Impact of the WHO Surgical Safety Checklist implementation on perioperative work and risk perceptions

A process evaluation by use of quantitative and qualitative methods

Hilde Valen Wæhle

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

This PhD thesis is based on studies emanating from the Department of Clinical Science, Faculty of Medicine, University of Bergen, conducted at the Patient Safety Unit, Department of Research and Development at Haukeland University Hospital. The studies were endorsed by the Norwegian Advisory Unit for Antibiotic Use in Hospitals (KAS), located at Haukeland University Hospital.

The PhD scholarship was funded by PhD grants from the Western Norwegian Regional Health Authority (no.: HV1174), and Haukeland University Hospital. Professor Stig Harthug (University of Bergen), Professor Eirik Søfteland (University of Bergen), PhD Arvid Haugen (Haukeland University Hospital), and PhD Ingrid Smith (WHO) have supervised and guided this project.

The nature of this patient safety research project has implied multidisciplinary collaboration, including research partners with complementary skills from clinical practice, surgery, anaesthetics, perioperative nursing, infection disease, implementation and patient safety research, evidence-based practice, biostatistics, epidemiology and ethnography.

This regional research project was carried out in collaboration with Førde Central Hospital, Førde, Norway, Haraldsplass Deaconess Hospital, Bergen, Norway, and Haukeland University Hospital, Bergen, Norway. Parts of the work were conducted in collaboration with partners from Centre for Resilience in Healthcare (SHARE), University of Stavanger, Stavanger, Norway, and Centre for Implementation Science, Health Service & Population Research Department, King's College London, London, United Kingdom.

I participated in the Postgraduate School of Clinical Medicine Program at the University of Bergen, Bergen, Norway; seminars on "Resilience in Healthcare-theory development in healthcare" and "Research methods: challenges and reflexivity during fieldwork" at SHARE, University of Stavanger, Stavanger, Norway; and attended the Implementation Science Masterclass at King's College London, London, United Kingdom.

During the course of this thesis, I have been part of the Research Network for Patient Safety Research, funded by the Western Norwegian Regional Health Authority.

"It is not the strongest of the species
that survive, nor the most intelligent,
But the most responsive to change."

-Charles Darwin

"Those who cannot change their minds
cannot change
Anything"

-George Bernard Shaw

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Haukeland University Hospital

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November 2019,
Hilde Valen Wæhle

Abstract

Background

Human performance deficiencies account for a large proportion of adverse surgical events. The World Health Organization (WHO) Surgical Safety Checklist (SSC) was launched to improve teamwork and patient outcome. Its introduction in hospitals worldwide has been associated with beneficial impacts on a range of patient and team outcomes. However, both the implementation quality and the comprehensive inclusion of all parts of the checklist is reported to differ among hospitals, surgical specialties and surgical staff members. To understand and engage with these differences, studies were warranted to investigate both perioperative work processes and process indicators associated with positive SSC outcomes.

Aims

1. To investigate the impact of WHO SSC implementation on perioperative care processes and patient outcome.
2. To explore perioperative work processes in the provision of surgical antibiotic prophylaxis (SAP) following the SSC implementation.
3. To explore how the WHO SSC fits with existing perioperative risk management strategies among the multidisciplinary team members.

Methods

A combination of quantitative and qualitative methods was used in the studies for this thesis, including data from patients, healthcare personnel and perioperative teamwork observations. In Study 1, we performed a secondary analysis of a WHO SSC stepped wedge cluster randomised control trial. A total of 3,708 surgical procedures were analysed from three surgical units (neurosurgery, cardiothoracic, and orthopaedic) from Haukeland University Hospital. We examined how the SSC implementation quality affected perioperative work processes and patient outcome.

In Study 2 and Study 3, we used a prospective ethnographic design, combining 40 hours of observations and 22 single face-to-face interviews of key informants, conducted at Haraldsplass Deaconess Hospital, Førde Central Hospital and Haukeland University Hospital. We explored perioperative work processes in relation to SSC utilisation. In Study 2, we outlined the provision of surgical antibiotic prophylaxis, and in Study 3, we analysed the integration of the SSC in local and professional perioperative risk management.

Results

In Study 1, the results showed that high-quality SSC implementation, i.e., all 3 checklist parts used, was significantly associated with improved perioperative work processes (preoperative site marking, normothermia protection, and timely provision of SAP pre-incision) and reduction of complications (surgical infections, wound rupture, perioperative bleeding, and cardiac and respiratory complications).

In Study 2, we identified that the provision of SAP was a complex process and outlined the linked perioperative work processes. This involved several interacting factors related to preparation and administration, prescription accuracy and systems, patient specific conditions and changes in the operating theatre schedules. The timeframe of 60 minutes described in the SSC was a prominent mechanism in facilitating administration of SAP before incision.

In Study 3, we identified three dominant strategies: “assessing utility”, “customising SSC implementation”, and “interactive micro-team communication”. Each of these reflected on how the SSC was integrated into risk management strategies in daily surgical practice. Each strategy had corresponding categories describing how SSC utility assessment was carried out and how performance of SSC was customized, mainly according to actual presence of team members and barriers of performance. The strategy of “interactive micro-team communication” included formal and informal micro-team formations where detailed, and specific risk assessments unfolded.

Conclusion

Utilisation of all 3 parts of the SSC was significantly associated with improved processes and outcomes of care. Overall improvement of SAP administration is likely to have been influenced by the SSC timeframe of “60 minutes prior to incision”, either as a cognitive “reminder” of timely administration and /or as an educational intervention. Although the SSC use has made significant impact on specific perioperative work processes, identified norms of behaviour and communication indicate that the SSC seemed not to be fully integrated into existing perioperative risk management strategies on a daily basis among the multidisciplinary team members.

List of publications

Paper 1

Haugen AS, Wæhle HV, Almeland SK, Harthug S, Sevdalis N, Eide GE, Nortvedt MW, Smith I, Søfteland E. Causal analysis of World Health Organization's Surgical Safety Checklist implementation quality and impact on care processes and patient outcomes: Secondary analysis from a large stepped wedge cluster randomized controlled trial in Norway. Annals of Surgery. 2019, February; 269(2):283–290. doi:10.1097/SLA.0000000000002584

Paper 2

Wæhle HV, Harthug S, Søfteland E, Sevdalis N, Smith I, Wiig S, Aase K, Haugen AS. Investigation of perioperative work processes in provision of antibiotic prophylaxis: A prospective descriptive qualitative study across surgical specialities in Norway. BMJ Open. 2019, June; 9:e029671. doi:10.1136/bmjopen-2019-029671

Paper 3

Wæhle HV, Haugen AS, Søfteland E, Sevdalis N, Wiig S, Harthug S. How does the WHO Surgical Safety Checklist fit with existing perioperative risk management strategies? An ethnographic study across surgical specialities. Submitted.

Paper 3: In process, preprint available at: https://dx.doi.org/10.21203/rs.2.12968/v1

Abbreviations

CI = Confidence Interval

ICPS = International Classification for Patient Safety

IHI = Institute for Healthcare Improvement

OR = Odds Ratio

OT = Operating Theatre

QI = Quality Improvement

RCT = Randomised Controlled Trial

SAP = Surgical Antibiotic Prophylaxis

SW = Stepped Wedge

SSC = Surgical Safety Checklist

SSI = Surgical Site Infection

WHO = World Health Organization

WNRHA = Western Norway Regional Health Authority (Helse Vest RHF)

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1. Introduction

1.1 Background

An estimated 313 million surgeries are performed globally each year.[1] Surgical care is a fundamental component of healthcare as a preventative, diagnostic, and/or supportive treatment of numerous chronic and acute conditions.[2] Provision of surgical service has improved public health worldwide and contributes to an overall social and economic development.[3] Yet almost 7 million patients experience a major complication and 1 million die during or immediately after surgery.[4] Adverse events in surgical care remain a frequent cause of injury or death and source of potentially avoidable health care expenditure.[5] Postoperative infections, particularly surgical site infections (SSIs), comprise a large proportion of the surgical complications, causing substantial morbidity, mortality, prolonged hospital stay and increased costs.[6-8] On average, care for patients with SSIs have been estimated to cost US$5,155 compared with US$1,733 for those with an uncomplicated postoperative course.[9] However, the total costs associated with SSIs vary considerably depending on type of microorganism and severity of the infection, which will affect both length of hospital stay and level of care. In addition, the societal expenditures related to patients' loss of productivity and function must be included.

One of the challenges of improving the quality in surgery originates from its complexity. Even the most straightforward procedures involve many critical steps, each with an opportunity for failure and the potential for patient injury.[10] In daily practice it is often unclear whether an undesired outcome, such as an SSI, occurs due to an inherent medical risk, or is the result of an error or a medical procedure that was carried out suboptimally.[11] However, the lack of compliance to infection prevention measures, such as timely administration of antibiotic prophylaxis, is verifiable as a contributory factor to SSIs.[12] Human performance deficiencies have been reported to exceed the technical execution errors; many factors contributing to adverse events originate from nontechnical errors and flawed teamwork rather than from lack of clinical skills.[5 13-15]

The safety of surgical care was selected as the topic for the second WHO Global Patient Safety Challenge in 2007-2008, resulting in the *Safe Surgery Saves lives programme,* and the development of the *Surgical Safety Checklist* (SSC).[10] Historically, preventing surgical infections has, to a large extent, involved development of aseptic methods, infection control programmes, and SSI surveillance.[16-18] The SSC is known as the first safety intervention to address some of the complexity in surgery by involving the whole perioperative team in identifying evidence based items of risk reduction in perioperative care.[10] During the decade since its launch, the SSC has been implemented globally, and clinical effectiveness studies have demonstrated beneficial impact of the SSC implementation on a range of patient and team outcomes.[19-27]

Yet despite the demonstrated SSC effectiveness, research shows that the SSC implementation results have been mixed and inconclusive, and that implementation quality differs at service level, provider level, and among specific parts of the SSC.[28-33] The success of safety interventions, such as the SSC, depend on their implementation and the clinical and organisational context within which they are applied.[34] Although safety improvements may be attributable to a change in perioperative work processes and teamwork following the SSC implementation, the mechanisms of action to explain these changes remain less clear.

The overall aim of this thesis was, therefore, to study perioperative work processes in relation to SSC utilisation, and, to gain knowledge on how and why the SSC intervention might best work in everyday clinical practice. As the SSC use is mandatory in most surgical departments in Norway, identifying active ingredients and how they exert their effects is important in continuing to improve the quality and safety for surgical patients.

1.2 What is patient safety?

Safety is not binary, but must be seen as a concept that can be graded.[11] Risk, on the other hand, is known as a quantifiable concept of "a probability, or the product of probability and adverse outcome".[11] Although safety cannot directly be measured in size and numbers, it can be quantified if interpreted as "the degree of reduction of risk". In this sense, risk is complementary to safety.

The International Classification for Patient Safety (ICPS) was developed by the WHO World Alliance for Patient Safety.[35] The final conceptual framework of ICPS is composed of ten major classes and concepts that group incidents into clinical categories, which provide descriptive information and represent system resilience.[36] This conceptual framework is based on universally accepted classifications of patient safety terms and key concepts. It provides an essential overview of *how* and *where* to gather information and data on patient safety to support strategies aiming to improve the quality of care. The conceptual framework is outlined in Figure 1.

It is important to distinguish the patient safety classification from a reporting system. A reporting system provides an interface which enable users to collect, store and retrieve data in a reliable and organised fashion. A classification comprises a set of concepts linked by semantic relationships and forms the structural underpinning of any type of reporting system.[36] It also provides information for a variety of other purposes including national statistics, descriptive studies of safety and evaluative research.

It is always fundamental to acknowledge that complex relationships exist between the incident type and its contributing factors. Depending on the context, circumstances and outcomes, an incident can be a contributing factor to another incident whilst some contributing factors can be a circumstance in their own right.[36]

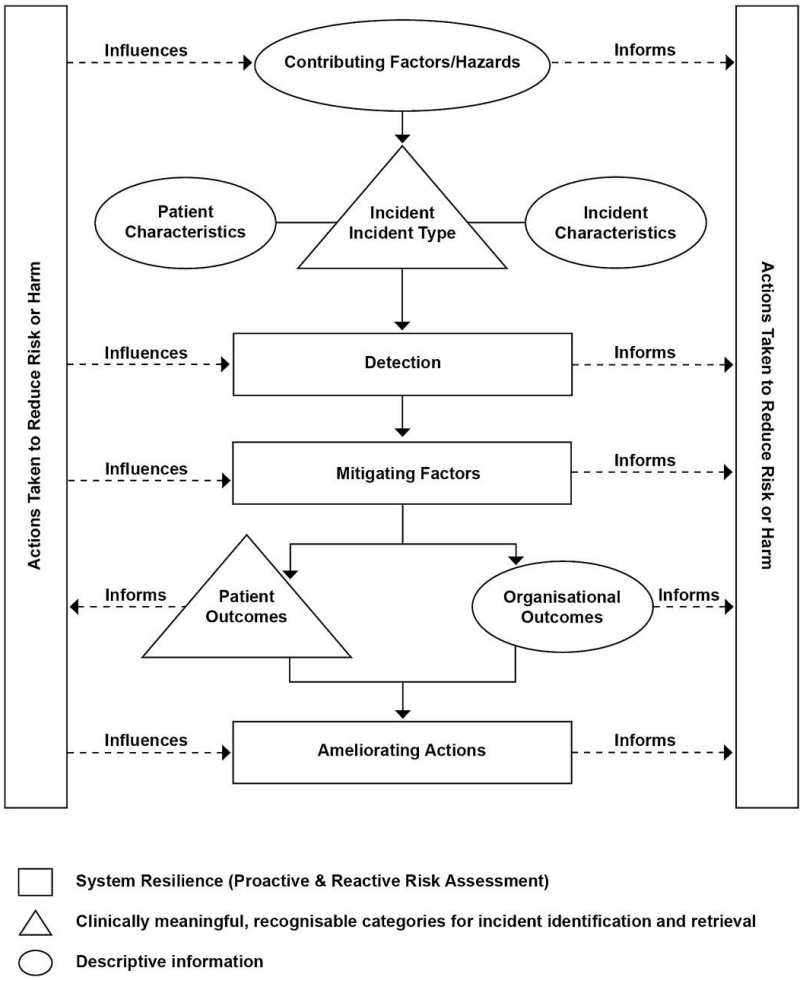


Figure 1. Conceptual framework for the ICPS. The solid lines enclose the 10 major classes of the ICPS and the dotted lines represent the semantic relationship between them.

Source: The World Alliance for Patient Safety Drafting Group. Sherman H, Castro G, Fletcher M., on behalf of The World Alliance for Patient Safety. Towards an International Classification for Patient Safety: the conceptual framework. Int J Qual Health Care 2009;21:2-8. Reprinted with license (no. 4672530792291) from Oxford University Press.

1.2.1 Definitions

Traditionally, *patient safety* has been defined as being "the absence of adverse outcomes, unnecessary harm or potential harm associated with healthcare", also referred to as Safety-I.[37]

The WHO defines *patient safety* as "the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum".[38] "An acceptable minimum" refers to the collective notions of current given knowledge, resources available and the context in which care was delivered, weighed against the risk of non-treatment or other treatment.[38]

Another term of *patient safety* used by The Institute for Healthcare Improvement (IHI) refers to both "the field of expertise and the practices used in the field". [39] IHI thereby involves the use of safety science and system thinking to create practices, procedures, and environments that enable the safest case and avoidance of harm.
A wider perspective on *patient safety*, also referred to as "Safety-II" focuses on what can go right as well as what can go wrong, and relates more to a system's ability to succeed under varying conditions.[37 40]

In this thesis, the term *patient safety* will be related to the definitions above, including "Safety I" and "Safety-II".

In hospitalised patients, an *adverse event or outcome* is defined as "an unintended injury or complication resulting in prolonged length of hospital stay, disability at the time of discharge or death caused by healthcare management and not by the patients' underlying disease".[41] Traditionally, the term *error* has also been used to describe an adverse outcome, defined as a failure to carry out a planned action as intended or application of an incorrect plan.[42] However, there is an important distinction between the two terms; not all errors result in adverse outcomes, e.g., patient harm, and not all adverse outcomes are necessarily a result of errors.[43] In this thesis, the term *error* will be used when describing actions, or lack thereof, that may contribute to an adverse

event, whereas *an adverse event* or *outcome* will be used when describing an incident of patient harm.

A *complication* is described as an unintended negative outcome which develops as a result of treatment of an illness already present during, or after care, and either necessitates (adjustments of) treatment, or leads to permanent harm.[11]

An *incident* is described as an unintended event stemming from the health care process which either effectuated, or could have effectuated, or still can effectuate harm to the patient.[11]

A *near-miss* is described as an unintended occurrence, with the capacity (potentiality) to cause error but which does not have adverse consequences because of timely and appropriate identification and correction of potential consequences for the patient; or where consequences do not affect patient's physical, mental, or social functioning.[11]

1.3 Adverse events and complications in surgery

A systematic review of the incidence reporting of in-hospital adverse events shows that the majority of the adverse events are associated with surgical care.[44] Another systematic review, including 16,424 surgical patients worldwide, reports that adverse events occurred in 14.4% of the patients, with potentially preventable adverse events occurring in 5.2%.[45]

In a recently published systematic review and meta-analysis of 337,025 patients, around one in 20 patients were exposed to preventable harm in medical care. This was more prevalent in advanced specialties such as surgery.[46] A pooled proportion of 12% of preventable patient harm caused permanent disability or patient death.[46] Whilst error rates differ according to medical domains, surgery seems to represent an area with high rates and more devastating consequences. This might be because intraoperative adverse events are independently associated with substantial increases in postoperative mortality, morbidity, and prolonged length of in-hospital stays.[47]

1.3.1 Surgical site infections

Surgical site infections encompass a large proportion of the surgical complications.[6-8] European Centre for Disease Prevention and Control (ECDC) defines an SSI as an infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure, or within one year if prosthetic material is implanted at surgery.[48] Clinical criteria for defining SSI is developed by The United States Centers for Disease Control (CDC) and Prevention and includes one or more of the following criteria;

- a purulent exudate draining from a surgical site,
- a positive fluid culture obtained from a surgical site that was closed primarily,
- a surgical site that is reopened in the setting of at least one clinical sign of infection (pain, swelling, erythema, warmth) and is culture positive or not cultured.[49]

The incidence of SSIs is reported to vary across surgical procedures, specialties and conditions, with a range of 0.1% to 50.4%.[50] In a European epidemiological surveillance report from 2016, including data from 15 countries, the percentage of SSIs varied from 0.5% (knee prosthesis surgery) to 9.0% (colon surgery).[51] The report, issued by the European Centre for Disease Prevention and Control (ECDC), provides an overview of surgical procedures under surveillance in countries within the European Economic Area (EU/EEA). SSI incidence is monitored by the following indicators:

- The percentage of SSIs per 100 operations: an indicator that includes SSIs diagnosed during hospital stay and after discharge from the hospital (detected at hospital readmission or by post-discharge surveillance).
- The incidence density of in-hospital SSIs per 1,000 post-operative patient-days: an indicator that only includes SSIs diagnosed during hospital stay in patients with a known hospital discharge date.

