares favourably with findings from other countries like the UK pilot implementation of the SSC, which was met with some resistance and compliance ranged from 42% to 80%.[31] Strategies for successful implementation of the SSC have included education (training and materials), champions, organizational leadership, clear roles in the team, regular audits, feedback, and local adaptation[5 31 36]—which are all elements that we used during implementation.

We thus have a rather paradoxical effect of a reasonably successful introduction of the SSC intervention but no major cultural impact. A number of explanations could be put forward here—all of which are amenable to further study. A first possibility is that culture and SSC are

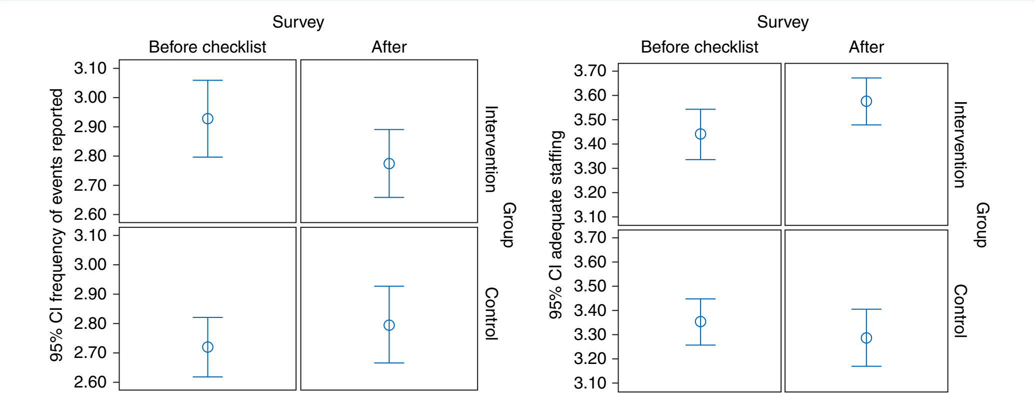

Fig 2 WHO SSC impact on safety culture perceptions of 'frequency of events reported' (near misses in theatres) and 'adequate staffing' (to be able to handle any difficult situation in theatre), before and after the SSC intervention at Haukeland University Hospital, Bergen, Norway in 2009–2010. CI, confidence interval.

Table 4 Effects on safety culture factors of the intervention (checklist) compared with control groups and pre-intervention (n=349) *vs* post-intervention (n=292) survey phases estimated by the linear mixed model. †β_i (i=1, 2, 3), estimated regression coefficients; β_0, estimated mean/constant; CI, confidence interval; NS, not significant and not included; †With interaction: $y=\beta_0+\beta_1\cdot$checklist group$+\beta_2\cdot$post intervention survey$+\beta_3\cdot$checklist group$\times$post intervention survey; without interaction: $y=\beta_0+\beta_1\cdot$checklist group$+\beta_2\cdot$post intervention survey$+0$. *$P\leq0.05$; **$P\leq0.01$

Predictors		**Constant**		**Differences for group checklist *vs* control**		**Overall change post- *vs* pre-intervention survey**		**Checklist effect for group × survey (pre/post) interaction**	
Safety factors (scale 1–5)	**Items**	β_0	**95% CI**	β_1	**95% CI**	β_2	**95% CI**	β_3	**95% CI**
Overall patient safety	4	3.49	3.43, 4.57	0.14	0.03, 0.24*	0.06	−0.01, 0.13	NS	—
Frequency of events reported	3	2.71	2.61, 2.81	0.20	0.04, 0.35*	0.11	−0.02, 0.23	−0.25	−0.43, −0.07**
Unit manager promoting safety	4	3.54	3.44, 3.64	0.22	0.08, 0.36**	−0.05	−0.13, 0.03	NS	—
Organizational learning	3	3.27	3.19, 3.35	0.16	0.04, 0.27**	0.07	−0.00, 0.15	NS	—
Teamwork within units	4	3.54	3.47, 3.62	0.14	0.03, 0.25**	−0.01	−0.08, 0.06	NS	—
Communication openness	3	3.52	3.43, 3.60	0.11	−0.01, 0.23	0.02	−0.06, 0.09	NS	—
Feedback/communication on error	3	3.03	2.97, 3.16	0.24	0.10, 0.37**	−0.08	−0.16, 0.01	NS	—
Non-punitive response to error	3	3.65	3.57, 3.74	0.21	0.09, 0.33**	0.01	−0.07, 0.09	NS	—
Adequate staffing	4	3.33	3.25, 3.42	0.10	−0.04, 0.23	−0.07	−0.17, 0.03	0.21	0.07, 0.35**
Hospital management promoting safety	3	2.84	2.75, 2.94	−0.04	−0.17, 0.10	0.12	0.04, 0.20**	NS	—
Teamwork across units	4	3.09	3.02, 3.15	−0.05	−0.14, 0.05	0.03	−0.03, 0.09	NS	—
Quality of handoffs and transitions	4	3.06	2.98, 3.13	−0.04	−0.15, 0.07	0.08	0.01, 0.14*	NS	—
SUM score (mean)	42	3.26	3.20, 3.31	0.12	0.04, 0.20**	0.02	−0.02, 0.06	NS	—

unrelated—but in the light of previous evidence, this is not the likeliest possibility. Secondly, the baseline culture levels of these services were already high—hence a ceiling effect prevented further improvements. A third, related possibility is that the timeline was too short to obtain such an improvement—after all introducing a new procedure is fairly quick, whereas a shift in experienced professionals' mind sets regarding their organization and practice might require a longer gestation period. Both of these explanations require longitudinal ongoing evaluations of culture and its fluctuations—and linking these with Checklist utilization. Cross-sectional studies between different countries and healthcare systems currently using the Checklist (e.g. Norway and UK) would also be useful in this respect. Further, observational assessments of how the SSC is actually used within the pressurized theatre environment are also required—culture measures are useful, but they cannot account for people reporting one thing yet doing another. A fourth explanation is that people can change their behaviour without necessarily visibly changing their underlying attitudes. Psychological theory suggests that this cannot hold for a very long time, as people strive to be consistent between their attitudes (i.e. perceptions of culture) and their behaviour[37] (i.e. usage of checklist)—which makes more compelling the longitudinal evaluation of both behaviour and culture perceptions.

Limitations and strengths

The response rate at baseline (61%) and at post intervention (51%) might be a limitation for sample representativeness. There were differences in professional backgrounds between responders and non-responders (but not for other patient characteristic factors). The significant differences within groups and variations within professions could indicate study weaknesses, thus the MLM analysis[30] adjusted for these—and indeed inclusion of the covariates in the analyses did not influence the results. Finally, information about the Checklist intervention and local enthusiasm could have been transferred to individuals in the control group and biased results ('spill-over' effect)—which is something that could not be controlled. In balance, key strengths of this study are the use of a carefully controlled design and matched assessments of safety culture pre- and post-intervention at the individual participant level (rather than group level).

Implications

Our findings, and overall experience with the study, have implications for the introduction of safety interventions, like the SSC, and for further research on the effectiveness of such interventions. In this study, seven of the safety culture factors showed overall significant differences between the intervention and control groups, with the intervention group being significantly more positive. Following WHO advice, one could advocate that implementation of an intervention should begin with healthcare teams or professionals who are positive towards the intervention—hence the concept of 'champions'. This, however, might be a challenge when designing evaluation studies that include a control group, as entire units or operating theatres that are more positive towards the intervention might show a 'ceiling effect'—that is, the size of the improvement triggered by the intervention is smaller in these groups precisely because they are more positively predisposed to the intervention to start with. Pre-/post-intervention designs are not the most suitable to tease out such effects—and indeed, we would argue that a deeper understanding of how exactly a healthcare organization moves across dimensions of culture over time cannot be gauged by such studies. We would thus advocate periodic and systematic assessments of an organization's culture using a well-validated instrument. This will allow longitudinal, time-series-based evaluation of whether the organization (or parts of it) moves in a certain direction, and whether interventions are causing such shifts.

Further, feedback of such measures within the organization can provide better self-insight and allow clinical units to self-evaluate and to compare themselves with their peers. We would hypothesize that such organization-wide assessments are an intervention in themselves and that a positive relationship should be expected between them and organizational readiness to improve safety and quality and to adopt novel interventions. These hypotheses await further study.

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Declaration of interest

S.H. is the leader of the advisory board for the Norwegian Patient Safety Campaign hosted by the governmental and non-commercial Norwegian Knowledge Centre for the Health Services.

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Appendix

The aim of the MLM regression analysis is to describe the effect of the checklist intervention on primary outcome; the safety culture factors of the Hospital SOPS (dependent variables) with intervention and control groups at baseline and post-intervention surveys (independent variables).

A hierarchical model was formed for the interaction and expressed as:

$$Y = \beta_0 + \beta_1 \times \text{Group} + \beta_2 \times \text{Survey} + \beta_3 \times \text{Group} \times \text{Survey} \quad \text{(A1)}$$

where β_0 is the model constant/intercept, $\beta_{1,2,3}$ the regression coefficients (estimated by restricted maximum likelihood methods), Group the independent variable as intervention (=1) or control (=0) group, and Survey the independent variable as baseline survey (=1) and post-intervention (=0) survey.

The models assume covariance type CSR (compound symmetry with correlation parameterization) for repeated response from subjects at baseline and at post-intervention. The analyses also include respondents replying only at baseline or post-intervention. Independent variables were fixed. To adjust for co-variables, we included profession, gender, patient contact, and work experience in the hospital in the models:

$$Y = \beta_0 + \beta_1 \times \text{Group} + \beta_2 \times \text{Survey} + \beta_3 \times \text{Profession} + \cdots + \beta_8 \times \text{Group} \times \text{Survey} \quad \text{(A2)}$$

For safety culture factors without significant interaction effects of the checklist intervention, we used an equation for assessing the variations between groups and between surveys:

$$Y = \beta_0 + \beta_1 \times \text{Group} + \beta_2 \times \text{Survey} \quad \text{(A3)}$$

Equations (A1) and (A3) are used in Table 4.

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III

OPEN

Effect of the World Health Organization Checklist on Patient Outcomes

A Stepped Wedge Cluster Randomized Controlled Trial

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Objectives: We hypothesized reduction of 30 days' in-hospital morbidity, mortality, and length of stay postimplementation of the World Health Organization's Surgical Safety Checklist (SSC).