An overview of SSI incidence associated with selected surgical procedures under surveillance by the ECDC is listed in Table 1.

Table 1. Percentage of SSIs and incidence density of in-hospital SSIs by year and selected types of surgical procedures, in EU/ EEA countries, 2016.[1]

Surgical procedure type	Percentage of SSIs per 100 operations [inter-country range]	Incidence density of in-hospital SSIs per 1000 post-operative patient-days [inter-country range]
Coronary artery bypass graft	2.8 [1.6–7.4]	1.0 [0.8–4.0]
Cholecystectomy	1.7 [0.8–3.4]	1.3 [0.6–2.5]
Colon surgery	9.0 [5.3–18.0]	5.5 [1.9–11.0]
Caesarian section	1.9 [0.5–5.2]	0.6 [0.1–3.0]
Hip prosthesis surgery	1.0 [0.1–4.0]	0.3 [0.1–2.0]

[1] Numbers are based on the Annual Epidemiological Surveillance report; Healthcare-associated infections: surgical site infections. ECDC 2016.[51]

In Norway, SSIs account for 23-28% of the healthcare-associated infections.[52] A previous study shows that between 2.2% and 13.5% of patients who undergo surgery in Norway develop an SSI.[52] National SSI surveillance data are provided by the Norwegian national nosocomial infections surveillance (NOIS-POSI), which is part of the Norwegian Institute of Public Health. Incidence reporting on SSIs in Norway is based on an active, mandatory post-discharge surveillance for 30 days after surgery (one year for implants). The incidence of SSIs in surgical procedures under mandatory surveillance in Norway is listed in Table 2. The table shows data from the most recent report on SSI incidence, including numbers at national and hospital level (Haukeland University hospital).

Table 2. The incidence of SSIs associated with surgical procedures under mandatory surveillance, on national level and local hospital level; 2016.

Types of surgery	[2]Incidence of SSIs in Norway (95% CI) %	[2]Incidence of SSIs at Haukeland University hospital, %
Coronary artery bypass graft	4,5% (3,2 - 5,7)	4,6%
Cholecystectomy	4,8% (4,2 - 5,3)	1,3%
Colon surgery	11,9% (10,8 - 13,0)	13,4%
Caesarian section	4,5% (4,1 - 4,9)	4,8%
Hip prosthesis surgery[2]	3,7% (3,1 - 4,3)	1,3%

[1] Numbers are based on the Norwegian national Nosocomial Infections Surveillance local report for Haukeland University Hospital, 2016.
[2] Numbers represent only hemi-prosthesis.

SSI incidence is higher in low and middle income countries,[53] yet SSIs remain the most common healthcare-associated infection in the USA, and the second most frequent in Europe.[18 49] Furthermore, SSIs are among the most preventable health-care-associated infections, but their prevention is complex[49]. At a macro level, hospitals are complex organisations by definition, and at a micro level, how the multidisciplinary surgical teams interact with the system and within each other is dynamic and multidimensional.

1.4 How to manage patient safety in surgery?

1.4.1 Theoretical perspectives

Understanding and managing patient safety can be derived from the "Safety-I" and "Safety- II". The "Safety-I" approach presumes that things go wrong because of potentially identifiable failures or malfunctions of specific components. These are components of technology, procedures, the human workers and the organisations in which they are embedded.[54] Within a hospital setting, healthcare workers — acting alone or collectively as a team — are, therefore, viewed predominantly as a liability or hazard, because they are the most variable of these components. The purpose of

accident investigation in “Safety-I” is to identify possible causes and contributory factors of adverse outcomes, and to assess risk to determine their likelihood. The safety management principle is to respond when something happens or is categorised as an unacceptable risk, usually by trying to eliminate causes or improve barriers, or both.[37]

The “Safety-II” perspective encompasses the concept of *resilience*. This is referred to as “the intrinsic ability of a system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required operations under both expected and unexpected conditions” (p. 275).[55] In relation to patient safety, this relates to the healthcare systems’ ability to detect and prevent the development of incidents and near-misses into adverse events and complications.

In surgery, monitoring patient safety by the “Safety-I” perspective includes measures of adverse events, harm and system failures, and is essentially retrospectively focused.[56] However, displaying resilience according to “Safety-II” is more difficult to measure and monitor. Some of the failures in perioperative care may be known and even predictable. Safety is partly achieved by operating theatre personnel being alert to these perturbations and responding rapidly to keep things on track. However, when they succeed, or the system compensates in other ways, these actions are, in a sense, invisible. Safety is then, as is often said, a ‘dynamic non-event’.[56]

1.4.2 Quality systems in surgical care

Numerous levels of health care policies, control systems and initiatives influence the quality of healthcare, see Table 3. In the following, the main institutions responsible for the quality of healthcare in Norway are outlined according to the four health care policy typologies described in the OECD Reviews of Health Care Quality: Norway 2014: Raising Standards.[57]

Table 3. A typology of health care policies that influence health care quality[57]

	Policy	Examples
1	Health system design	Accountability of actors, allocation of responsibilities, legislation
2	Health system input (professionals, organisations, technologies)	Professional licensing, accreditation of healthcare organisations, quality assurance of drugs and medical devices
3	Health system monitoring and standardisation of practice	Measurements of quality of care, national standards and guidelines, national audit studies and reports on performance
4	Improvement (national programmes, hospital programmes and incentives)	National programmes on quality and safety, pay for performance in hospital care, examples of improvement programmes within institutions

1. Health system design: The Norwegian health system is regulated through a large number of acts and legislations containing a number of quality requirements. The most relevant to the specialist healthcare and surgery, are the following:

- The Patients' Rights Act of 1999 (*Pasientrettighetsloven*)[58]
- The Health Personnel Act of 1999 (*Helsepersonelloven*)[59]
- The Specialist Health Services Act of 1999 (*Spesialisthelsetjenesteloven*)[60]
- The Norwegian national regulation on quality, patient safety and quality improvement *(Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten*)[61]
- The Norwegian national regulation of infection prevention and control (*Forskrift om smittevern i helsetjenesten*)[62]
- The Norwegian national regulation for medication management *(Forskrift om legemiddelhåndtering for virksomheter og helsepersonell som yter helsehjelp)[63]*

2. Health system input: The Ministry of Health and Care Service (*Helse-og omsorgsdepartementet*) and the Norwegian Directorate of Health (*Helsedirektoratet*) are responsible for the planning of health care professional education requirements. They are required to ensure that the health workforce has adequate and relevant competence; to facilitate clinical practice training programmes for health

professionals and students, including operating theatre nurses and nurse anaesthetists; and to organise internship programmes for graduate physicians.[57]

3. Health system monitoring and standardisation of practice: The Norwegian Board of Health Supervision (*Statens helsetilsyn*) is the national authority with responsibility for supervision and quality control of all health, social and childcare services. County Governors, through their County Medical Officers, are (with few exceptions) the actual supervisory body of all health services and health professionals. Supervision is a regular activity to ensure that services are run in accordance with the professional quality standards required by the national Act and Regulations. When health services or health professionals do not comply with these Regulations, the supervisory authority can impose sanctions to enforce compliance.[57 64]

National-SSI surveillance data are provided by the Norwegian national nosocomial infections surveillance (*NOIS-POSI*), which is part of the Norwegian Institute of Public Health.[65] NOIS is responsible for describing occurrences of healthcare-associated infections (such as SSIs) by time and other characteristics, detecting outbreaks, providing a basis for preventive measures, and evaluating such measures. NOIS-SSI has three important key characteristics:

- It is a mandatory, national surveillance system
- It has a highly computerised data collection system in the hospitals
- It has an active, mandatory post-discharge surveillance (PDS) for 30 days after surgery (one year for implants)

The regulation of infection prevention and control requires that the data sent to the national database are anonymised. This entails that personal identifiers for each patient, such as name and personal identification number, are removed before submission.[65]

The Directorate for Health is an executive agency and authority subordinate to the ministry. It issues clinical guidelines such as the National guidelines for antibiotic use in hospitals, maintains the National System for the Introduction of New Health Technologies, coordinates 18 patient ombudsmen, and is responsible for the national quality indicator system.[64]

4. Improvement: From 2014 to 2018, the Directorate for Health has been in charge of the secretariat for the National Patient Safety Program, and still has responsibility for the follow-up of included interventions. From 2016-2019 the Directorate has administered a reporting and learning system for adverse events in hospitals.[64] This structure is now governed by The Norwegian Healthcare Investigation Board (Statens undersøkelseskommisjon for helse- og omsorgstjenesten), established in 2019.[66]

1.4.3 Measures of quality in surgical care

In healthcare, patient safety cannot be seen in isolation from broader concerns about quality. Both quality and safety are ultimately determined by the degree to which health care improves important patient outcomes.[67] Safety must therefore be regarded as one of the aspects concerning the quality of care, which also encompass efficiency, effectiveness, timeliness and patient experience.[68] Quality of healthcare can be defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge, and can be divided into different dimensions according to the aspects of care being assessed".[67] A model for measuring the quality of care includes the three components of structure, process, and outcome as described by Donabedian,[67] illustrated in Figure 2 (page 14).

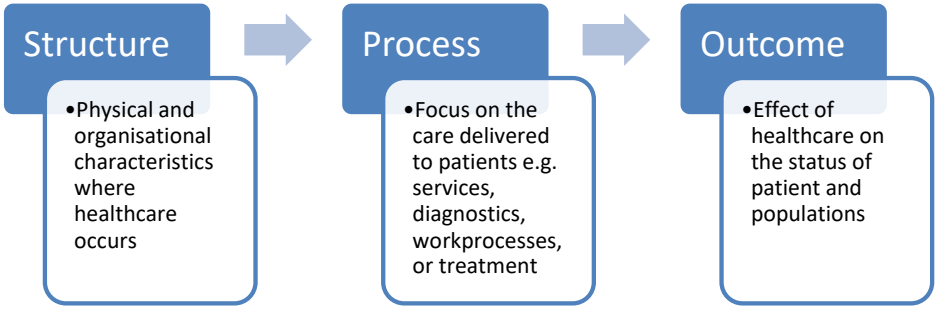


Figure 2: The Donabedian model for quality of care

Clinical indicators are measurable aspects of care and there is evidence that they represent quality.[69] The following distinction between structure, process and outcome indicators is useful.[11]

Structure denotes the attributes of the settings in which care occurs. In surgery, this includes the attributes of material resources (operating theatre facilities and equipment), human resources (number and qualifications of operating theatre staff), and the organisational structure, including methods of peer review and reimbursement. Structure measures or indicators thereby reflect the attributes of the service/provider.

Process denotes what is actually done in giving and receiving care. Process measures or indicators reflect the way the surgical systems and processes work to deliver the desired outcome.

Outcome denotes the effects of care on the health status of patients and population. Outcome measures or indicators reflect the impact of surgical treatment on patient outcome.

Multiple factors potentially affect the safety and quality of care delivered to surgical patients. The structural factors, as described by Donabedian's model, represent not only physical structures, but also basic institutional characteristics such as specific quality programmes being in place.[56] Establishment of an infection control programme is an essential part of SSI prevention and is considered a structural element within the hospital. An effective programme can reduce the rate of SSIs by 40 %.[70] The content of an infection control programme includes several processes of care that are known to reduce the risk of SSIs. Some of the fundamentals are hand hygiene, use of gloves and other barrier devices by operating theatre personnel, patient decolonisation, skin antisepsis, and method hair removal.[70] Other perioperative measures include maintaining normothermia, oxygenation, controlling blood glucose, minimizing red blood cell transfusion, limiting traffic through the operating room, and possibly the use of laminar flow in selected cases.[70] However, the most important factor in the prevention of an SSI, in addition to careful attention to operative technique, is timely administration of effective preoperative surgical antibiotic prophylaxis.[49 70]

The Norwegian national guidelines for antibiotic use in hospitals[71] is considered a structural element of healthcare in the same way as the infection control programme is. The active surveillance and reporting of selected surgical procedures is mandatory, with SSI incidence as outcome indicator of surgical care (page 12).[65] Data collected by medical registries such as the Norwegian Arthroplasty Register also provide important measures of quality related to patient outcome. Different types of prostheses and surgical techniques are compared according to the risk of reoperation and hence the durability of the prostheses is measured and monitored longitudinally. Here, the risk of reoperation, patient function, and patient reported outcomes, such as pain and quality of life after surgery, are considered the most important quality measures.[72]

Employment of such structure and outcome measures is used to assess quality of care in surgery. However, the surgical teamwork and perioperative care, including SSI prevention, are mediated by factors related to staff attitude, behaviours, knowledge,

competencies, and motivation, which all influence clinical work processes.[56] Monitoring and measuring specific SSI preventative measures by process indicators might reveal how surgical micro systems and processes work to deliver the desired outcome.

1.5 The WHO Surgical Safety Checklist

The WHO Surgical Safety Checklist with embedded evidence based bundles of SSI preventative measures was launched in 2009 to improve surgical care adherence, consistency and communication.[10] The standardised visual checklist requires perioperative procedures to be interrupted at certain time points to allow for important information and safety items to be reviewed: Sign in (before induction of anaesthesia), Time out (before skin incision) and Sign out (immediately after skin closure).[10] The SSC is reported to have been distributed to more than 3,000 hospitals worldwide, has been made mandatory in more than 26 countries, and has been endorsed by a range of professional societies and organisations globally.[10]

1.5.1 The clinical effectiveness of SSC

Since the first evaluation of the WHO SSC was published in 2009 by Haynes et al., there have been more than 20,000 publications indexed in PubMed by query combinations of "WHO" and "Surgical Safety Checklist". Studies of clinical effectiveness have demonstrated a beneficial impact of the SSC implementation on a range of patient and team outcomes including mortality rates, complication rates, length of in-hospital stay, teamwork, and adherence to safety processes.[19-21 23-26 73]

The exact mechanisms by which the SSC improves outcomes have been poorly understood, and several studies have been unable to consistently reproduce the marked reduction in mortality and morbidity.[33] A review including 26 studies, that assessed SSC compliance and team attitudes post SSC implementation, showed a mean SSC completeness of 59.64% (range; 31% - 85%).[74] The review identified that compliance rates were contradicted by low accuracy rates classified by direct observations (2% - 99%).[74] Discrepancies between compliance rates and observed

accuracy of SSC performance have also been reported by others.[31 32 75] The extensive differences between checklist documentation and observed compliance rates, indicating low fidelity to actual SSC use, has been suggested as an explanation to lack of positive findings.[31 76 77] In fact, evidence supports that high-fidelity use of the SSC is required for the positive effects to be attained.[78]

1.5.2 WHO SSC in the Norwegian surgical context

The SSC was translated into Norwegian in 2009 in collaboration with researchers at the Norwegian Knowledge Centre for Health Services, Haukeland University Hospital and Førde Central Hospital. It was adapted to the Norwegian surgical care and workflow. Minor adaptations were made with removal of the items "patient consent" and "use of pulse oximetry". Items of "prophylaxis for thrombosis administered if indicated", "patient warming" and "blood glucose level" were added to the SSC, and the item "essential imaging displayed" was moved from the Time Out phase to the Sign In phase. The original translated Norwegian version of the SSC is seen in Figure 3. (page 18). Its clinical effectiveness was tested in a stepped wedge cluster randomised multicentre trial, carried out in Western Norway, with significant reduction of overall surgical procedure complications from 19.9% at baseline assessment to 11.5% post-intervention ($P<0.001$).[20] In addition, length of stay was reduced significantly by a mean of 0.8 days. To understand the causal mechanisms of improvement, follow-up investigations on how the SSC improved patient outcomes was needed.