Background: Reductions of morbidity and mortality have been reported after SSC implementation in pre-/postdesigned studies without controls. Here, we report a randomized controlled trial of the SSC.

Methods: A stepped wedge cluster randomized controlled trial was conducted in 2 hospitals. We examined effects on in-hospital complications registered by *International Classification of Diseases, Tenth Revision* codes, length of stay, and mortality. The SSC intervention was sequentially rolled out in a random order until all 5 clusters—cardiothoracic, neurosurgery, orthopedic, general, and urologic surgery had received the Checklist. Data were prospectively recorded in control and intervention stages during a 10-month period in 2009–2010.

Results: A total of 2212 control procedures were compared with 2263 SCC procedures. The complication rates decreased from 19.9% to 11.5% ($P < 0.001$), with absolute risk reduction 8.4 (95% confidence interval, 6.3–10.5) from the control to the SSC stages. Adjusted for possible confounding factors, the SSC effect on complications remained significant with odds ratio 1.95 (95% confidence interval, 1.59–2.40). Mean length of stay decreased by 0.8 days with SCC utilization (95% confidence interval, 0.11–1.43). In-hospital mortality decreased significantly from 1.9% to 0.2% in 1 of the 2 hospitals post-SSC implementation, but the overall reduction (1.6%–1.0%) across hospitals was not significant.

Conclusions: Implementation of the WHO SSC was associated with robust reduction in morbidity and length of in-hospital stay and some reduction in mortality.

Keywords: checklist, morbidity, mortality, randomized controlled trial, surgery

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As global surgical volume increase and exceed 234 million surgical procedures annually,[1] surgical mortality has declined over the previous decades.[2] Still, crude mortality rates are reported to vary between 0.4% and 4% in high-income countries.[3–5] Increased risk of mortality is associated with major complications in hospitals with higher overall mortality.[6] In-hospital complications occur in 3% to 22% of admitted patients, with 36% to 54% related to surgery.[7–9] Prevention of complications and incidents of iatrogenic harm are deemed feasible for nearly 50% of such incidents.[3,9] Introduction of checklists in surgery can intercept and prevent such incidents[10–12] and may reduce both morbidity and mortality.[13–16]

In 2008, the World Health Organization (WHO) introduced the Surgical Safety Checklist (SSC) designed to improve consistency of care.[17] The pilot pre-/postevaluation of the WHO SSC across 8 countries worldwide, which found reduced morbidity and mortality after SSC implementation,[14] constituted the first scientific evidence of the WHO SSC effects. A number of subsequent studies to date have reported improved patient outcomes with use of checklists.[18] Furthermore, checklists have also been shown to improve communication,[19–22] preparedness,[23] teamwork,[24,25] and safety attitudes[26]—findings that have been corroborated by a recent systematic review.[27]

Although checklists are becoming a standard of care in surgery,[28] the strength of the available evidence has been criticized as being low because of (i) predominantly pre-/postimplementation designs without controls; (ii) lack of evidence on effect on length of stay; and (iii) lack of evidence on any associated cost savings. Randomized controlled trials (RCTs) are required[29]—however, in some countries or settings, they can no longer be carried out, as the WHO SSC has already become national policy (eg, United Kingdom).

We report a stepped wedge cluster RCT aimed to evaluate the impact of the WHO SSC on morbidity, mortality, and length of hospital stay (LOS). We hypothesized a reduction of 30 days' in-hospital morbidity and mortality and subsequent LOS post-Checklist implementation.

METHODS

Study Design

We conducted a stepped wedge cluster randomized controlled checklist intervention trial in 2 hospitals in Norway[30]; a tertiary teaching hospital (1100 beds) and a central community hospital (300 beds). Following the WHO implementation guidelines for the SSC,

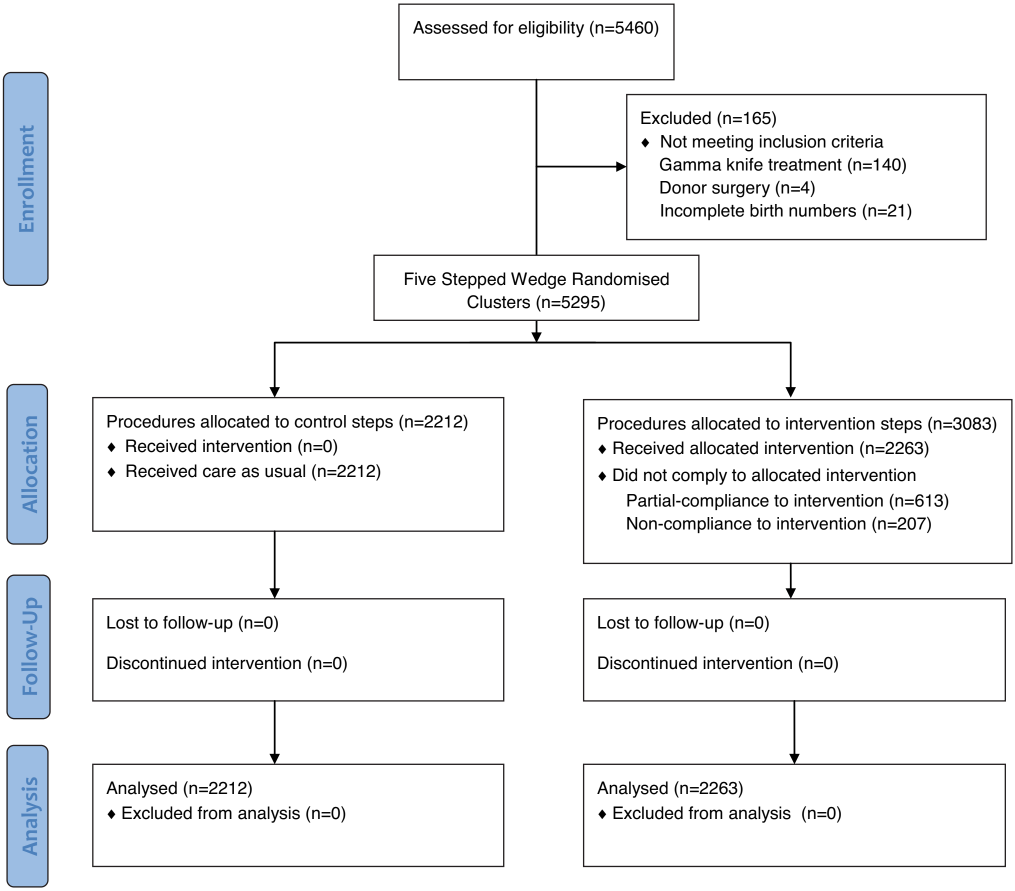

FIGURE 2. CONSORT 2010 flow diagram of the stepped wedge cluster randomized Surgical Safety Checklist intervention trial.

characteristics including age, sex, and comorbidity (American Society of Anesthesiologists score) were obtained from hospital administrative data. Types of surgery, form of anesthesia, and LOS were collected. Data were registered electronically by nurse anesthetists, operating room nurses, anesthetists, and surgeons in the operating room per regular practice (alongside other data). To reduce information bias, the clinicians were not informed as to which endpoints were measured during the study. Compliance with the SSC was assessed by nurse anesthetists and operating room nurses while performing the Checklist. This prospective assessment was performed on a pro forma and also registered in the operating room electronic database. Outcome data on all patients were extracted from the hospitals' administrative databases and collected by research assistants. Mortality was assessed from the public mortality register. All postoperative complications were prospectively assigned *ICD-10* codes by the surgeons or ward doctors as per routine practice in the hospitals at patients' discharge.

Data Handling

All research assistants were blinded to the randomization of patients into intervention and control cohorts when they handled the data and evaluated data quality. Quality check of the extracted data included a random analysis of 360 cases to check whether data concurred with the original patient administrative data. There were discrepancies in 1.7% (6/360) for names, 0.8% (3/360) for procedure and diagnostic codes, and 0.3% (1/360) for operation times and 100% match for remaining data variables. Variation was mainly due to differences between manually registered Checklist data and electronically recorded data, of which the latter was used for analysis. All *ICD-10* codes predefined as complications were identified and coded as complications and quality rechecked against the patients' medical records. The complication codes were checked for relevance to the actual surgical procedure to ensure that they were true complications and not merely an indication for surgery. The in-hospital mortality was associated to the unique patient and coded with "0" if alive at discharge/or after 30 days or "1" if mortality occurred before discharge within 30 days postoperatively.

Data from the postintervention cases (n = 3083) were handled as the total intervention group and included cases with noncompliance (intention to treat), partial compliance, and full compliance to the SSC. To investigate the SSC effects of full compliance, data from these cases (n = 2263) were handled separately in the analysis.

Statistical Analysis

The surgical specialty cohorts acted as their own controls and hence provided data in all steps of the wedge, before and after the Checklist intervention, thus reducing risk of bias. Analyses of stepped wedge RCTs involve comparing all data in the steps before (controls) with the steps after the intervention.[33] Accordingly, all patient characteristics for the controls and postimplementation of the SSC were compared using Pearson exact χ^2 test (categorical data) or with independent samples *t* test (numerical data) as appropriate. Furthermore, calculations on absolute risk reduction and relative risk reduction of morbidity and mortality with 95% confidence intervals (CIs) were based on Pearson exact χ^2 test with Bonferroni correction. For parametric analyses, effect sizes were calculated with η^2 defined as small (0.01), medium (0.06), or large (0.14).[36] Numbers needed to treat were used to calculate the preventive effect of the Checklist.[37] The sample size needed to detect a decrease in the mortality rate (in the first 30 days) from 0.08 to 0.06 at significance level 5% with 91% power was calculated to be 1110 in each group (without/with use of checklist). Intracluster correlation is considered to have minimal effect on power due to the unidirectional stepped wedge implementation of the intervention[30]; hence, it was not calculated. Binary logistic regression was used to adjust the Checklist effect on mortality and morbidity for possible confounding factors. Any difference in complication rates and procedure complexity in each surgical specialty between pre and postintervention was controlled for in the regression model with interactions. "Time" (study time points) was entered into the model to adjust for variation in complication rates at the different study time points throughout, as well as comorbidity (and other risk factors as age, surgical specialty, elective or emergency surgery, and type of anesthesia). Comparison of LOS before and after checklist implementation was tested by independent samples *t* test. For all analyses, a 2-sided *P* value of less than 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 21.0 (IBM Corp., Armonk, NY).