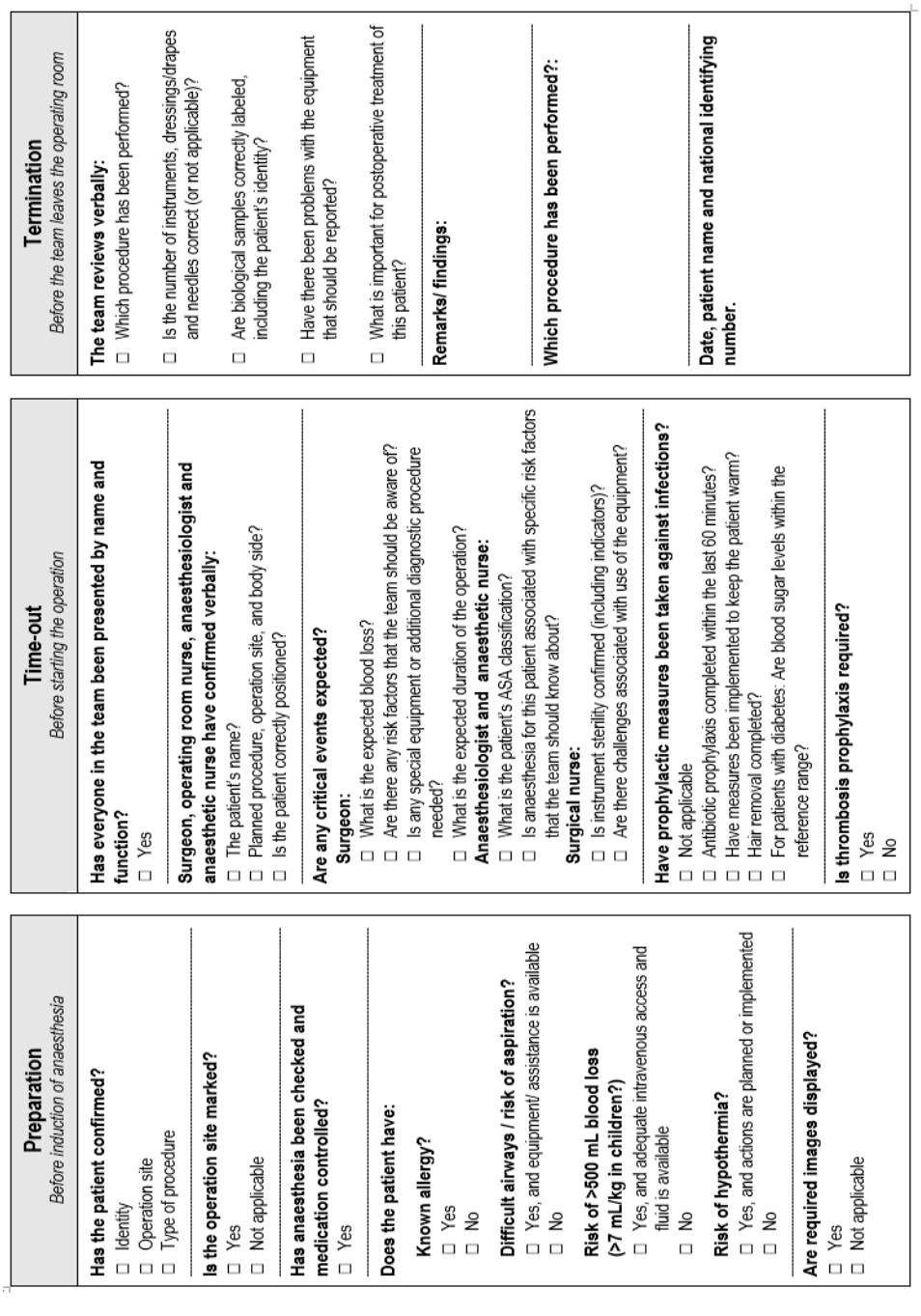


Figure 3. The original Norwegian translated version of the WHO SSC – 2009

1.5.3 Implementing the WHO SSC – a complex intervention

Interventions that contain several interacting components, such as the WHO SSC, are commonly described as *complex interventions*.[79] The complexity of these interventions is further characterised by the interactions between intervention components, the difficulty of behaviours by those delivering and receiving the intervention, and the degree of flexibility in the tailoring of, rather than the number of, components within the intervention.[80] Complex interventions work by introducing mechanisms that are sufficiently suited to their context to produce change. Causes of problems targeted by interventions may differ from one context to another.[80] The evidence base for the SSC was formed by ten essential objectives - taken from the WHO safe surgery guidelines - that could relate to any surgical case.[10] Yet according to the WHO SSC implementation manual, the checklist should be modified to account for facility differences with respect to local processes and culture.[10] Although tailoring the SSC to fit local contexts is crucial to increase intervention fidelity, this may also impede SSC evaluation, as capturing what is delivered in practice with close reference to the theory of the SSC is dispersed.[80]

Effectiveness of a team is indicated by the group-produced outcomes such as the quantity or quality of production, the speed, the consequences a team has for its members, or the enhancement of a team's capability to perform effectively in the future.[81] Teamwork in perioperative surgical teams refers to the way members of different disciplines interact with each other. This includes surgeons, anaesthetists, operating theatre nurses, nurse anaesthetists, and cardiovascular perfusionists, each with specific responsibilities of task executions during the perioperative care. While "taskwork" refers to behaviours related to the technical aspects of the team task, e.g., understanding task requirements, information, and operating procedures, "teamwork" reflects the behavioural interactions and attitudes that team members must develop to function effectively as a team.[81] These include, but are not limited to, adaptability, shared situational awareness, leadership, interpersonal relations, co-ordination, communication and decision making.[81] Although the importance of teamwork for the delivery of safe, high quality surgical care is highlighted, one of the challenges is the need for team members to interact and develop relationships quickly, as they may

only work together for a limited time. Also, when new challenges are introduced due to specialisation of surgical care, the gaps between different specialties' areas of expertise becomes wider, with less overlapping or shared knowledge within the team.[82]

The impact of the SSC on the quality of teamwork and communication in the operating theatre was assessed in a systematic review involving 20 articles.[25] The review concluded that the SSC is beneficial for teamwork and communication. However, even though team members perceive the SSC to improve teamwork, patient safety and staff awareness of adverse events, optimal SSC utilisation is highly dependent on staff perceptions, training, implementation strategies, and effective senior leadership.[74] Factors related to the operating theatre context such as workflow adjustments, alignment of perioperative workflow, and organisational culture have also been identified as barriers to SSC use.[83]

1.6 What are the knowledge gaps of SSC utilisation?

The SSC is designed to improve adherence to clinical practices, as well as enhancing wider aspects of interprofessional teamwork and communication in the operating theatres.[10] All members of the perioperative multidisciplinary team play a role in ensuring the safety and success of surgery. Each surgical department must therefore practise utilising the SSC and examine how to sensibly integrate these essential safety steps into their normal surgical workflow. The goal of the WHO SSC is to help ensure that teams consistently follow a few critical safety steps and thereby minimise the most common and avoidable risks.[10] However, if the SSC is to serve as a barrier to patient safety risks, its evaluation should be aligned with this aim. The following knowledge gaps of SSC utilisation have been identified:

- The need to elucidate the nature of how the SSC is used within the perioperative team.[25]

- The need to explore the mechanisms throughout which the SSC brings about change is crucial to understand both how the effects of the specific intervention occurred and how these effects might be replicated.[80]

- The need to include context in evaluation of SSC implementation can advance science and practice.[84]

In their process evaluation framework, the British Medical Research Council describes a feasible approach to performing a process evaluation of complex interventions.[80] This approach includes using quantitative data to test hypothesised causal relationships of the use of SSC, while using qualitative methods to better understand complex pathways and identified mechanisms of effect.

2. Aims and objectives

The overall aim of this PhD thesis was to gain knowledge on how SSC utilisation impacts perioperative processes and risk perceptions. In order to demonstrate possible relationships of the SSC variables, provide further insight about these relationships, and to clarify and explain important concepts, the project used a combination of quantitative and qualitative research methods. Three studies were included, with the following aims listed below. The studies were submitted for publications as three separate papers.

Study 1.

This study aimed to assess how WHO SSC implementation quality correlated to care processes in the operating room and patient outcomes. The objective was to test the hypothesis that high-quality SSC implementation would improve perioperative care processes and subsequently lead to improved patient outcomes. (Paper 1.)

Study 2.

This study aimed to identify and describe the complexity in the provision of SAP in perioperative care. The objective was to explore underlying work processes in the provision of SAP following SSC implementation, in regard to perioperative procedures and actual team working. (Paper 2.)

Study 3.

This study aimed to identify and describe relationships of multidisciplinary surgical team members' perceptions of SSC use and clinical risk management. The objective was to explore, from a clinical perspective, how team members considered SSC use being a part of their risk management strategies in perioperative care. (Paper 3.)

3. Materials and methods

3.1 Research methods

The present PhD project used a combination of quantitative and qualitative methods. Data from patients, healthcare personnel and teamwork observation contributed to the studies directed for this thesis. Data on WHO SSC implementation quality, operating theatre staff's perioperative care processes and patient data on complications are presented and discussed in Paper 1. Data from perioperative team observations and surgical team members' perspectives on surgical antibiotic prophylaxis, SSC use and teamwork are presented and discussed in Paper 2 and Paper 3. An overview of the different aims and methodological approaches is illustrated in Table 4 (page 24).

In Study 1, the dataset from a previous stepped wedge cluster RCT quality service improvement trial[20] was used to investigate the SSC implementation quality and the impact on care processes and patient outcomes. In studies 2 and 3, an ethnographic, explorative design was used, where observations of surgical teams and face-to face interviews of key informants were performed to study checklist utilisation, corresponding perioperative work processes, and teamwork.

Table 4. Outline of the aims, designs, settings, study participants, population and outcomes for studies 1-3.

	Aim	Design	Setting	Participants/ Population	Outcomes
Study 1	To investigate WHO SSC implementation effects on perioperative care-processes, and patient outcomes	Stepped Wedge Cluster RCT	1 Norwegian hospital, 3 surgical clusters (Tertiary teaching hospital)	3708 surgical procedures (1398 control vs. 2304 intervention proceures)	Primary endpoints: -Operating room care processes -Patient outcomes (postoperative complications) Secondary endpoint: -Quality of SSC implementation
Study 2	To explore perioperative work processes of SAP, to identify key elements to improve provision of surgical prophylaxis	Prospective ethnographic design, combining observations and single, face-to-face interviews	3 Norwegian hospitals (Tertiary referral hospital, Secondary care hospital, and Secondary referral hospital)	19 Informants (nurse anaesthetists, OT nurses, consultant anaesthetists, consultant surgeons, and surgeons)	Workflow process of SAP provision in perioperative care, including SSC utilisation
Study 3	To explore how members of perioperative multi-disciplinary teams integrate SSC in their risk management strategies	Prospective, ethnographic case study, combining observations and single, face-to-face interviews	2 Norwegian hospitals (Tertiary referral hospital, and Secondary referral hospital)	17 Informants (nurse anaesthetists, OT nurses, consultant anaesthetists, consultant surgeons, and cardiovascular perfusionists)	Factors and strategies influencing SSC integration in local and professional risk management

3.2 Ethics

All studies included in this PhD project were performed in accordance with the Helsinki declaration[85] and reviewed by the Western Regional Committee for Medical and Health Research Ethics (REK VEST) prior to data collection. For Study 1, the use of routinely collected anonymised data was regarded as clinical service improvement by REK VEST (Ref.: 2009/561), and final approval of the study was given by the hospitals' Data Privacy Ombudsman (Ref.: 2010/413) and local hospital managers prior to initial SSC implementation.[20] For studies 2 and 3 the final approval of the studies was given by REK VEST (Ref.: 2015/1741, part A). Collection of data was further commissioned by the respective Data Privacy Ombudsman and local managers at Helse Bergen and Helse Førde.

Study 1 was considered a clinical service improvement project, thus obtaining informed patient consents was not required. For studies 2 and 3, all interview-participants gave written informed consent prior to the interviews. As the surgical environment in the region is relatively defined, confidentiality was ensured. Non-disclosure agreements were signed, ensuring that the participants could withdraw from the study at any time. The local managers informed all OT staff of the research project prior to case observations, and cases where any staff member or the patient withheld consent were excluded.

All data were stored anonymously at a quality and research server at Helse Bergen, to which only the PhD candidate and supervisors had access. The published data for studies 1-3 were reported anonymously, and study results were published in scientific, peer reviewed, open access journals in accordance with the Creative Commons Attribution Non Commercial (CCBY-NC 4.0) license. Nonetheless, the analysed datasets have not been made publicly available due to confidentiality issues.

3.3 Clinical settings

All three studies were conducted in hospitals in the WNRHA. For Study 1, data from the three included study clusters were collected at Haukeland University Hospital. For Study 2, interviews were carried out at Haraldsplass Deaconess Hospital, Førde Central Hospital, and Haukeland university Hospital. For Study 3, the interviews carried out at Førde Central Hospital and Haukeland University Hospital were included. Observations for studies 2 and 3 were carried out at Førde Central Hospital and Haukeland University Hospital.

3.4 Study 1

3.4.1 Study design

The WHO SSC was initially implemented by using a stepped wedge cluster randomised design,[86] which is increasingly being used in evaluation of service delivery interventions in learning healthcare organisations.[87] The design includes a baseline collection period where no clusters are exposed, followed by a sequential, random crossover (which cannot be reversed) to the intervention arm of the trial.[86] For each number of points in time, observations will be captured to form the data for the analysis. Thus, the SSC was sequentially introduced to the three clusters in a randomised order, at different time points and as a one-way crossover intervention until all clusters were exposed, as shown in the design pattern matrix in Figure 4.[86] Cells with a "1" indicate that the clusters at that point in time was exposed to the intervention, and cells with a "0" indicate that the clusters at that point in time were not exposed to the intervention (controls). Details of the SSC implementation have previously been reported.[20 73]

Surgical clusters included, in randomised order	Time			
	Baseline	Step 1	Step 2	Step 3
1. Orthopaedic surgery	0	1	1	1
2. Thoracic surgery	0	0	1	1
3. Neurosurgery	0	0	0	1

Figure 4. Illustration of the stepped wedge complete design, used in Study 1.

3.4.2 Participants

Participants in Study 1 included patients from 3,702 surgical procedures in orthopaedic, cardiothoracic and neurological surgery from Haukeland University Hospital. Patients from all age groups, both genders, elective and emergency surgery, and with a variety of comorbidities as defined by the American Society of Anaesthetists (ASA) classification, were included. Surgical procedures that did not use the SSC (e.g., gamma knife treatment or donor surgery) and patients with incomplete data were excluded. Surgical clusters without relevant process metrics registered were also excluded. An outline of the details are given in the CONSORT flow diagram[88] in Figure 5.

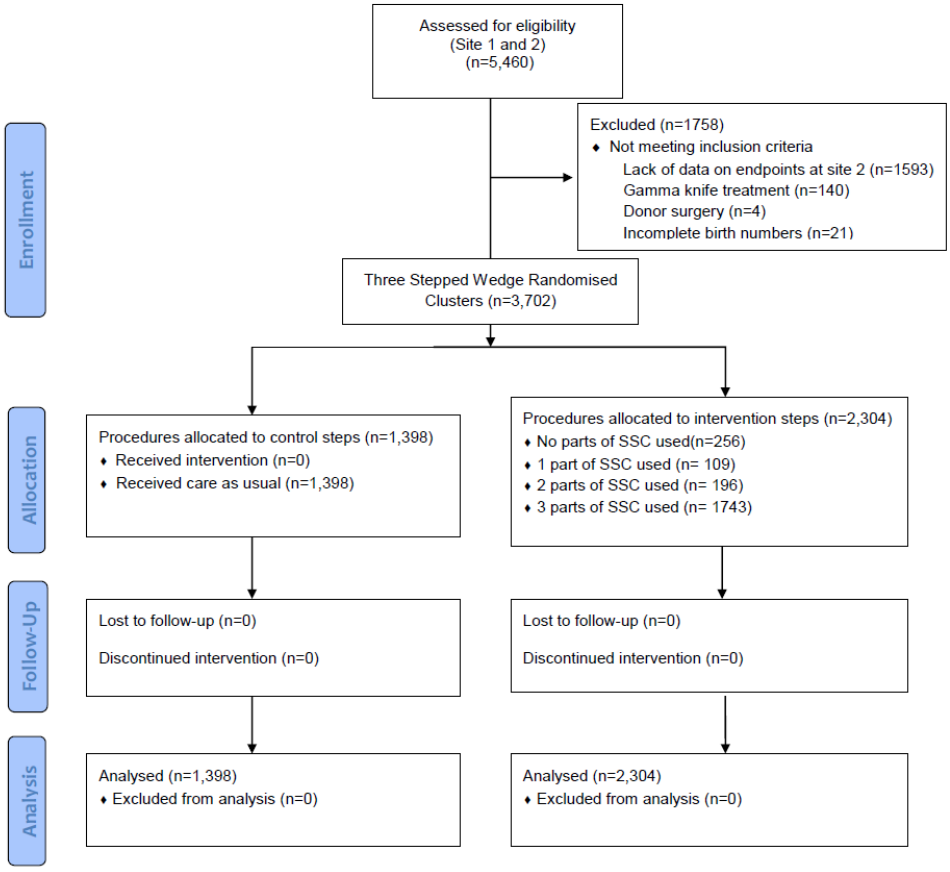


Figure 5. Flow diagram of inclusion/exclusion criteria in the secondary analysis of the stepped wedge cluster RCT.

3.4.3 Outcomes

The study outcomes were operating room care processes, patient outcomes and quality of SSC implementation. All outcome data were extracted from hospital administrative systems.

Operating room care processes

Only those process metrics already registered as routine practice in perioperative care were used. The following care process metrics were analysed: preoperative site marking; actions to sustain normothermia, i.e., use of prewarmed intravenous fluids, prewarmed blankets, and forced air warming blankets; and timeliness in the provision

of surgical antibiotic prophylaxis (SAP). Process metrics were classified as dichotomous variables (no actions/verified actions) whereas the registration of SAP administration was classified as a categorical variable: 1) before incision, 2) after incision, and 3) no antibiotics given.

Patient outcomes

Postoperative complications included surgical infections, surgical wound ruptures, cardiac and respiratory complications. Perioperative bleedings and intraoperative blood transfusions were also included as patient outcomes. The complications were classified as dichotomous variables (no complications/verified complications), based on assigned codes by International Classification of Diseases – tenth version (ICD 10). The ICD 10 codes were extracted from the patients' medical records, as registered by surgeons or ward physicians at patients' discharge.

SSC implementation quality

Implementation quality of the SSC was prospectively measured by fidelity to actual utilisation of the SSC; all SSC items, and all three SSC parts were marked for all included patients during performance of the SSC. To determine a minimum requirement for whether the SSC had been used or not, we decided to implement a compliance cut-off that required more than 60 % of SSC items to be registered. We classified the degree of SSC implementation quality as categorical variables of: 1) no parts used, 2) compliance with 1 part, 3) compliance with any 2 parts, 4) compliance with all 3 parts, and 5) compliance with any parts of the SSC.

3.4.4 Data handling

This study was conducted by use of the dataset from a previous stepped wedge cluster randomised controlled quality service improvement trial. Data on perioperative care processes and patient outcomes were registered by healthcare personnel as part of their perioperative registration routine. Compliance data on SSC utilisation were collected from a paper checklist by the primary investigators and from routine registrations in the electronic patient administrative system by a research assistant. Patient complication data were compared to the patients' medical records. The data

handling and quality assessment are described in detail in previous publications.[20 73] As the original dataset was collected to answer the original hypothesis proposed in these published studies, all other analysis of this dataset is considered "secondary analysis of existing data", as used by National Institute of Health, USA.[89] This terminology applies regardless of whether or not the persons conducting the secondary analysis participated in the primary collection of the data.[89] The aim of any secondary analysis is to test new hypotheses or explore new relationships by use of the data gathered in a previous study.[90] There are two general approaches for analysing existing data: the "research question-driven" approach and the "data driven approach". We used Donabedian's quality improvement framework as a model for an a priori hypothesis, and therefore had a research question-driven approach.

The included SSC compliance and process metrics were registered in the standard operating planning database ORBIT by nurse anaesthetists and operating theatre nurses. Compliance data of the SSC items were also ticked off at the proforma paper checklist, entered electronically by a research assistant, and quality checked by the principal investigator. In case of discrepancies between the paper checklist data and the electronic checklist data, the latter was used.

At the time of collecting baseline data, ORBIT did not have registry options for time of SAP administration (i.e. administration completed). This registration option was introduced along with the SSC implementation. Timing of SAP administration was therefore manually collected retrospectively for all controls (n = 1,398). Timing of SAP administration was retrieved from the patients' paper anaesthesia record, which had been routinely scanned postoperatively and registered into patients' medical records. The registration categories for SAP administration (i.e., before incision, after incision, and no antibiotics given) were agreed upon prior to collecting data, and the data were entered by the principal researcher, in collaboration with ASH.

3.4.5 Statistics

The original sample size calculation required a minimum of 1,100 patients in each of the two study arms (control and SSC intervention) for adequate study power.[91] Categorical data were analysed using Pearson's exact χ^2 test, which was applied for patient characteristics (except age), SSC impact on both care processes and patient outcomes for the control and intervention group.

Continuous data were analysed using independent samples *t* test (patients' age), and non-parametric test (Mann-Whitney *U* test) as appropriate. For all tests, a two-sided $P<0.05$ value was considered to be statistically significant.

SSC impact on operating care processes and patient outcomes was modelled with logistic regression. The model was calculated by SSC fidelity and in the final version (adjusted model) the SSC effects were adjusted for age, case-mix, comorbidity, anaesthesia type, knife time, study time point and process metrics. Estimates were measured with odds ratio (OR) and 95% confidence intervals

Statistical analyses were performed with SPSS version 23.0 (IBM Corp, Armonk, NY) SPSS, Chicago, IL, USA)

3.5 Studies 2 and 3

3.5.1 Reflexivity

The concept of reflexivity or critical subjectivity plays an important part when planning qualitative studies. The first step of reflexivity refers to the concern of *acknowledging that the researcher is part of the setting*, context or social phenomenon under study. This involves identifying personal biases, views, and presumptions vis-à-vis the phenomenon or the study site, as well as ideological stances.[90 92]

Firstly, the explicit "position" of my background has primarily been as a nurse anaesthetist with more than 15 years of clinical experience within operating theatres and emergency teamwork.

Secondly, I participated in the Norwegian national feasibility pilot of SSC implementation, which was conducted at Haukeland university Hospital. I was a member of the project group, that was led by the Norwegian Knowledge Centre for the Health Services (which joined the Norwegian Institute of Public Health in 2016).[93]

Thirdly, as a quality advisor in the Research and Development Department at Haukeland University Hospital, I have participated in the SSC post implementation follow-up monitoring of the different surgical units. This work has applied a traditional PDSA quality improvement approach, i.e., longitudinal monitoring of SSC compliance, identification of local barriers and facilitators, continuous monitoring, and provision of SSC compliance reports, to service managers of the respective surgical units and local staff involved.

Finally, as a master's student in "evidence-based practice in health care", I studied SSC implementation barriers and facilitators as the research topic for my Master Thesis,[94] resulting in a publication.[95]

3.5.2 Study design

An explorative, prospective ethnographic design was used in studies 2 and 3. This type of qualitative inquiry involves the description and interpretation of cultural practice and actions, capturing routine behaviours in their natural settings.[90 96 97]

3.5.3 Participants

The participants included in studies 2 and 3 were healthcare professionals who were working in a clinical setting as member of a perioperative multidisciplinary team. The study participants were recruited by email-invitations from the Manager of Section of Patient Safety at Haukeland University Hospital to Directors of Research and Development at the respective study hospitals. Participants were selected by the local Service Managers, and included surgeons from different specialities, anaesthetists, nurse anaesthetists, operating theatre nurses, and cardiovascular perfusionists. All the professions listed were represented in the perioperative observations, and participated in one-to-one interviews. Although patients were present in the OTs during observations, they were not considered study participants. Healthcare professionals present in the OT during observations, were indirectly part of the data collection, as the purpose was to capture their actions and interactions peri-operatively in the OT. However, the total number of team members during each observation was not registered. A total of 22 healthcare professionals participated in the interviews. An outline of data included in studies 2 and 3 is illustrated in Figure 6 (page 34).

3.5.4 Observations

A total of 40 hours of observations were performed in 2016 in OTs at Førde Central Hospital and Haukeland University Hospital. The dates for each observation were agreed upon with Hospital- and Service Managers. All the surgical cases involved were elective, performed under general anaesthesia, and were a mix of day surgeries and complex cases, where extracorporeal circulation equipment was involved. Only those cases performed during normal working hours were included. Cases where either any staff members or the patient withheld consent were excluded. Observations aimed to map routine behaviours related to the provision of SAP and team performance of SSC. Field notes taken during observations were reviewed by the

research team. These were then used to develop the interview guide and as inputs to the data analysis. The observation guide is included in the Appendices (Appendix 10.2.).

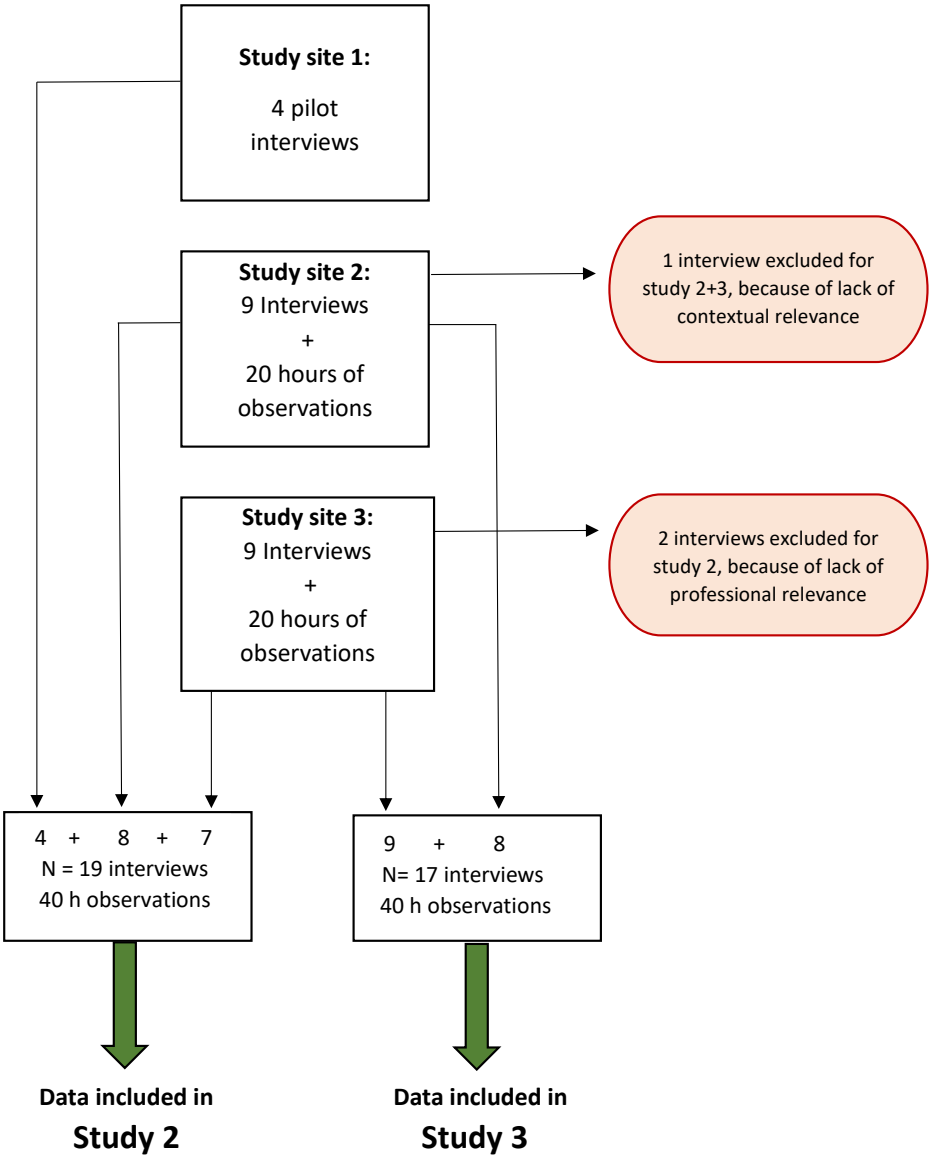


Figure 6. Flow diagram of collection and inclusion of data in studies 2 and 3.

3.5.5 Interviews

Four pilot interviews were carried out at Haraldsplass Deaconess Hospital in November 2015; the informants included 2 nurse anaesthetists and 2 operating theatres nurses. Based on the results from the pilot interviews, the interview guide was adapted to include a general approach to SSC use (not only question about SAP items), as well as follow up teamwork questions. In addition, the Norwegian national regulation framework for medication management[63] was considered applicable as an a-priori model for a deductive, concept-driven analytic process. The pilot experience also induced observations to take place prior to the remaining interviews. An example of different types of questions used in the semi-structured interview-guide is outlined in Table 5.

Table 5. Example of questions used in the semi-structured interviews

	Research topic: SSC utilisation	**Aim**
Descriptive question	As (the relevant profession): In your opinion, do you think the SSC works as intended at your surgical unit?	To make participants describe utilisation of the different items and parts of the SSC in their own language.
Probes	*How?* *Why?*	
Structural question	As (the relevant profession): In your opinion, what are your experiences of using the SSC in relation to specific perioperative work processes?	To develop the range of terms in categories or domains.
Probes	*When?* *How?* *Why?*	
Contrast question	Can you describe a situation in which using the SSC has been useful or positive?	To distinguish differences in the meaning of terms and professional perceptions of SSC.
Probes	*How?* *Why?*	

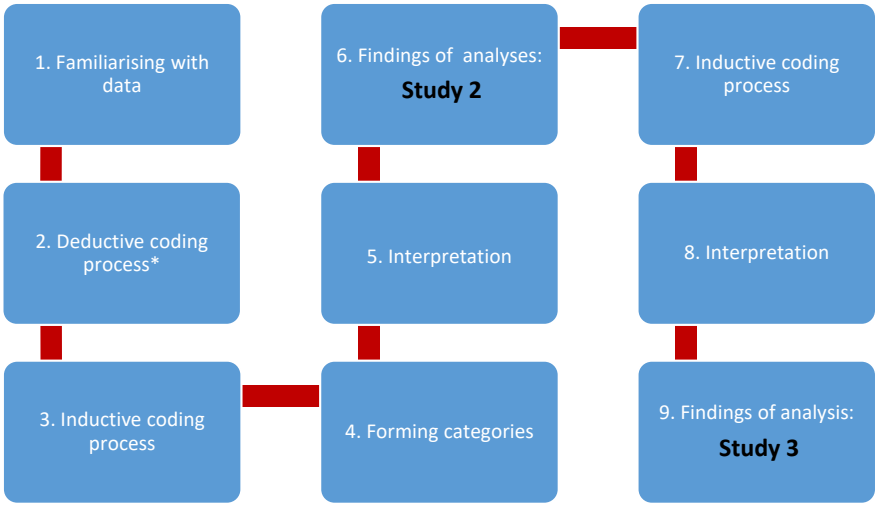
The final version of the semi structured interview guide is enclosed in the Appendices (Appendix 10.3).

A total of 22 interviews were performed. All healthcare personnel in the perioperative team were considered key informants. A maximum variation purposefully sampling strategy was used to obtain the different professionals' perspective on the provision of SAP, SSC performance and general OT teamwork. Invitations to participate were reviewed and approved by hospital managers at the respective study hospitals. This also applied for the pilot interviews. The participants were recruited by the Surgical Unit Managers. Details of study informant characteristics are described in Table 2, as reported in Study 2, and Table 3, as reported in Study 3.

All interviews were conducted within the OT departments of the respective study hospitals, or in meeting rooms and offices free of distractions. Each participant was interviewed once, and the interviews were audiotaped, transcribed verbatim and transferred to NVivo Pro V.11.4 computer software (QSR International ABN 47006357213) for coding. The interviews lasted between 28 and 47 minutes, with a median length of 36 minutes.

3.5.6 Data analysis

Both the field notes and the transcribed interviews were included in the materials that formed the units of analyses. Data were analysed by using the content analysis approach, as described by Graneheim and Lundman.[98 99] A combination of deductive and inductive elements were used in Study 2, whereas a solely inductive approach was undertaken for Study 3. At the outset, the analytic process was driven by a deductive reasoning, and consensus on a coding list was made by the analytic team (HVW, ASH, and SH) prior to commencing the analyses. The coding list included the "who", "where" and "when", in relation to initial and follow-up prescription, preparation, and administration of SAP. An outline of the steps in the analytic process is illustrated in Figure 7.



*The deductive coding process was directed at the Norwegian national regulation framework for medication management.

Figure 7. An overview of the process of the deductive and inductive content analyses for studies 2 and 3.

In the following, each step in the analytic process is described in detail.

Step 1: Familiarising with data

Prior to coding, I, as the principal researcher, transcribed all 22 interviews and read through all transcriptions once. A selection of transcriptions was also read by supervisors SH and ASH in order to obtain a sense of and validate the whole coding procedure. Three interviews were excluded for further analyses (Figure 6) due to lack of relevance to context (exclusion of 1 interview, study site 2) and lack of participation in SAP work processes (exclusion of 2 interviews, study site 3).

Step 2: Deductive coding process

19 interviews were included for the deductive coding and were transferred into NVivo Pro V.11.4 computer software for analysis. All text parts, which were considered appropriate to fit into the predetermined coding list, were extracted and mapped into a tentative outline of the clinical pathway of SAP. This part of the analysis was performed at a concrete analytic level, where abstractions and degrees of interpretations were low.

Step 3: Inductive coding process

The leftover data that did not fit in to the previously selected codes constituted the data used for the inductive analysis. During this part of the analysis, we looked for similarities and differences in the data, searching for patterns that could further elaborate on the work processes surrounding the provision of SAP. During this step, the analytic process moved between a close approach, at a concrete analytic level, and a distant approach, at a more abstract level.

Step 4: Forming categories

Codes that were derived from condensed meaning units were grouped into categories, which shared common characteristics. The categories were labelled to describe the content of the category, also referenced as the manifest content or the "what".[98] An example of category development is illustrated in Table 5 (page 39). The presented category is part of study results reported in Study 2.

Step 5: Interpretation

In the final step of the analyses, we moved to a high degree of interpretation, at a more abstract level of analysing the latent content. This search, for a unifying "red thread" running through the already labelled categories, resulted in subthemes and a main theme.

Table 5. Example of category development in the qualitative analysis

Category	**Diverse prescription order systems**	
Description of category	Different units have different SAP prescription practises, and prescriptions may be performed electronically or in paper forms.	
Codes	• Electronic, surgical planning system • Electronic medication chart • Paper-forms • Wall poster in operating theatre • Oral prescription • Pre-authorised prescription protocols	
Examples from the data	Field notes	**Observations of how SAP is prescribed and documented;** 1) standardised, as a default prescription in the surgical planning system, 2) electronic medication chart, 3) signed preoperative paper surgery-schedule forms, 4) wall-poster of a standardised, authorised procedure, describing which types of surgery require which types of antibiotics, in the OT with the anaesthesia team.
	Informant quotes	**Nurse anaesthetist:** *"…we have a laminated wall poster document of the standardised types of surgeries; this surgery requires this.. [antibiotic] and this type of surgery requires that [antibiotic]". "The surgical antibiotic prophylaxis is to be prescribed in the patient's medication chart by the surgeon, if there is an indication. Sometimes, the antibiotic prophylaxis is prescribed in the electronic surgical planning system as well".* **Anaesthetist:** *"The antibiotic is administered accordingly to a standardised template. This template was reviewed and updated one year ago by infection disease specialists, and management of antibiotic prophylaxis vary accordingly to the different types of surgery, either with or without implants. We just totally comply with this template".* **Surgeon:** *"As long as the patient belongs to this department, the antibiotic prophylaxis is to be prescribed in the medication chart. In case it is not written in the medication chart, then, it [the antibiotic] is not prescribed properly".*

Step 6: Findings of analysis for Study 2

A total of 9 categories, divided into 3 subthemes with one overarching theme, comprised the findings of the analytic process, reported in Study 2.

For the analysis of the data used in Study 3, we included 8 interviews from study site 2, and all 9 interviews performed at study site 3.

Step 7: Inductive coding process

A total of 17 interviews and all observations were included in the inductive coding process in exploring how members of the perioperative multidisciplinary teams integrate the SSC within their risk management. The inductive coding process, at this stage, involved an already established familiarity with the data, as 15 of the interviews had been thoroughly read. Despite this, we looked for new similarities and differences in the data regarding how the team members viewed utilisation of the SSC in relation to perioperative teamwork. The analytic process moved between a concrete approach of identifying specific parts of importance, either in support of or against the SSC, and a distant approach at a more abstract level, thus indicating the former.

Step 8: Interpretation

In the final step of analyses, the themes derived from the categories were kept at a low abstraction level. Yet the interpretation in relation to the research question was of a higher degree.