RESULTS

A total of 5295 surgical procedures were carried out throughout the stepped wedge cluster RCT, that is, 2212 in control and 3083 (of which 2263 had the SSC performed) after implementation of the SSC. Patients (14.9%; 667/4475) underwent more than 1 procedure. The control and SSC study steps included 1778 and 2033 unique patients, respectively. Characteristics of patients and their distribution across study steps are reported in Table 1. Patients did not differ in sex, age, or comorbidity between the control/SSC stages. However, patients were more likely to undergo orthopedic and emergency surgery and regional anesthesia in the SSC than the control cohort ($P < 0.001$). Compliance with the SSC was 73.4%.

The overall complication rate during the study period was 15.7% and decreased from 19.9% in the control steps to 11.5% in the SSC steps ($P < 0.001$) (Table 2). Absolute risk reduction was 7.5 (95% CI, 5.5–9.5) post-Checklist implementation when all procedures (3083) were included. Absolute risk reduction was 8.4 (95% CI, 6.3–10.5) when all 3 parts of the SSC were used. Relative risk reduction was 0.42 (95% CI, 0.33–0.50). A large effect size by parametric η^2 at 0.14 was found. Number needed to treat (overall Checklist use) in order to prevent one of these complications was 12 (95% CI, 9–16). Using logistic regression, we adjusted the Checklist effect on complications for possible confounding factors including sex, age, comorbidity (American Society of Anesthesiologists score), surgical specialty, urgency of surgery, type of anesthesia, and times (this refers to study time points from August 2009 to June 2010). Even with these adjustments, the Checklist remained significantly related to complication outcome, with OR of 1.95 (95% CI, 1.59–2.40) in the final regression model (Table 3). To control for possible differences in complication rates and complexity within surgical specialties from pre- to postintervention, we adjusted for interactions with time (study time points). In the final step, the Checklist effect remained with OR 1.84 (95% CI, 1.27–2.65). Checklist introduction resulted in significant decreases of complications in 4 of the 5 surgical specialties included but not in general surgery.

The overall in-hospital mortality rate during the whole study period was 1.3% and decreased from 1.6% in the control steps to 1.0% in the steps after SSC implementation ($P = 0.151$). The result did not change after controlling for possible confounders including sex, age, comorbidity (American Society of Anesthesiologists score), surgical specialty, urgency of surgery, type of anesthesia, and times (study time points from August 2009 to June 2010) (Supplemental Digital Content 2, available at http://links.lww.com/BRS/A868). Analysis of mortality by hospital revealed a significant decrease from 1.9% to 0.2% ($P = 0.020$) post-SSC implementation in the smaller community hospital of the study.

Patients' LOS was compared at control and SSC intervention stages of the study. The total in-hospital LOS for both study hospitals was significantly reduced from 7.8 days to 7.0 days after introduction

TABLE 1. Characteristics of Patients in the Stepped Wedge Cluster Randomized Controlled Trial in 2 Hospitals in Western Norway in 2009–2010

	Control	SSC	*P*
All procedures (n)	2212	3083	
Procedures with all parts of checklist used	2212	2263	
>1 procedure (%)	19.6	10.2	**< 0.001**
Unique patients (n)	1778	2033	
Mean age in years (SD)	54.1 ± 23.0	54.3 ± 23.3	0.869
Male sex (%)	55.6	55.9	0.718
Comorbidity by ASA (%)			0.272
ASA I	21.8	24.0	
ASA II	43.3	43.5	
ASA III	31.3	29.6	
ASA IV	3.4	2.9	
ASA V	0.1	0.0	
No ASA score (n)	87	73	
Surgical specialty (%)			**< 0.001**
Orthopedic	32.7	55.3	
Thoracic	13.4	12.5	
Neuro	17.6	9.3	
General*	27.0	16.9	
Urologic	9.3	5.9	
Surgery (%)			**0.001**
Elective	59.0	54.2	
Emergency	41.0	45.8	
Anesthesia			**< 0.001**
Regional	31.8	45.3	
General	68.2	54.7	
Patients by hospitals (%)			**< 0.001**
Tertiary hospital	63.7	77.2	
Central community hospital	36.3	22.8	
Mean length of in-hospital stay (d)	7.8	7.0	**0.022**

P value indicates Pearson exact χ^2 test with Bonferroni correction and independent samples *t* test for continuous variables. Significant values are in bold.

*Includes procedures with gastrointestinal, endocrine, and plastic surgery.

ASA indicates American Society of Anesthesiologists comorbidity/risk score.

TABLE 2. Morbidity and Mortality Outcome of the Stepped Wedge Cluster Randomized Controlled Trial in 2 Hospitals in Western Norway in 2009–2010

Procedures (n = 4475) With 1 or More Complications	Control (%)	SSC (%)	ARR Percent Points	ARR 95% CI	*P*
Respiratory complication	**6.4**	**3.2**			**<0.001**
Pneumonia	**3.7**	**1.9**			**<0.001**
Respiratory failure	1.0	0.5			0.062
Other*	**1.8**	**0.8**			**0.008**
Cardiac complication	**6.4**	**4.3**			**0.004**
Cardiac arrest	0.5	0.4			0.644
Arrhythmia	3.3	2.7			0.188
Congestive heart failure	0.7	0.3			0.061
Acute myocardial infarction	1.0	0.5			0.062
Angina pectoris	0.9	0.4			0.058
Infections	**6.0**	**3.4**			**<0.001**
Sepsis	0.6	0.3			0.075
Surgical site	2.2	1.5			0.149
Urinary tract	**2.8**	**1.4**			**0.001**
Other†	0.7	0.3			0.089
Surgical wound rupture	**1.2**	**0.3**			**<0.001**
Nervous system complication‡	0.5	0.3			0.232
Bleeding§	**2.3**	**1.2**			**0.008**
Embolism¶	0.5	0.2			0.092
Mechanical implant complication	**1.1**	**0.4**			**0.005**
Anesthesia complication	0.3	0.2			0.772
All other complications‖	**2.0**	**0.7**			**<0.001**
Unplanned return to operating theatre	**1.7**	**0.6**			**<0.001**
Complications (SSC)	**19.9**	**11.5**	**8.4**	**6.3–10.5**	**<0.001**
Complications in all (n = 2212/3083)	**19.9**	**12.4**	**7.5**	**5.5–9.5**	**<0.001**
In-hospital death (n = 3811)					
Tertiary hospital (n = 2715)	1.4	1.3	0.1	−0.7–1.1	0.865
Central hospital (n = 1083)	**1.9**	**0.2**	**1.7**	**0.4–3.0**	**0.020**
Total deaths	1.6	1.0	0.5	−0.2–1.3	0.151

P value indicates Pearson exact $\chi 2$ test. Significant values are in bold. No interactions between SSC and the other variables in the final model were significant.
*Including asthma, pleura-effusion, and dyspnea.
†Including meningitis, peri- and endocarditis, and gastroenteritis.
‡Including delirium and somnolence.
§Bleeding: A complication to surgical or medical procedures and valid for major or severe acute bleedings associated with the surgical procedure that required erythrocyte transfusions unplanned for and noted in the medical record by the surgeon.
¶Including arterial-, venous-, lung-, and air emboli.
‖Including circulatory collapse, unintended punctures or lacerations, kidney failure, complications after surgical and medical procedures, and complications to surgery not classified.
ARR indicates absolute risk reduction.

of the Checklist, with a mean difference of −0.8 days, $t = 2.30$ (95% CI, 0.11–1.43). Furthermore, there were no significant changes in length of surgery or in total time spent in the operating room.

DISCUSSION

Comparison With Other Studies

To our knowledge, this is the first stepped wedge cluster RCT on the clinical effectiveness of the WHO SSC. The study showed substantial improvements in surgical outcomes. Across 2 hospitals of a well-developed and funded health care system (Norway) including 5 surgical specialties, complication rates fell by 42% on average when the SSC was introduced. The effect was largest when all 3 parts of the SSC were conducted. The effect was significant even when surgical procedures included "intention to treat" with the SSC (in all 3083 surgical procedures postintervention, Table 2). The findings support our hypothesis and are consistent with previous pre-/poststudies having found similar effects of the WHO Checklist use.[14–16] Our results of reduction in morbidity also correspond to findings on use of the comprehensive "surgical patient safety checklist system" (SURPASS) in The Netherlands.[13]

The in-hospital stay decreased significantly in this study by almost a day. This is the first time the WHO SCC is shown to reduce LOS. The finding is consistent with a reduction in LOS by 0.6 days previously obtained after introducing the SURPASS checklist, which, however, did not reach statistical significance.[13] Furthermore, our study reflects similar findings in intensive care units, where LOS has been significantly reduced after use of a daily checklist (goal sheet).[38] LOS reduction provides a potential of significant cost savings in surgical care by improved patient outcome, as costs of complications and unplanned returns to operating room are reduced.[39] Although the WHO SSC was designed for quality improvement, a secondary effect—cost savings—should further encourage health care leaders to adopt and support its use.

After implementation of the WHO SSC, the overall study mortality deceased from 1.6% to 1.0% but did not improve significantly

TABLE 3. Results From Logistic Regression Analyses of Complications on Patient and Treatment Variables in the Stepped Wedge Cluster Randomized Controlled Trial of the WHO SSC in 2 Hospitals in Norway in 2009–2010