Step 9: Findings of analysis for Study 3

A total of 8 categories, divided into 3 themes comprised the findings of the analytic process, were reported in Study 3.

4. Summary of results

4.1 SSC implementation quality – impact on perioperative care processes and patient outcomes

In Study 1, we investigated the implementation impact of the WHO SSC on perioperative care processes and patient outcome. A total of 3,702 (1,398 controls vs. 2,304 interventions procedures) were analysed. The objective of this study was to investigate how the WHO SSC improves patient outcomes by using Donabedian's clinical improvement framework in which improved structures enhance care processes; both structures and care processes improve patient outcomes. Three associated hypotheses were tested via causal analysis of clinical structures, processes, and outcomes related to SSC implementation. The complete results ofthis study were reported in Paper 1.

4.1.1 Implementation outcomes

Implementation outcomes were measured by fidelity to SSC utilisation in the intervention procedures (n = 2,304), outlined in Table 6.

Table 6. Implementation outcomes

Fidelity to SSC utilisation; intervention procedures (n = 2304)			
SSC non-compliance	1 SSC part	Any 2 SSC parts	3 SSC parts
11.1% (256/2304)	4.7% (109/2304)	8.5% (196/2304)	75.7% (1743/2304)

4.1.2 Perioperative care process outcomes

Perioperative care processes were measured by preoperative site marking, use of normothermia protective means (reported here are use of prewarmed intravenous fluids, prewarmed regular blankets and forced air warming blankets) and the provision of SAP before incision. All measures were used significantly more in the intervention procedures compared to the controls. The normothermia protective measures and the provision of SAP are outlined in Table 7 (page 42).

Table 7. The WHO SSC impact on care process metrics (n = 3702)

Care process metrics	Controls (n = 1398)	Interventions (ITT) (n = 2304)
Prewarmed intravenous fluids	54.8% (766/1398)	64.1% (1477/2304)
Prewarmed regular blankets	75% (1049/1398)	80.6% (1856/2304)
Forced air warming blankets	54.8% (766/1398)	64.1% (1477/2304)
Antibiotic administration pre-incision	54.5% (762/1398)	63.1% (1454/2304)
Non-administration of antibiotics	33.0% (462/1398)	27.1% (624/2304)

In a subgroup analysis of the WHO SSC impact on the timing of SAP administration, we compared the control procedures (n= 1,398) to the intervention procedures (n= 2,304). Before implementation of the SSC, the overall SAP administration in the control procedures was 67% (936/1,398), whereas after the SSC implementation, the overall SAP administration comprised 72.9% (1,680/2,304) of the intervention procedures (P < 0.001). The distribution of the timing of SAP administration across the four analysed subcategories is illustrated in Figure 8.

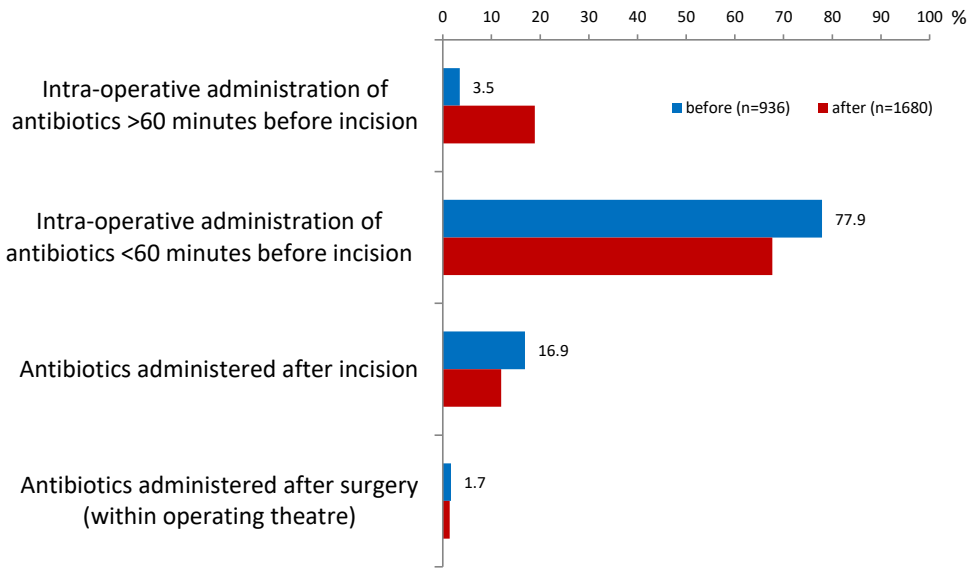


Figure 8: Subgroup analysis of the timing of SAP administration before and after the SSC implementation.

4.1.3 Patient outcomes

The main registered complications were all significantly reduced in the intervention procedures. Cardiac complications decreased from 8.0% to 5.0%. Respiratory complications decreased from 8.3% to 4.0%. Surgical infections decreased from 7.4% to 3.6%. Wound rupture decreased from 1.8% to 0.2%. Finally, perioperative bleeding decreased from 2.6% to 1.0%. Further evaluation of the intraoperative blood loss percentiles detected a significant reduction of between 750 mL to 1000 mL blood loss and an increase in no (0 – 49 mL) or minor bleeding (50 – 249mL).

Overall, the results showed that high-quality SSC implementation, i.e., all 3 checklist parts used, was significantly associated with improved processes and outcomes of care.

4.2 Perioperative work processes in provision of antibiotic prophylaxis

Based on the results from Study 1, we identified a need to study, in detail, the underlying work processes of SAP provision in relation to use of the SSC. Therefore, in Study 2 we aimed to explore perioperative work processes of SAP and to identify key elements to improve provision of surgical prophylaxis. We applied the Norwegian national regulation framework as a coding frame to identify the perioperative work processes of SAP. The findings of this study, including illustrative participant quotes, are reported in Paper 2.

Analysis of observations (40 h) and informant interviews (n = 19) identified the provision of SAP as a complex process of balancing timeliness (of 60 minutes prior to incision) when considering and responding to multiple interacting factors. These factors were classified and interpreted into three subthemes: 1) handling SAP in the preoperative phase in general, 2) timing SAP administration prior to incision, and 3) use of formal and informal SAP checks, including the use of the SSC. An outline of the workflow for SAP in perioperative care is illustrated in Figure 8 (page 45).

4.2.1 Handling SAP in the preoperative phase in general

This subtheme encompassed 5 categories of factors; 1) Preparation and administration, 2) Prescription accuracy, 3) Diversity of prescription order systems, 4) Patient specific conditions, and 5) Changes in operating theatre schedules. These five categories highlighted interacting preoperative factors that need considerations when handling SAP.

4.2.2 Timing SAP administration prior to incision

The second subtheme referred to perceived importance of knowledge and clinical experience in provision of timely SAP administration and encompassed 2 categories: 6) Cognitive task reminders, and 7) Importance of knowledge and clinical experience.

4.2.3 Use of formal and informal SAP checks, including the use of SSC

The third subtheme encompassed the two categories specifying how formal and informal checks were performed: 8) Performance variety of the SSC, and 9) Indirect and direct prescription validity checks.

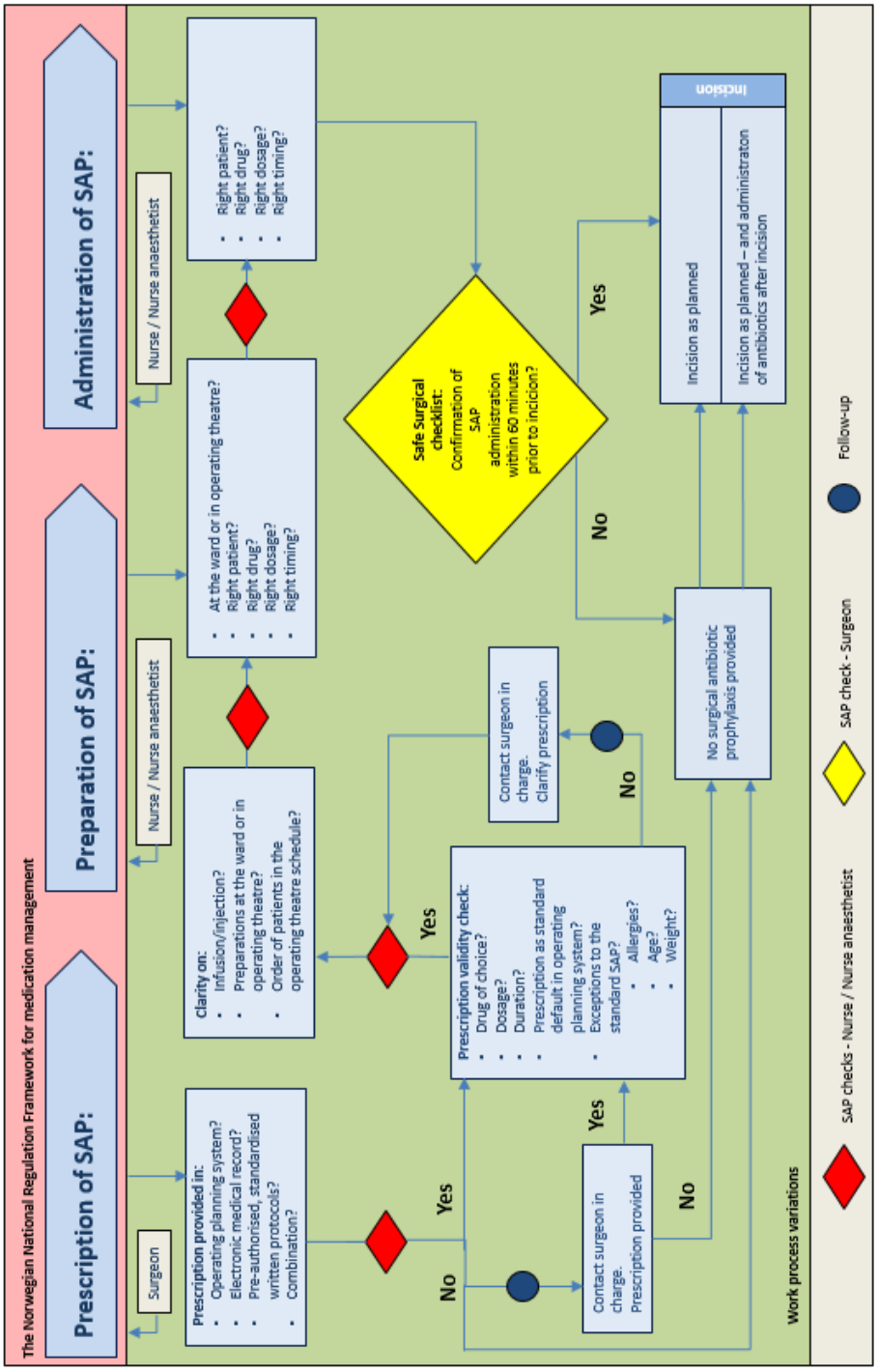


Figure 8. The clinical pathway of surgical antibiotic prophylaxis: an outline of the workflow for SAP in perioperative care (reported in Paper 2.)

4.3 Integration of SSC in perioperative risk management

In Study 3 we explored the integration of the SSC in clinical risk management strategies by frontline personnel in operating theatres. Our aim was to identify how members of the multidisciplinary team integrate SSC use within their risk management strategies in perioperative care. The findings of this study include illustrative participant quotes and observation notes, and are reported in Paper 3.

Analysis of observations (40h) and informant interviews (N= 17) identified three major themes reflecting the integration of the SSC in daily surgical practice: 1) Utility assessment, 2) Customising SSC implementation, and 3) Interactive micro-team communication.

4.3.1 Assessing utility

This theme reflected various views related to the SSC's practical utility and encompassed two categories: lack of practical utility and perceived utility. Perception of utility varied between professionals, items of the SSC and timing of the performing the SSC.

4.3.2 Customising implementation

This theme reflected variations in how the different items and parts of the SSC were carried out which also included the electronic registration of the SSC. This theme encompassed four categories: review and confirmation of items, presence of team members, barriers of performance, and registration practices.

4.3.3 Interactive micro-team communication

This theme reflected patterns of how risk communication and critical information exchange were performed during perioperative care. The team members' individual and professional perception of identified or potential patient safety challenges influenced SSC utilisation, and how, when, and to whom information on risk was passed in the perioperative phase of surgery. This theme encompassed two categories: patient specific risk communication, and selected communication of risks.

5. Discussion

The overall aim of this thesis was to study perioperative work processes in relation to SSC utilisation in order to expand on the knowledge of how SSC intervention might work in everyday clinical practice. Firstly, investigation of the SSC implementation quality on perioperative care processes and patient outcomes was conducted to identify causal relationships of variables. Secondly, this investigation led to a detailed exploration of the specific work process of SAP provision in perioperative care. The study topic was chosen for several reasons: SSIs are the most common nosocomial infections and represent a large proportion of surgical complications,[49] correct provision of SAP is an important and recommended measure in the prevention of SSIs,[12] and the provision of SAP is a frequent event in perioperative care involving interdisciplinary approach.[100] Thirdly, findings from the two conducted studies led to further exploration on how the WHO SSC might fit with existing perioperative risk management strategies among multidisciplinary team members.

5.1 Methodological considerations

Based on the overall aim, this PhD thesis has undertaken a combination of quantitative and qualitative research methods. Quantitative methods can demonstrate that variables are systematically related, while the qualitative materials can be used to clarify important concepts and elaborate findings from the statistical analysis to provide more global and dynamic views of the phenomena under study.[90] In the following, the strengths and limitations of the methodologies used in the quantitative study (Paper 1) and the two qualitative studies (Papers 2 and 3) of this thesis, will be critically reviewed and assessed.

5.2 Study 1: the quantitative approach

5.2.1 Study design

Randomised controlled trials are considered the gold standard method for evaluating quality improvement, service delivery and healthcare interventions to yield reliable

evidence between cause and effects.[101] The stepped wedge RCT design was used in the unidirectional crossover delivery of the WHO SSC intervention.[20] The stepped wedge is a pragmatic study design which can reconcile the need for robust evaluations of service delivery and patient interventions such as the SSC.[87] This is particularly evident with interventions expected to do more good than harm. The design requires randomisation of clusters to different sequences (Figure 4). These sequences dictate the order (or timing) in which each cluster will switch to the intervention condition, described as the step.[102] Implementing complex interventions, such as the SSC, requires sufficient recourses available.[80] Thus, the stepped wedge cluster RCT fulfils a dual role, serving as a scientific tool that incorporates a fair way to determine the order of rollouts under logistic constraints.[87] Moreover, to avoid contamination of the SSC from the intervention to the control group, randomising organisations or healthcare professionals in clusters was performed as recommended, rather than at the individual patient level.[86 87 102]

There are methodological complexities involved in using the SW cluster RCT design, which may increase complexity of reporting, such as potential confounding with time, possibility of contamination within a cluster and time varying treatment effects.[102] However, implementing the SSC by use of the stepped wedge cluster RCT was considered the best suited RCT design for this intervention. The Consolidated Standards of Reporting Trials (CONSORT) has been updated and published in 2018 to include an extension for the stepped wedge cluster randomised trials.[102] As the initial implementation study of the SSC intervention was conducted in 2009-2010, the study was reported in compliance with the CONSORT guideline at that time (Appendix 10.5).

5.2.2 Validity

Validity is a quality criterion referring to the degree to which inferences made in a study are accurate, well-founded and in measurement: the degree to which an instrument measures what it is intended to measure.[90] The researchers involved in the primary data collection, analysis and handling of the original study[20] were also engaged in this follow-up study. Access to data, assessment of the identified data set

(in terms of the appropriateness for the research question), adequacy of data quality and technical usability of the data were, therefore, endorsed by the research group. By performing the secondary analysis together with the original research group, the samples and variables previously measured were well known, and so the risk of detecting deficiency in the data set was reduced. The following four types of validity will be discussed in relation to Study 1: internal, statistical conclusion, construct and external validity.

Internal validity

The internal validity concerns the validity of inferences that, given the existence of an empirical relationship, it is the independent variable: here meaning the actual utilisation of the SSC that caused the outcome, rather than other factors.[90] The secondary analyses were based on data previously collected, and detailed descriptions of the data collection method, quality controls and definition of SSC compliance cut-off have previously been reported.[20 73 91]

The timing of SAP administration was retrieved from the patients' medical records and registered as categorical data. To reduce the risk of threat to internal validity, the corresponding categories were agreed upon in the research team prior to the data collection. In case of several SAP administrations, we classified provision of SAP according to the time point of the first dosage. Also, for SAP infusions > 500mL, provision of SAP was sorted according to the time-point at the end of the infusion. In contrast to SAP injections, or the short time infusions <100mL, the former might endure for 30-60 minutes. To further ensure the validity of case classification of SAP provision, ambiguities were discussed among HVW and ASH.

Another threat to internal validity is that routinely collected data might be hampered by random errors or inaccuracies in data quality. However, using the routine data registered in the daily clinical practice reflects the "real world", and there were no changes in how the perioperative data were recorded during the study period. Also, the healthcare personnel who registered the perioperative care processes were employed in the specific surgical units constituting the surgical clusters. Thus, they

were part of the same cluster before and after the SSC introduction. The random errors were, therefore, likely to be equally present before and after the SSC intervention. The healthcare personnel were also blinded as to which measures were of interest to the study. This applied to process data as well as the patient outcomes.

To avoid the bias in detecting positive SSC effects, the intervention arm of the study equalled intention to treat.

Statistical conclusion validity

Statistical conclusion validity concerns the validity of the inferences, where the inferences are that there truly is an empirical relationship, or correlation, between the cause and effect.[90] Statistical power was based on the sample size calculation from the original study.[20] As we performed a secondary analysis, there was no possibility of increasing sample size to avoid risk of committing a type II error (accepting the null hypothesis when it is false). Yet when the relationship between variables (effect size) is considered strong (as assumed with recommendations in perioperative guidelines and patient outcomes), effects can be detected statistically significant even with small research samples.[90] Given the available process measures, the statistical analyses were performed as appropriate for the different variables. A limitation to the study was lack of patients' core temperature as a parameter. Also, we had no available measures for important items such as preoperative risk assessment or team briefing. Such variables, although difficult to measure, might have influenced the statistically confirmed relationship.