		Unadjusted			Fully Adjusted			Final Model*		
	n	OR	95% CI	*P*	OR	95% CI	*P*	OR	95% CI	*P*
Absence of the WHO SSC (after = reference)	2212 (2263)	1.91	1.62–2.26	<0.001	2.01	1.40–2.88	<0.001	1.95	1.59–2.40	<0.001
Age	4475	1.03	1.02–1.03	<0.001	1.01	1.01–1.02	<0.001	1.01	1.01–1.02	<0.001
Male sex (female = reference)	2516 (1959)	1.32	1.12–1.55	0.001	1.14	0.93–1.40	0.205	—	—	
Comorbidity by ASA score	4266			<0.001			<0.001			<0.001
Healthy (reference)	977	1			1			1		
Mild systemic disease	1852	3.04	2.06–4.50		2.42	1.59–3.69		2.41	1.59–3.68	
Moderate systemic disease	1298	14.09	9.67–20.53		5.74	3.69–8.94		5.78	3.70–8.93	
Severe systemic disease	135	25.92	15.84–42.41		8.14	4.60–14.40		8.15	4.61–14.41	
Morbid	4	91.55	9.26–905.19		23.71	1.54–365.39		23.98	1.54–373.27	
Surgical specialty	4475			<0.001			<0.001			<0.001
Orthopedic (reference)	1975	1			1			1		
Cardiothoracic	580	8.40	6.75–10.45		8.15	5.56–11.96		8.49	5.82–12.40	
Neuro	600	1.27	0.96–1.68		1.61	1.12–2.33		1.66	1.16–2.38	
General	981	1.24	0.97–1.57		1.61	1.16–2.24		1.64	1.19–2.26	
Urology	339	0.71	0.46–1.09		1.02	0.62–1.68		1.09	0.67–1.77	
Surgery emergency (elective = reference)	2532 (1943)	1.18	1.00–1.39	0.045	3.18	2.45–4.12	<0.001	3.19	2.46–4.13	<0.001
Anesthesia† general (regional = reference)	2528 (1588)	1.78	1.48–2.15	<0.001	1.56	1.19–2.04	0.001	1.55	1.18–2.03	0.002
Time: Study time points	4475	0.90	0.88–0.93	<0.001	1.01	0.94–1.07	0.884	—	—	

P values in the regression model are based on the likelihood ratio test.

∗Backward stepwise selection from the fully adjusted model at $P < 0.05$, with SSC entered into all models. No interactions between SSC and the other variables in the final model were significant.

†General anesthesia included patients induced with anesthesia requiring respirator support through laryngeal mask or endotracheal tubes. Regional anesthesia included patients anesthetized through epidural-, spinal-, or plexus anesthesia. Combinations of regional and general anesthesia were classified as general anesthesia.

ASA indicates American Society of Anesthesiologists; OR, odds ratio; WHO SSC, World Health Organization Surgical Safety Checklist.

($P = 0.151$). However, we observed a highly significant reduction of mortality from 1.9% to 0.2% ($P = 0.02$) in the smaller community hospital (albeit on fewer cases due to small hospital size), with a relative risk reduction of 91%. The Checklist effect on mortality was thus present but weaker in our RCT than in previous reports from pre-/postintervention studies.[13–16]

Strengths and Limitations of This Study

In our view, this study's major contribution to our better understanding of Checklist effects lies in its stepped wedge cluster RCT design. Such designs have been considered unfeasible because in countries such as the United Kingdom, the WHO SSC is now national policy (and hence a control arm is not available) and also due to contamination and biases resulting from "control" operating room teams treating control patients as patients assigned to the checklist arm.[13] However, such contaminations and biases were minimized by randomization of the study clusters in "stepped wedges."[33] Each cluster acted as its own control and hence provided data in both the control and SSC stages, comparable with a crossover design, with all data being compared between the control and SSC stages. To reduce uncertainty of variation in surgical procedure complication rates and complexity within each cluster from pre- to postintervention, we adjusted for possible risk factors as age, sex, comorbidity, surgical specialty, emergency or planned surgery, type of anesthesia, and time (study time points). The stepped wedges provided the possibility to control complication and morbidity for time effects during the study period. Complications rates varied at different study time points but when controlled for, time was not a confounding factor for the Checklist effect on complications (Table 3). The stepped wedge cluster RCT design is considered particularly appropriate for studying patient safety interventions.[30,32] To control for leakage and possible contamination of surgeons between the 2 hospitals and the 5 surgical specialties, we did not include the same surgical specialty in both hospitals. The SSC was first introduced to the intervention groups. Hence, any possible contamination would have leaked from the intervention group to improve care in the controls, eventually. The results do not suggest that this was apparent.

The degree of blinding is important for the validity of RCTs, and in our study, operating room staff were not informed of the study outcomes, as they routinely registered the patient data on the electronic data system of their operating rooms. To further prevent information bias, the outcome assessors were masked to which cohort (control and SSC stages) patients were enrolled. Furthermore, to reduce the risk of performance and information bias, all recovery and ward staff carried out care as usual and were blinded to the study cohorts and outcomes, following the extended CONSORT statement for nonpharmacological randomized trials.[40]

Our study has several limitations. First, the clusters that had not yet received the intervention could have been contaminated by possible enthusiasm for the SSC from colleagues in other specialties that were in the SSC study stage. Such bias would have likely minimized any positive effects of the Checklist. The substantial and robust decrease of complications that we found suggests that such bias did not affect the study significantly. A second limitation is the way in which the data were registered. A selection of *ICD-10* codes was used to identify complications. It is possible that surgeons and ward doctors reported the *ICD-10* codes variably. As far as we could account for, there were no changes in the *ICD-10* code implemented during the study period. Furthermore, variable recording would equally affect the control and the SSC stages of the study. A final limitation is that recording of complications was confined to the in-hospital admission period. Data on complications after discharge were not recorded or obtained. The total number of postoperative complications could, therefore, be higher. A more extensive follow-up of the patients after discharge would be beneficial in future studies, though costly.