Construct validity

Construct validity involves inferences from the particulars of the study to the higher-order constructs that they are intended to represent.[90] One threat to construct validity is the effect on the dependent variable resulting from the healthcare personnel's awareness that they are participants under study, known as the Hawthorne effect. To reduce risk of information bias, all clinical personnel participating in the SSC performance were not informed as to which study outcomes were measured. Yet the risk of healthcare personnel crossing over from intervention to control was also

present, in particular for the junior anaesthetists who did rotations between the surgical units. However, the substantial decrease in complications found in the study based on the original dataset indicate that such bias did not affect the study significantly.[20]

External validity

External validity concerns inferences about the extent to which relationships observed in a study hold true over variations in people, conditions, and settings, as well as over variations in treatments and outcome.[90] Even though data were included from only one hospital, the surgical specialities involved represent heterogeneity, which increases the external validity of the study. In addition, the included perioperative care processes measures and the use of the WHO SSC relate to universal recommendations of evidence based guidelines of perioperative patient safety, which also supports external validity of the study results.[10 12]

5.2.3 Reliability

Reliability refers to stability of measures when repeatedly used.[90] The quality performance of the SSC's utilisation, involving registration of items listed in the SSC and describing cut-off limit of SSC fidelity, were quality assessed as previously described.[20 73 91] Categorisation of measures involving SAP provision, were quality assessed by categories previously agreed upon, and ambiguous cases were assessed, together with clinical expertise, to reach consensus.

5.3 Studies 2 and 3: the qualitative approach

5.3.1 Reflexivity

The first part of reflexivity refers to the sensitivity of how researchers position themselves towards theoretical inclinations and their previous experiences with the phenomenon being explored. The second part involves the process of a critical self-reflection on the ways in which the researcher and the research process may have shaped the collected data to enhance the credibility of the findings.[92 103] This includes, but is not limited to, the role of prior assumptions and experience, i.e., preferences,

preconceptions and stakes in the research, which may potentially influence inductive inquiries. Qualitative researchers are encouraged to explore these issues, and to be reflexive about their every decision made during the inquiry. As a nurse anaesthetist with more than 15 years of clinical experience, it was, therefore, essential for me to discuss my own professional experience in relation to the topics addressed in the studies, as well as the OT context and issues of teamwork. Several meetings, where one or more of the supervisors participated, were conducted during the study period.

It is recommended that qualitative researchers keep a personal record of reflexive thoughts in personal diaries and memos to retain critical sensitivity during the research period.[90 92 99] Thus, reflexive memos and notes were written and discussed with supervisors at different time points of the study, e.g., after observations and interviews, during the verbatim transcribing, and during the analytic process. To validate the analytical process, the inductive and deductive content analysis approaches were discussed in detail to create a mutual understanding of the different steps included.

Reflexivity is typically discussed as an individual activity engaged by researchers working "solo" on a project, but others have argued to promote reflexivity in studies conducted by teams of researchers, as both individual and group reflexivity are needed. Thus, different epistemological and professional views on patient safety perspectives were discussed amongst members of the research group. To achieve trustworthiness of the findings, the evolving categories and themes were also discussed with safety science research partners without a clinical background, during the course of analysis.

5.3.2 Study design

The ethnographic design is recommended and preferable when one wants to study behaviours and interactions of a culture-sharing group, where shared or regular patterns of language or behaviour exist.[92] The ethnographic approach is, therefore, well suited to identifying conditions of risk, particularly where these involve human performance, organisational and cultural dynamics, and interactions between people

and technology.[97] As the objectives for studies 2 and 3 were to explore underlying work processes of SAP provision and SSC performance at the intersection of perioperative procedures and team working, the use of an ethnographic design was well suited to capture the multidisciplinary team members' "everyday" routine behaviours in the OTs. By using the ethnographic approach, it was possible to query understandings and practices that are likely to be taken for granted by healthcare professionals, managers and policymakers, as with the process of SAP provision. In addition, the ethnographic approach was particularly useful in the complex context of the study setting, which involved the clinical pathway of perioperative care where long chains of safety of causations exist in terms of health and safety outcomes.[97]

The focus on a narrowly defined culture, such as that in the perioperative multidisciplinary teams, is referred to as micro-ethnography or focused ethnography.[90] Studying organisations of professional services examined from the perspective of the front-line workers has also been described as institutional ethnography.[90] The focus for this specific ethnographic approach is on social organisation and institutional work processes, where research findings may contribute to organisational changes and improvements. Although a general, holistic ethnographic approach was undertaken for the qualitative inquiry in studies 2 and 3, the use of "an institutional, micro-ethnographic design" would probably have implied a more precise description of the research design applied.

5.3.3 Trustworthiness in qualitative research

Developing the trustworthiness of a qualitative inquiry involves the frequently used criteria of credibility, dependability, authenticity, confirmability, and transferability, as outlined by Lincoln and Guba.[90 92] These five criteria represent parallels to quantitative research criteria of internal validity, reliability, objectivity and external validity, respectively.[90 92]

Credibility refers to confidence in the truth of the data and interpretations of them, again involving two aspects. The first is carrying out the study in a way that enhances

the believability of the findings. The second aspect refers to how well researchers can demonstrate confidence in interpretations of data to external readers.

To establish confidence of the research process, we used triangulation of methods, time, space and person in collection of the data. Method triangulation involved the combination of non-participant observations and in-depth, one-to-one interviews. For Study 3, we used additional longitudinal SSC compliance rate reports. Time triangulation involved gathering data at different time points for the different study sites. Space triangulation involved observations, and pilot and study interviews at three different hospitals, all of which were part of the WNRHA. Aside from the pilot interviews, we used the same observation and semi-structured interview guide for collection of all data. Person triangulation involved including perspectives of all the members of the perioperative multidisciplinary team, from different surgical disciplines, at different hospitals.

Traditionally, the ethnographic approach requires substantial fieldwork, where researchers need to be immersed for long periods of time in the field to develop relationships, understand the local context, and collect in-depth and rich data.[90 92] In total, approximately 40 hours of observations were carried out at two study sites, which might seem considerably less than presumed by a traditional approach. An extended observational study period might have provided more in-depth data of normative behaviours and social patterns and reduced possibility of the "Hawthorne effect" on team members' behaviours in OTs. However, the extensive experience in the field, as a former nurse anaesthetist and member of the multidisciplinary team, provided an a-priori knowledge of the studied field as an "insider". This may justify spending less time in the field than researchers being "outsiders" to the culture under study. In addition, the use of rapid-ethnography research methods have been increasingly acknowledged due to the importance of generating findings within time frames when they can still be actionable and used to inform improvements in care.[104]

Furthermore, we neither reported the number of days of observations, nor total number of cases or team members present in the OTs, as we did not consider this

relevant for the studies' objectives. A more structured reporting of observations might have contributed to increase trustworthiness. Yet in one systematic review of the use of rapid ethnographies in healthcare organisations, the study durations of the 26 included studies ranged from 5 days to 6 months, with several studies only reporting the numbers of hours of observations.[104] Of these, three studies spent 5-6 days at each site, only one study reported spending intensive 1-2 weeks at each site, and several studies did not specify length of the study. This systematic review identified variabilities in the timespan of observations and the reporting of the rapid-ethnography study design in general, indicating a need to develop more robust structures and reporting processes.

The second aspect of credibility is to take steps to demonstrate confidence in interpretations of data to external readers. One important technique for establishing this credibility is to perform member checking, where researchers provide feedback to study participants about emerging interpretations and obtain participants' reactions.[90] Credibility, in this sense, was endeavoured through deliberate probing during the interviews to ensure the participants' meanings and expressions had been thoroughly understood. Yet we did not provide feedback to interview participants about emerging interpretations in order to obtain their reactions or support during or after completing analyses. This means that the participants neither got the chance to comment or correct their statements, nor verify findings of the study, which could have contributed to increased credibility of the findings. However, the study findings represent the etic perspective, i.e., the outsiders' interpretation of observations and interview transcripts. Consequently, there is a risk that individual participants may not recognise their own experiences or perspectives during member checking, as the study results have been synthesised, decontextualised and abstracted from and across various study participants. Nevertheless, all interview participants were informed that they could withdraw from the study at any time before conclusion of the data analyses and signed written consent forms prior to interviews. None of the interview participants withdrew their consent.

Dependability refers to the stability of data over time and conditions.[90] To collect data, we used a combination of non-participant observations, and in-depth, one-to-one interviews. Despite being experienced in the field, four pilot interviews were performed. The aims of the pilot interviews were to 1) map work processes of SAP in an operating theatre context different from the one of which I had previously been a part, 2) to validate the interview guide, and 3) to form ideas of direction for analyses of data in terms of being either concept or data driven, or both. To cover the specific set of topics for the remaining interviews, a semi-structured interview guide was created to include topics of SSC performance, the provision of SAP, and teamwork in general. A combination of descriptive, structural, and contrast questions was used for each of the topics, encompassing probes to elicit more detailed information (Table 5, page 35).

Authenticity refers to the extent to which the researchers fairly and faithfully show a range of different realities.[90] The steps used for self-scrutiny during the study involved a purposeful selection of study participants to represent the professional perspectives of all the members in the multidisciplinary team. In addition, to limit the risk of not being objective about the group observations, ASH participated in 6 hours of the observations. Notes from the common observations were then reviewed to ensure objectivity in relation to accuracy, relevance, and meaning. Analogous, the criterion of **confirmability** is also concerned with establishing that the data represent the information that participants provided and that interpretations of those data are not the figments of the researchers' imagination. Hence, all interviews were audiotaped and transcribed verbatim, to ensure that the emic perspectives, i.e., the insiders' views of the work processes and local culture, were consistent in informing the analysis. In addition, we used a pragmatic investigator triangulation during analyses where the research team progressed the analytic decisions based on consensus meetings.

Transferability refers to the extent to which the findings can be transferred to or have applicability to other settings or groups.[90] All data were collected in surgical settings in Norway, and recommendations of SAP regimes were based on the

Norwegian national guidelines of antibiotic use in hospitals. Also, the deductive analysis was directed at the Norwegian national regulation framework for medication management. The reported SAP work processes may, therefore, be limited to reflect roles and responsibilities of teamwork practices in Norway. However, interpretations reflecting the SSC impact on timely SAP provision - as well as strategies related to variable SSC integration in clinical risk assessment - may apply to a wider setting of the surgical teamwork. This assumption is based on the maximum variation sampling strategy used in collecting data and triangulation of data across time, hospital settings and professions.

5.4 Discussion of results and main findings

The three studies constituting this thesis have shed light on the perioperative mechanisms through which the SSC improve surgical care, how these effects may be replicated and which areas of perioperative teamwork need strengthening. In the following, the results of the studies will be discussed in relation to previous publications and theoretical perspectives of patient safety.

5.4.1 A causal, clinical pathway of the WHO SSC.

Implementation of the SSC significantly increased the use of normothermia protecting measures, as well as antibiotic prophylaxis, as shown in Study 1. Determining whether or not an intervention is responsible for such an observed effect, is usually worked out through correlational logic.[84] Based on the available data, we were able to adjust for possible influences (confounding factors) on the postoperative outcomes by using logistic regression. In the final model analysing postoperative complications on checklist fidelity, SSC effects were adjusted for age, sex, case-mix, comorbidity, anaesthesia type, knife time, study time points and process metrics. Provision of surgical antibiotic prophylaxis before incision reduced the OR for infections and wound rupture. This indicates a robustness of the WHO SSC fidelity on reducing postoperative infections.

The WHO recommendations on preoperative measures for surgical site prevention strongly advocate that administration of SAP, when indicated, should be performed before surgical incision.[12] This recommendation is also in line with Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017, emphasising that the use of antimicrobial prophylaxis to achieve bactericidal concentrations in serum and tissues is based on moderate or high-quality evidence.[105] In addition, maintaining perioperative normothermia is strongly recommended and graded high to moderate-quality evidence.[105] Based on these recommendations and robust study results, it is reasonable to predicate that one of the mechanisms throughout which the SSC brings about change is the causal pathway of improved normothermia protective care processes, and provision of antibiotics before incision caused by high SSC fidelity.

The robust stepped wedge cluster randomised control trial design has been used in quality improvement intervention trials, such as the Enhanced Peri-Operative Care for High-risk patients (EPOCH) study.[106] Even though the quality improvement programme was delivered as planned at the cluster level, this study did not demonstrate any improvement in the primary study outomes. To our knowledge, no other study has used the stepped wedge cluster randomised control trial design to investigate effectiveness of the SSC and further estimate the causal pathway of clinical perioperative care processes correlating to the significant reduction in patient complications, including postoperative infections.

5.4.2 The clinical pathway of surgical antibiotic prophylaxis

Further investigations of the clinical pathway, in provision of surgical antibiotic prophylaxis, outlined the workflow for SAP in perioperative care. The identified complexity highlights the real-world balancing of professional judgements regarding patient, antibiotic and surgery-related factors, as well as coordinating the OT scheduling and workflow for SAP to be administered in due time before incision. Surgical workflow complexity is reported as obstacle to proper timing of SAP by surgeons, because antibiotic management is considered more peripheral among their many perioperative responsibilities.[107 108] Other factors influencing appropriate SAP

administration are described as: individual knowledge, attitudes, beliefs and practice; team communication and allocation of responsibilities for antibiotic prophylaxis; and institutional support for promoting and monitoring antibiotic prophylaxis.[109] Taken together, this adds to the understanding that SAP provision is a complex process of balancing timeliness by considering and responding to multiple interacting factors, as described in Paper 2.

The findings of our study indicate ambiguities in ownership for SAP, especially seen at the intersections of prescription transfers to providers where suboptimal use of prescription order systems, or poorly completed SAP orders, provided unclear indications to the nurse anaesthetist providers. Particular contributors to delayed SAP administration were related to the need of clarifying alternative SAP, in case of patient allergies, and precise dosages for complex medical cases. Previous investigations of cultural determinants of antibiotic decision-making in surgery report that priorities are split between the settings of operating theatres, outpatient clinics, and wards.[110] As a result, senior surgeons were often absent from the ward, leaving junior staff to make complex medical decisions. As patients with impaired physical status may have increased risk of developing SSIs, these subgroups are vulnerable and should therefore be given particular attention during the planning and prescription of SAP.[71]

Provision of SAP is only one element of the many tasks carried out by the perioperative, multidisciplinary team. Prescription, preparation, and administration of SAP is carried out by different professionals at different time points, where each of the steps rely on the individual healthcare providers' skills and competencies. Yet the quality and effectiveness of this specific teamwork is dependent on the skills of the team as a whole, depending on communication, monitoring, and coordination. The determinants of good (or poor) performance and safety are collectively described as "systems approach" to patient safety. This recognises that human operators are fallible and problems related to either individual skills, teamwork, and/or the clinical environment, are identified as "latent risk factors".[111]

Traditionally, surgical outcome has been focused on patient outcomes and clinical processes because these endpoints are evidently relevant to patients and can be assessed more objectively. However, if team effectiveness is considered a key endpoint in itself, a good performing operating theatre team is one whose patient always gets SAP on time. Assessing the levels of performance by establishing reliability measures of key processes in the provision of SAP is then a necessity. By including indicators of team performance in relation to prescription orders and timely administration, the provision of SAP could then serve as a proxy measure for the teams' effectiveness and quality.

An antimicrobial stewardship programme might be a suitable framework to introduce these measures as this framework includes a system approach of coordinated interventions designed to improve and measure the appropriate use of antimicrobial agents.[109 112] The goal of such programmes is to reduce the development of antibiotic resistant organisms and to ensure that misguided overuse or inappropriate use of prophylactic and therapeutic antibiotics does not result in direct deleterious effects to patients.[100] Antimicrobial stewardship programmes should, therefore, be of particular importance to surgical specialties due to their prominent role in prophylactic antibiotic usage and management of surgical infections. However, as the characteristics and culture of antibiotic prescribing and decision making in surgery vary from those encountered in the medical disciplines, the implementation and execution of the antimicrobial stewardship programme needs to be tailored to the surgical context.[100 107 110]

5.4.3 SSC utilisation and perioperative risk assessment

Investigations of how frontline personnel integrated the SSC with pre-existing perioperative clinical risk management indicated an individual and professional "cost-benefit" assessment of the practical usefulness of SSC. As a consequence, the identified variability of SSC utilisation in regard to which checks were given attention, and by whom, were interpreted as strategies of customising SSC implementation to one's professional obligations. In addition, observed patterns of micro-team risk communication clearly took precedence over formal SSC utilisation.