Further Research

Further research should investigate how use of the SSC and other checklists achieves its positive impact on patient outcomes. Improved outcomes post–checklist implementation have been explained by improvements in communication and teamwork in the operating room[27] and a wider improvement in safety attitudes.[20,22,24–26] In a concurrent with this study evaluation of the impact of the introduction of the WHO SSC on patient safety climate in operating rooms, we did not find the hypothesized improvement in culture—although we did find that operating room teams reported being better able to handle a complex situation when the Checklist is used.[34] We also anecdotally observed that the introduction of the WHO SSC drove behavior change, as the team members paused, introduced themselves, and carried out team briefings prior to the operative list. Such behavioral changes may precede deeper changes in organizational safety culture—which may in turn underline the sustainability of long-term appropriate implementation of a checklist and improved patient outcomes. These questions require longitudinal controlled research designs to be addressed.

CONCLUSIONS

This stepped wedge cluster RCT adds to this growing body of evidence on the positive effects on patient outcomes driven by the WHO SSC. We conclude that the use of the WHO Checklist prevents complications and reduces in-hospital length of stay and potentially also mortality across a wide range of patients undergoing simple or complex surgical procedures in hospitals within a well-developed and funded health care system.

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Supplemental Digital Content Table 1. Complications identified by ICD-10 codes.

Complications	ICD-10 codes
Respiratory complication	
Pneumonia	J15, J18
Respiratory failure	J96, R09
Other respiratory complications	
asthma, pleura-effusion, dyspnea	J45, J90, J91, R06
Cardiac complication	
Cardiac arrest	I46, R96
Arrhythmia	I44, I48, I49
Congestive heart failure	I50, I51, J81
Acute myocardial infarction	I21
Angina pectoris	I20
Infections	
Sepsis	A40,41, R65
Surgical site	T81.1, T81.4-6, T82.7, T85.7, T88.0
Urinary tract	N30, N39
Other infections	
meningitis, peri- and endocarditis, gastro enteritis	G00, I31, A04
Surgical wound rupture	T81.3
Nervous system complication	
Delirium and somnolence	F05, R40
Bleeding	T80.3, T80.4, T81.0, T82.8
Embolism	
Arterial-, venous-, lung- and air emboli's	I77, I26, I80, T80.0, T81.7
Mechanical implant complication	T82.0, T83.0, T83.1-4, T84.0-4, T85.0-6
Anaesthesia complication	T88.1-9
Other complications	
Circulatory collapse, unintended punctures or lacerations , kidney failure, complications following surgical and medical procedures and complications to surgery not classified	T81.1-2, T81.8-9, N17, T87

Abbreviations: ICD-10 = International Classification of Diseases 10th version

Supplemental Digital Content Table 2.
Results from logistic regression analyses of mortality on unique patient and treatment variables in the stepped wedge cluster randomised controlled trial of the WHO SSC in two hospitals in western Norway in 2009-2010.

		Unadjusted			Fully adjusted			Final model [a]		
	n	OR	95% CI	P-value	OR	95% CI	P-value	OR	95% CI	P-value
Absence of the WHO SSC *(After = reference)*	1778(2033)	1.53	(0.87, 2.71)	0.141	1.25	(0.40, 3.86)	0.703	1.48	(0.80, 2.78)	0.214
Age	2343(1468)	1.05	(1.03, 1.07)	<0.001	1.02	(0.99, 1.05)	0.058	-	-	
Male gender *(female = reference)*	2126(1685)	0.76	(0.43, 1.33)	0.336	0.81	(0.41, 1.60)	0.543	-	-	
Comorbidity by ASA-score	3811			<0.001			<0.001			<0.001
Healthy (reference)	885	1			1			1		
Mild systemic disease	1564	1.13	(0.10, 12.50)		0.75	(0.06, 8.89)		1.24	(0.11, 13.73)	
Moderate systemic disease	1091	23.29	(3.16, 171.48)		10.48	(1.20, 91.45)		25.36	(3.43, 187.64)	
Severe systemic disease	104	160.73	(21.06, 1226.4)		41.68	(4.46, 389.23)		116.06	(15.06, 894.18)	
Morbid	4	294.67	(14.75, 5886.8)		-	-		-	-	
Surgical specialty	3811			0.159			0.104			
Orthopaedic (reference)	1688	1			1					
Cardiothoracic	525	2.36	(1.15, 4.84)		4.70	(1.25, 17.67)		-	-	
Neuro	502	0.93	(0.35, 2.53)		2.56	(0.65, 10.07)		-	-	
General	813	1.16	(0.53, 2.51)		4.67	(1.10, 19.88)		-	-	
Urology	283	0.99	(0.29, 3.40)		3.06	(1.09, 8.61)		-	-	
Surgery *Emergency (Elective = reference)*	2244(1567)	3.64	(1.95, 6.79)	<0.001	6.31	(2.53, 15.72)	<0.001	3.43	(1.67, 7.05)	0.001
Anaesthesia *General (Regional = reference)*	2178(1352)	1.62	(0.89, 2.94)	0.111	0.86	(0.35, 2.14)	0.745	-	-	
Time M*onths*	3811	0.94	(0.85, 1.04)	0.362	1.01	(0.82, 1.24)	0.965	-	-	

Abbreviations: WHO SSC = World Health Organization Surgical Safety Checklist; ASA = American Society of Anaesthesiologists; OR = odds ratio; CI = confidence interval; P values in the regression model are based on the likelihood ratio test.

a) Backward stepwise selection from the fully adjusted model at $P < 0.05$, with SSC entered into all models. No interactions between SSC and the other variables in the final model were significant.