SSC performance variability has been well documented in studies reporting how the SSC implementation quality differs among hospitals, surgical specialities, surgical staff members, and among specific items and parts of the checklists.[29 31-33 83 113-116] Barriers to buy-in and effective use are related to attitudes regarding SSC appropriateness for workplace environment, e.g., applicability to complex patient groups, repetition of existing checks causing disruption to workflow and lack of feasibility in everyday practice.[29] Many of the reported issues related to concerns of SSC appropriateness and feasibility, including our findings in Study 3, relate to the inherent complexity of the SSC intervention. This complexity is clearly presented in a systematic review of barriers and facilitators related to SSC implementation, where identified themes, derived from qualitative research, are mapped out as contributory factors related to context, implementation and the SSC intervention.[83] This review offers an insight into the diversity of essential, empirical contributors in the surgical context that need to be handled in order to achieve SSC sustainability over time. Findings correlate with factors of importance to achieve sustainability, as described in the British medical Research Council process evaluation framework.[80]

Considering the findings in Study 3, as well as the numerous studies by others describing variability of SSC utilisation, one might question to what extent the SSC (as a complex intervention) is the adequate solution for issues of both interprofessional communication, teamwork and safety practices, given the complexity of the surgical context. Despite a general understanding that ineffective communication compromises patient safety,[13 14 25 117] few studies have focused on the implementation, uptake and consequences of a specific interprofessional team intervention, such as the SSC. However, the growing body of research describing SSC performance variations indicate that the complex surgical culture in which the SSC is implemented has been largely ignored.[118] Engaging with SSC performance variability might, therefore, provide an opportunity to identify potential latent risk factors, and better understand the cultural determinants that influence uptake of the SSC. Using the “Checklist Usability Tool” (CUT), which has demonstrated good levels of interrater reliability, might also be a feasible approach to improve

understanding of the reality of how the SSC is used in practice and help identify areas for improvement, modification and training.[31]

Previous research on the effectiveness of teams has suggested that shared mental models facilitate coordination and team performance.[119] Building expectations of performance standards into work processes, including the SSC reviews, might contribute to the development of a shared mental model within perioperative teams.[120] An example here is the national standard for the safe practice of anaesthesia and the Helsinki declaration on patient safety in anaesthesiology, which include normative guidelines for everyone who provides anaesthesia care.[121] [122] In the UK, the National Safety Standards for Invasive procedures which build on the WHO SSC, have been developed to set out the key steps necessary to deliver a safe and common care standard for surgery.[123]

In addition, non-technical skills, e.g., decision-making, situation awareness, communication, leadership and teamwork, are seen as important contributors to reducing adverse events and improving team work in healthcare teams.[81] Although core non-technical skills can be identified across these five domains, behaviours emerge specific to each of these domains.[81] Identifying and analysing the non-technical skills appropriate to the different phases in perioperative surgical care, is, therefore, essential in order to determine and design specific training objectives, evaluation and feedback. Using the WHO Behaviourally Anchored Rating Scale (WHOBARS) to measure the overall quality of SSC performance, allows observers to assess behaviours of healthcare personnel when using the SSC, and is reported as being a feasible tool for clinical audits to discriminate between well or poorly performing teams.[124]

5.4.4 SSC in relation to theoretical perspectives

The overall aim of this thesis was to gain knowledge on how and why the SSC intervention might work in everyday clinical practice, by studying perioperative work processes related to SSC utilisation. In Study 1, improved perioperative processes of care and subsequently improved patient outcomes followed the SSC implementation.

From a “Safety I” perspective, where things can go wrong due to potentially identifiable failures,[37 54] we have demonstrated that the SSC has served as a barrier between the dangers, i.e., hypothermia and delayed administration of SAP, and the patient. In this sense, according to the conceptual framework for the ICPS[35] (page 4), the study results indicate that SSC use works indirectly to reduce risk of SSI, by proactively influencing crucial factors to sustain normothermia. The SSC also has the potential to detect missing prescriptions of SAP and thereby influence its administration, albeit, in this manner as a reactive response. Taken together, this shows that the SSC has the potential to serve as both a proactive and a reactive safety intervention.

A key finding in Study 2 that seemed to drive task and behaviours related to SAP administration, was the given timeframe of 60 minutes prior to incision as provided in the SSC. From a “Safety II” perspective, two of the essential capabilities of resilience are known as “the ability to monitor what changes”, and “the ability to respond to regular and irregular variability, disturbances, and opportunities either by adjusting the way things are done or by activating ready-made responses”.[40] Findings in Study 2 indicate that the SSC facilitates the work processes required for the administration of SAP within the given timeframe. The predictability of this timeframe made the nurse anaesthetists able to proactively respond when in need of clarifications of prescriptions. The obvious advantage of proactive adjustments is that they may “buy time”, whereas reactive adjustments always will “take time”.[40] In understanding and managing the perioperative patient safety, it is important to acknowledge the complex relationships that exist between an incident type and its contributing factors. In perioperative care, incidents such as lack of hypothermia prevention and timely administration of SAP, can be contributing factors to other incidents, such as SSI. If team members’ perceptions of risk are solely concerned with their professional perceptions of active failures instead of including underlying conditions, such as risk of developing surgical site infections, important safety aspects of the team communication are neglected.[32 116 125] Thus, based on the findings of our studies, it is reasonable to assume that the SSC not only serves as a barrier, but can potentially facilitate resilient mechanisms by building expectations of performance.

6. Conclusions

This thesis examined the impact of SSC implementation on perioperative care processes and patient outcomes in a Norwegian context. It highlighted the work processes of SAP provision and potential integration of SSC utilisation as part of the risk management in perioperative care, following the SSC implementation. By combining quantitative and qualitative methods, we have been able to assess SSC implementation fidelity and explore its interaction with related work processes.

The findings illustrate some of the causal mechanisms of improvement and resilient mechanisms driven by the WHO SSC implementation. These findings differ from the numerous studies questioning the correlational logic of the SSC's effect on patient outcome in particular. That said, identified performance variability reflected SSC utilisation post-implementation, which corresponds to previous research of identified contextual barriers causing performance variability and low fidelity of the SSC.

The summary of the conclusions:

- High-quality SSC implementation, including the utilisation of all 3 checklist parts, was significantly associated with improved processes and outcomes of care. One of these perioperative care processes was the provision of SAP.
- SAP administration practice is likely to have been influenced by the timeframe of "60 minutes prior to incision" as stated in the SAP item of the SSC.
- The mechanisms of SSC influence on SAP practice was inferred as either a cognitive "reminder" of timely administration and /or as an educational intervention, facilitating proactive, rather than reactive, involvement and enquiries by SAP providers.
- Identified norms of behaviour and communication among the multidisciplinary team members reflect subpotimal integration of the SSC into existing perioperative risk management strategies in daily work.

To conclude, the thesis adds important knowledge on how and why the SSC might work in everyday clinical practice, yet also identifies a need to advance mutual understanding of safety perspectives and communication on risk in perioperative multidisciplinary teams.

7. Implications for practice

The results highlighted in this thesis have important implications for practice in perioperative care. To further improve the quality and safety of surgical care, the following three approaches are suggested. Firstly, the empirical findings present a robust causal pathway of how the use of a safety intervention as a clinical structure improved processes of care; the subsequently high-quality intervention implementation and improved processes of care led to better patient outcomes. Although safety measurement and monitoring is complex and multifaceted, it is vitally important if safety is to improve. In addition to standard outcome measures of complications and mortality, we propose that quality indicators, which should encompass behaviours, processes and systems of care related to the surgical context, are needed to better reflect dimensions of safety in the future.

Secondly, the findings support the use of the SSC for providers to adhere to timely SAP administration prior to incision. However, future SSC utilisation needs integration into antimicrobial stewardship programmes in surgery, including items of SAP prescription as well as SAP administration. Standardising SAP prescription order systems and defining possible risks of SAP failures at each step in the preoperative planning of surgery, may improve SAP workflow. In addition, aligning the recommended time frame of SAP administration to the pharmacokinetic property of the specific antibiotic should be integrated with the SSC utilisation to reduce risk of imprecise timing of SAP administration.

Thirdly, interpretation of findings indicate that perioperative multidisciplinary safety reviews need to be better incorporated into national normative standardisation of surgical care, including utilisation of the SSC. Strategies to enhance patient safety in surgery should focus on a multidisciplinary approach to foster shared mental models of safety standards in the OT. Aligning risk-assessment in SSC staff education, where the SSC is part of a safe surgical risk assessment system, might provide an improved sense of value to all OT personnel, improve team learning of risk communication and foster mutual understandings of safety perspectives.

8. Suggestions for further research

Advancing conceptualisation, measurement and empirical understanding of patient safety and teamwork outcomes in surgical care requires research on several critical issues. However, based on the findings, discussion and conclusion of the thesis, we propose two specific directions for further research: implementation of antimicrobial stewardship in surgery and improving SSC quality performance in perioperative care.

In Study 2, findings illustrated how nurse anaesthetists were important stakeholders in the provision of SAP. Although nurses' roles in antimicrobial stewardship practices in hospitals are emphasised, their role and responsibility of SAP in perioperative care needs to be explored. Also, the SSC itself, and factors at individual, team, and organisational level, could be tailored to improve adherence with both antibiotic guideline recommendations and SSI preventative measures. The effectiveness of the various strategies needs to be rigorously evaluated, in addition to investigation of intervention effects. The use of "effectiveness-implementation hybrid" designs could contribute to a greater understanding of how organizational structures and processes enable quality improvement.

Investigations of teamwork improvements are needed to better inform policy making and health system inputs on improving standardisation of perioperative care. The use of the "Checklist Usability Tool" (CUT) and the WHO Behaviourally Anchored Rating Scale (WHOBARS) have showed promise to better understand the SSC delivery in perioperative care, and help identify areas for improvement, modification and training. These tools need to be translated and validated to the surgical context in Norway.

To better understand the complexity in surgical care, the safety culture, teamwork and communication, further studies are necessary to investigate relationships between specific checklist items, related care processes, team outcomes and complications.

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10. Appendices

Appedix I

Observation guide for study 2 and 3

Observation guide no. **Date:**

Key tasks/ points of particular interest:

Antibiotic prophylaxis:

- **Prescribing:**
- **Administration:**
- **Timeliness:**
- **Registration:**
- **Duration:**

Safe surgical checklist:

- **Sign In**
- **Time Out**
- **Sign Out**

Appedix II

Interview guide for study 2 and 3

Interview number:___ **Date:_____**

Setting:_____

Interview participant (profession):_____

Opening information to establish relationship with participants:

- Information on protection of anonymity of interview participants
- Clarification on role of the interviewer
- Clarification of the purpose of the study

Topic 1: World Health Organization`s Surgical Safety Checklist:
The SSC has been introduced as a safety tool to enhance perioperative teamwork and information exchange, by systematically reviewing critical patient factors before the induction of anaesthesia, before the incision of the skin, and before the patient leaves the operating facility.

As (the relevant profession):

- In your opinion, do you think the SSC work as intended at your surgical unit?
  - How?
  - Why?

- Can you describe a situation in which using the SSC has been useful or positive?
  - How?
  - Why?
  - Any experiences in relation to specific perioperative work processes?

- Can you describe a situation in which using the SSC has been difficult?
  - How?
  - Why?
  - Any experiences in relation to specific perioperative work processes?

Topic 2: Surgical antibiotic prophylaxis
Surgical antibiotic prophylaxis is crucial in the prevention of surgical site infections, and provision of antibiotic prophylaxis is standardized for many surgical procedures. In the following, I will ask questions related to the work processes surrounding provision of surgical antibiotic processes.

- Can you tell me how surgical antibiotic prophylaxis is prescribed?
  - (Pre-, per- and postoperatively)
- Can you tell me how surgical antibiotic prophylaxis is prepared?
- Can you tell me how surgical antibiotic prophylaxis is administered?
  - (When?)
  - (Who?)
  - (How?)
- In your opinion, what is challenging in relation to surgical antibiotic prophylaxis?
  - (Can you describe a challenging episode?)
- In your opinion, what works well in relation to surgical antibiotic prophylaxis?
  - (Can you describe a «well-functioning» situation?)

Topic 3: Perioperative teamwork:
In the following, I will ask questions related to local team work- and communication.
As (the relevant profession):

- How do you experience that the SSC influence the perioperative teamwork?
  - How?
  - Why?

- Do you have any experiences of this in relation to "Sign In»?
  - (Issues and «patterns» of communication?)

- Do you have any experiences of this in relation to "Time Out»?
  - (Issues and «patterns» of communication?)

- Do you have any experiences of this in relation to "Sign Out»?
  - (Issues and «patterns» of communication?)

- Have you experienced that the SSC may influence your professional role in the perioperative teamwork?
  - How?
  - Why?

- How do you think that the SSC influence or contribute to patient safety at your surgical unit?
  - How?
  - Why?

Closing questions:

- Is there anything you would like to add, that you believe is of importance in relation to the topics we have discussed?
    - The Surgical safety checklist and hospital compliance data?
    - Perioperative teamwork?
    - Specific perioperative work-processes?

- Do you have any thoughts or feedback on this interview?

Thank you for your participation!

Appedix III

CONSORT 2010 checklist for report of a cluster RCT (Paper 1)

Table 1: CONSORT 2010 checklist for report of a cluster RCT

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract		**Causal analysis of World Health Organization's Surgical Safety Checklist implementation quality and impact on care processes and patient outcomes: Secondary analysis from a large stepped wedge cluster randomized controlled trial in Norway**		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)[1,2]	See table 2	2,3
Introduction				3
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3,4
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	4
Methods				4-7
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	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		-
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	4,5
	4b	Settings and locations where the data were collected		4
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	4,5
Outcomes	6a	Completely defined pre-	Whether outcome measures	5

		specified primary and secondary outcome measures, including how and when they were assessed	pertain to the cluster level, the individual participant level or both	
	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	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines		-
Randomisation:				4
Sequence generation	8a	Method used to generate the random allocation sequence		4,5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	-
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	-,4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	4

	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	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		**6**
	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	6,7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		7
Results				7-9
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		4
	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	7, Table 1
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	7
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 intracluster correlation (ICC or k) for each primary outcome	8-9, Tables 2-5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		9
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		-
Discussion				9-11
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		11,12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	12,13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		12,13

Other information			-
Registration	23	Registration number and name of trial registry	(REC West 2009/561)/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	1,2

** Note: page numbers optional depending on journal requirements*

Appedix IV

COREQ checklist for report of a qualitative research study (Paper 2)

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	5
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	5,7
Occupation	3	What was their occupation at the time of the study?	5,7
Gender	4	Was the researcher male or female?	N/A
Experience and training	5	What experience or training did the researcher have?	5,7,18
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	Supplementary
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Supplementary
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Supplementary
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	4-5
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	5-6
Sample size	12	How many participants were in the study?	6
Non-participation	13	How many people refused to participate or dropped out? Reasons?	N/A
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	5-6
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	5-6
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	4-6
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	6
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	6
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	6
Field notes	20	Were field notes made during and/or after the inter view or focus group?	5
Duration	21	What was the duration of the inter views or focus group?	6
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	7
Description of the coding tree	25	Did authors provide a description of the coding tree?	7
Derivation of themes	26	Were themes identified in advance or derived from the data?	6-7
Software	27	What software, if applicable, was used to manage the data?	6
Participant checking	28	Did participants provide feedback on the findings?	N/A
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	8-13
Data and findings consistent	30	Was there consistency between the data presented and the findings?	7-8
Clarity of major themes	31	Were major themes clearly presented in the findings?	8-13
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	7-13

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Appedix V

COREQ checklist for report of a qualitative research study (Paper 3)

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	7
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	7
Occupation	3	What was their occupation at the time of the study?	7
Gender	4	Was the researcher male or female?	N/A
Experience and training	5	What experience or training did the researcher have?	7,8
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	Supplementary file
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Supplementary file
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Supplementary file
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	5
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	6,7
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	6,7
Sample size	12	How many participants were in the study?	6,7
Non-participation	13	How many people refused to participate or dropped out? Reasons?	19
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	6,7
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	6,7
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	8
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7

Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	7
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	7
Field notes	20	Were field notes made during and/or after the inter view or focus group?	6,7
Duration	21	What was the duration of the inter views or focus group?	7
Data saturation	22	Was data saturation discussed?	8
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A
Topic	**Item No.**	**Guide Questions/Description**	**Reported on Page No.**
		correction?	N/A
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	8
Description of the coding tree	25	Did authors provide a description of the coding tree?	8
Derivation of themes	26	Were themes identified in advance or derived from the data?	8
Software	27	What software, if applicable, was used to manage the data?	N/A
Participant checking	28	Did participants provide feedback on the findings?	N/A
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	13,14
Data and findings consistent	30	Was there consistency between the data presented and the findings?	9
Clarity of major themes	31	Were major themes clearly presented in the findings?	9-14
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	9-14

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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Papers 1-3

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OPEN

Causal Analysis of World Health Organization's Surgical Safety Checklist Implementation Quality and Impact on Care Processes and Patient Outcomes

Secondary Analysis From a Large Stepped Wedge Cluster Randomized Controlled Trial in Norway

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Objective: We hypothesize that high-quality implementation of the World Health Organization's Surgical Safety Checklist (SSC) will lead to improved care processes and subsequently reduction of peri- and postoperative complications.
Background: Implementation of the SSC was associated with robust reduction in morbidity and length of in-hospital stay in a stepped wedge cluster randomized controlled trial conducted in 2 Norwegian hospitals. Further investigation of precisely how the SSC improves care processes and subsequently patient outcomes is needed to understand the causal mechanisms of improvement.
Methods: Care process metrics are reported from one of our earlier trial hospitals. Primary outcomes were in-hospital complications and care process metrics, e.g., patient warming and antibiotics. Secondary outcome was quality of SSC implementation. Analyses include Pearson's exact χ^2 test and binary logistic regression.
Results: A total of 3702 procedures (1398 control vs. 2304 intervention procedures) were analyzed. High-quality SSC implementation (all 3 checklist parts) improved processes and outcomes of care. Use of forced air warming blankets increased from 35.3% to 42.4% ($P < 0.001$). Antibiotic administration postincision decreased from 12.5% to 9.8%, antibiotic administration preincision increased from 54.5% to 63.1%, and nonadministration of antibiotics decreased from 33.0% to 27.1%. Surgical infections decreased from 7.4% (104/1398) to 3.6% ($P < 0.001$). Adjusted SSC effect on surgical infections resulted in an odds ratio (OR) of 0.52 (95% confidence interval (CI): 0.38–0.72) for intervention procedures, 0.54 (95% CI: 0.37–0.79) for antibiotics provided before incision, and 0.24 (95% CI: 0.11–0.52) when using forced air warming blankets. Blood transfusion costs were reduced by 40% with the use of the SSC.
Conclusions: When implemented well, the SSC improved operating room care processes; subsequently, high-quality SSC implementation and improved care processes led to better patient outcomes.

Keywords: care process, checklist, complications, implementation fidelity, operating room, randomized controlled trial, surgery

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The World Health Organization's (WHO) Surgical Safety Checklist (SSC) has been reported to reduce both morbidity and mortality.[1,2] The SSC was developed to improve teamwork, communication and consistency of care in operating rooms.[3] Enhanced teamwork and communication is one of the mechanisms used to explain SSC effects on patient outcome.[4–6] Facilitators of SSC use that strengthen implementation are reported to be education and training, audit and feedback interventions using local data on actual checklist usage, fostering local champions and leadership, and accountability for compliance.[7] Perceived implementation barriers are design-related issues (including poor local tailoring of items, nonintegration into operating room workflow), lack of structured implementation approach, and resistance from senior clinicians.[7,8]

Precisely how the SSC, or indeed any other checklist that has been evaluated to date, achieves its effectiveness is far from clear. Mechanisms postulated to drive SSC positive effects have been associated with implementation strategies and actual utilization of the checklist.[9,10] Moreover, in studies that find reduced morbidity and mortality,[10–12] quality of SSC implementation is assumed to be

an important explanatory mechanism.[9] A large scale study of the SSC effects in Canadian hospitals, including 215,711 procedures, did not find similar results.[13] Nonetheless, the study raised concerns about quality of implementation strategies.[14] In other studies high fidelity to the checklist intervention has proven important for improved patient outcomes.[11,12,15] Taken together, the evidence-base to-date implies that explanatory mechanisms behind effectiveness (or lack thereof, as in the Canadian dataset) are yet to be fully understood.

Lack of understanding of what makes implementation of the SSC effective in some settings, but not in others severely hampers our ability to improve SSC implementation. We remain unaware of which implementation element matters the most and in which settings. In turn, this limits our ability to improve patient outcomes via better application of the SSC. In the WHO SSC implementation guide, hospital leadership, and monitoring of surgical results and complications are recommended to achieve successful implementation.[16] Tracking of process and outcome measures have been encouraged, exemplified by percent of procedures having antibiotics provided at the correct time.[16] Accordingly, the WHO SSC implementation guide rests on Donabedian's approach to clinical quality improvement,[17] in which improved structures enhance care processes; and both structures and care processes, in turn, improve patient outcomes.

This study investigates how exactly the SSC improves patient outcomes via analysis of clinical structures, processes, and outcomes related to SSC implementation in the operating room. The main hypotheses we are testing are:

H_1: High-quality implementation of the SSC improves care processes in the operating room;
H_2: Improved care processes lead to better patient outcomes;
H_3: Improved implementation (fidelity to SSC) leads to improved compliance with critical standards (improved care processes), and improved compliance leads to improved outcomes.

The clinical improvement framework and associated hypotheses we tested, based on Donabedian's approach, are illustrated in Figure 1.

METHODS

Study Design

Our study was designed as a stepped wedge cluster randomized controlled (RCT) quality service improvement trial in 2009 to 2010.[12] The stepped wedge cluster RCT design is increasingly used to evaluate patient safety interventions that inherently are expected to do more good than harm.[18] The intervention is sequentially introduced to the clusters in a random way at different time points, which is particularly useful when the intervention cannot be delivered to all participants at the same time. Hence, the checklist intervention was provided to 1 cluster at the time.[12] This study was conducted in 2 Norwegian hospitals, a community hospital and a tertiary teaching hospital, and included 5 surgical specialties (orthopedic, cardiothoracic, neurosurgery, urology, and general surgery). The dataset from the original study was further analyzed to search for the effects of process metrics on patient outcomes. Three of the study clusters had such process metrics registered, and were therefore included, hence all other clusters were excluded (SDC 1, http://links.lww.com/SLA/B343).

The 3 specialties (clusters of the RCT) were randomly allocated to receive the SSC intervention. Allocation sequences were generated by a draw of numbers into a rank order deciding the roll-out of the checklist intervention. The allocation assessor was blinded for clusters corresponding to the numbers. The SSC implementation started sequentially over 3 to 4 weeks after a 3-month baseline period. The intervention continued for 3 months after all clusters received the intervention. Details of the stepped wedge cluster (RCT) design and the SSC intervention have previously been described.[12,18–20]

The SSC consists of 3 parts, the Sign in before anesthesia induction, the Time out before incision, and the Sign out at the end of the surgical procedure—before transfer to postoperative care unit. The SSC adapted for use in Norwegian operating rooms is presented in SDC 2, http://links.lww.com/SLA/B343. In the Norwegian checklist version, items to prevent hypothermia are listed both under the Sign in and under Time out parts.

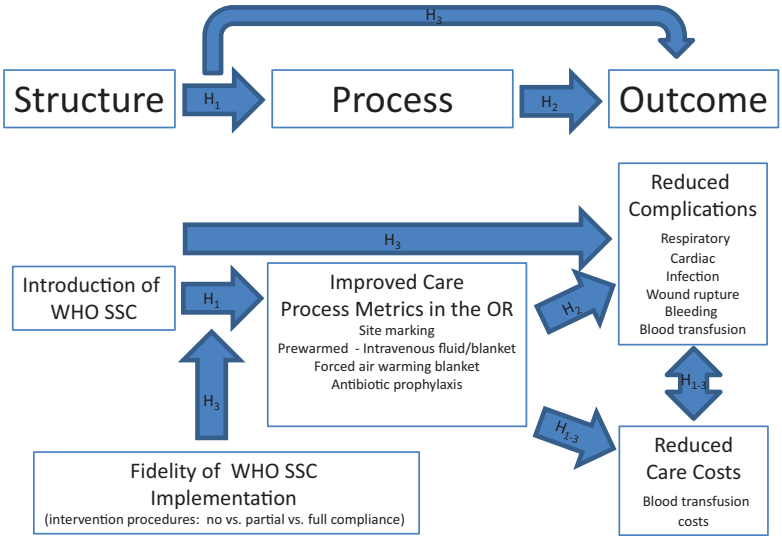

FIGURE 1. A clinical improvement framework and associated study hypotheses, based on Donabedian's approach on structure, process, and outcome.

Use of routinely collected anonymized data was regarded as clinical service improvement by the Regional Committee for Medical and Health Research Ethics (Unique identifier: 2009/561). Hence, approval of the study was given by the hospital privacy Ombudsmen (Ref: 2010/413) and hospital managers.

Outcome Measures

Measures relevant to operating room care processes and patient outcomes were the primary endpoints; quality of SSC implementation was a secondary endpoint.

To avoid possible study biases by introduction of new measurements on process metrics associated with items on the checklist, which could be regarded as competing interventions, we used process metrics that were already being registered as routine practice. Care process metrics were preoperative site marking; actions to sustain normothermia (prewarmed intravenous fluid, prewarmed blankets, forced air warming blankets); and timeliness of infection prophylactic provision of intravenous antibiotics. The latter was categorized into before and after incision, and no antibiotics.

Patient outcomes included surgical infection, surgical wound rupture, cardiac complication, respiratory complication, postoperative bleeding, and intraoperative blood transfusion. We classified the primary endpoints as 0 for no complication and 1 for verified complication. Secondary outcome was blood transfusion costs in USD.

Implementation quality was prospectively measured by the fidelity to actual use of the SSC, defined as compliance with all 3 parts of the checklist. To investigate SSC fidelity impact on patient outcomes as previously shown by Mayer et al,[10] we categorized utilization of the Sign in, Time out and Sign out parts used as: no checklist; one of the checklist parts; combinations of 2 of parts; all 3 parts; and any parts.

Data Collection

Data from all age groups and elective or emergency surgery are included. Surgical procedures which the SSC was not adapted for were excluded (ie, donor surgery). Patient characteristics include age, sex, and comorbidity with the American Society of Anesthesiologists (ASA) classification. Further, data on elective or emergency surgery, type of anesthesia (general vs. regional), surgical procedures as orthopedic, cardiothoracic or neurosurgical, and duration of surgical procedures (knife time) were recorded in the hospital administrative data system as routine practice by clinical staff. Adherence to the SSC was prospectively recorded on a paper form by nurse anesthetists and operating room nurses. All items were marked for each patient, as the SSC parts were carried out. To decide whether it had been used or not, we determined a cut-off requiring more than 60% of items to be registered on the paper version. Additionally, the SSC parts were electronically recorded as used (all items required performed) or not, by the operating room nurse. If there were any discrepancies between paper and electronic recordings of SSC fidelity, the latter was preferred.

To ensure high fidelity to checklist performance, members of our multidisciplinary implementation team were present in the operating rooms. They provided advice through direct guidance and observations on site. Evaluation meetings on checklist fidelity were conducted with the operating teams in the operating theater 2 weeks and 2 months postimplementation of the SSC. Feedback on checklist compliance rates was posted on wall posters outside the operating rooms throughout the study.

Patient complications were assigned *International Classification of Diseases – tenth version (ICD-10)* codes recorded by surgeons or ward physicians at patients' discharge from hospital. All outcome data were extracted from hospital administrative databases and quality checked to verify incidence of any recorded complications.[12]

Data Handling

The assessors handling and evaluating data validity were blinded to the randomization of patients and procedures into control and intervention cohorts. To protect the study from information bias, clinicians were not informed as to which study endpoints that were measured. All recovery and postoperative ward staff were not informed about the study, cohorts, or outcome of interest, and performed care as usual. Complications identified through *ICD-10* codes and care process data were verified against the patients' medical records.[12] This study followed the extended CONSORT statement for nonpharmacological randomized trials.[21]

Statistical Analysis

The surgical clusters provided data in all the stepped wedges, being their own controls before and after the introduction of the SSC intervention. Hence, data across the cluster steps before (controls) were compared with the steps after SSC implementation (intervention).[19] Fuller implementation of the SSC (ie, more parts completed) indicates higher fidelity to the intervention.[22] To investigate effect of procedures with highest SSC compliance we also compared controls to intervention procedures with full implementation of the SSC ($n = 1743$). Patient outcome, patient, and procedure characteristics for the control and intervention stages, and fidelity of checklist implementation (full vs. none) were analyzed using Pearson's exact χ^2 test for categorical data, independent samples t test for continuous data, or nonparametric test (Mann–Whitney U test) as appropriate.

Based on our original sample size calculation, a minimum of 1100 patients were required in each one of the control and checklist groups for adequate study power.[12] Intracluster correlation was not calculated as it is considered to have minimal impact on power due to the unidirectional stepped wedge implementation of the intervention.[18] The primary endpoints were modeled with logistic regression. Model I: by SSC fidelity, and in Model II: controlling for patient and procedure characteristics, and process metrics. Analyses were carried out in SPSS version 23.0 (IBM Corp, Armonk, NY), and a 2-sided P value less than 0.05 was considered statistically significant.

RESULTS

Patient Characteristics

Overall, 3702 surgical procedures were included in this stepped wedge cluster RCT, with 1398 control procedures and 2304 intervention procedures. Distributions of patient and procedure characteristics across control and intervention arms are reported in Table 1. There were no differences between patients in age, sex, or comorbidity from control to intervention, though patients more often underwent orthopedic procedures, elective procedures, and regional anesthesia in the intervention arm.

Implementation Outcomes (Fidelity of Checklist Usage)

We measured the fidelity to the use of each SSC part. In the intervention group there was complete compliance with 1 part of the SSC only (mostly Sign in or Time out), in 4.7% (109/2304) of the surgical procedures. Combinations of 2 parts (Sign in and Time out, Time out and Sign out, or Sign in and Sign out) being fully utilized were found in 8.5% (196/2304) of the procedures. Full compliance, using all 3 parts (Sign in, Time out, and Sign out) of the SSC, was identified in 75.7% (1743/2304) of the procedures. A total of 88.9% (2048/2304) had used any parts of the checklist, including all cases of

TABLE 1. Patient and Procedure Characteristics of the Stepped Wedge Cluster RCT Study Sample (n = 3702) in a Norwegian University Hospital in 2009–2010

Characteristic Category	Control (n = 1398)	Intervention* (n = 2304)	*P* Value†
Age in years, mean (SD)	53.5 (23.4)	53.9 (23.4)	0.621
Male sex, n (%)	759 (54.3)	1247 (54.1)	0.919
Comorbidity by ASA, n (%)			0.107
ASA I	238 (17.0)	464 (20.1)	
ASA II	568 (40.6)	964 (41.9)	
ASA III	474 (33.9)	700 (30.4)	
ASA IV	57 (4.1)	86 (3.7)	
ASA V	2 (0.1)	2 (0.1)	
No ASA score	59 (4.2)	87 (3.8)	
Surgical procedure, n (%)			<0.001
Orthopedic	721 (51.6)	1557 (67.6)	
Thoracic	293 (21.0)	392 (17.0)	
Neuro	384 (27.5)	355 (15.4)	
Surgery, n (%)			0.001
Elective	693 (49.6)	1274 (55.3)	
Emergency	705 (50.4)	1030 (44.7)	
Anesthesia, n (%)			<0.001
Regional	446 (32.9)	1013 (45.5)	
General	909 (67.1)	1213 (54.5)	

*Procedures that include full use of WHO SSC, partial use of WHO SSC, or noncompliance.
†From Pearson's exact χ^2 test, except *t* test for age.
ASA indicates American Society of Anaesthesiologists' risk score; RCT, randomized controlled trial; SD, standard deviation.

complete compliance with 1, 2, or 3 parts. Noncompliance with the checklists was 11.1% (256/2304) in intervention arm procedures.

Care Processes

The results of comparing all care process metrics from controls to intervention procedures and in procedures with high fidelity of SSC usage are reported in Table 2. Measures for preoperative site marking, normothermia protection (prewarmed intravenous fluids, prewarmed blankets, forced air warming blankets), and antibiotics before incision were all significantly more often used in the intervention procedures compared with the controls. When adjusting for elective and emergency procedures, surgical case-mix, and type of anesthesia, the use of normothermia protecting measures and infection prophylactic antibiotics remained better applied in the checklist arm of the trial (Table 3).

Patient Outcomes

Primary endpoints are reported in Table 4. Complications including respiratory, cardiac, surgical infections, wound rupture, bleeding, and blood transfusions were all significantly reduced in the intervention arm of the trial. In procedures with no use of the checklist (n = 256), there was a borderline significant reduction for infections and wound rupture, but not for the remaining outcomes.

To statistically control for patient and procedure characteristics and process metric effects on complications, we used logistic regression analysis. Results are presented in Table 5. Use of forced air warming reduced odds ratio (OR) for cardiac complications and wound ruptures significantly. Further, infection prophylactic antibiotics provided before incision reduced OR for infections and wound rupture. In the intervention arm the SSC effects remained significant for all complications except respiratory complications,

TABLE 2. WHO SSC Impact on Care Process Metrics in the Stepped Wedge Cluster RCT (n = 3702) in a Norwegian University Hospital (2009–2010)

	Control	Intervention*		No Checklist Parts Used vs. Control		All SSC Parts Used vs. Control	
Care Process Metrics Category	(n = 1398) Cases (%)	(n = 2304) Cases (%)	*P* Value†	(n = 256) Cases (%)	*P* Value†	(n = 1743) Cases (%)	*P* Value†
Site marking	971 (69.4)	1689 (73.3)	0.012	140 (54.7)	<0.001	1336 (76.6)	<0.001
Prewarmed intravenous fluid	766 (54.8)	1477 (64.1)	<0.001	136 (53.1)	0.633	1152 (66.1)	<0.001
Prewarmed regular blankets	1049 (75.0)	1856 (80.6)	<0.001	183 (71.5)	0.242	1439 (82.6)	<0.001
Forced air warming blankets	494 (35.3)	977 (42.4)	<0.001	58 (22.7)	<0.001	815 (46.8)	<0.001
Antibiotics			<0.001		<0.001		<0.001
Antibiotics before incision	762 (54.5)	1454 (63.1)		118 (46.1)		1194 (68.5)	
Antibiotics after incision	174 (12.5)	228 (9.8)		85 (33.2)		143 (8.2)	
No antibiotics	462 (33.0)	624 (27.1)		53 (20.7)		406 (23.3)	

*Full use of WHO SSC, partial use of WHO SSC, and noncompliance.
†Pearson's exact χ^2 test.

TABLE 3. WHO SSC Impact on Care Process Metrics in the Stepped Wedge Cluster RCT (n = 3702) in a Norwegian University Hospital (2009–2010)

	Intervention Procedures vs. Control			Use of All 3 WHO SSC Parts vs. Control		
Care Process Metrics	**OR**	**95% CI**	***P* Value**	**OR**	**95% CI**	***P* Value**
Intravenous fluid (room tempered* vs. prewarmed)	1.46	(1.23, 1.73)	<0.001	1.53	(1.27, 1.85)	<0.001
Blankets (room tempered* vs. prewarmed)	1.31	(1.10, 1.56)	<0.001	1.44	(1.19, 1.75)	<0.001
Forced air warming (regular* vs. forced)	1.25	(1.07, 1.45)	<0.001	1.43	(1.22, 1.68)	<0.001
Antibiotics (no* vs. preoperative provided)	1.25	(1.07, 1.48)	<0.001	1.51	(1.27, 1,79)	<0.001
Site marking (no marking* vs. marking)	1.01	(0.82, 1.24)	0.966	1.23	(0.97, 1.55)	0.084

*Reference value.
OR indicates odds ratio; *P* value = from likelihood ratio test in logistic regression adjusted for emergency vs. elective surgery, surgical case-mix, and anesthesia provided.

TABLE 4. WHO SSC Impact on Patient Outcome in the Stepped Wedge Cluster RCT (n = 3702) in a Norwegian University Hospital (2009–2010)

	Control	*Intervention		No Checklist Parts Used vs. Control		Used All Parts of the WHO SSC vs. Control	
Main Complications	**(n = 1398) Cases (%)**	**(n = 2304) Cases (%)**	***P* Value**	**(n = 256) Cases (%)**	***P* Value**	**(n = 1743) Cases (%)**	***P* Value**
Cardiac	112 (8.0)	116 (5.0)	<0.001	15 (5.9)	0.253	81 (4.6)	<0.001
Respiratory	116 (8.3)	93 (4.0)	<0.001	20 (7.8)	0.807	60 (3.4)	<0.001
Infection	104 (7.4)	82 (3.6)	<0.001	10 (3.9)	0.043	57 (3.3)	<0.001
Wound rupture	25 (1.8)	5 (0.2)	<0.001	0 (0.0)	0.044	5 (0.3)	<0.001
Bleeding†	36 (2.6)	24 (1.0)	<0.001	3 (1.2)	0.190	17 (1.0)	<0.001
Blood transfusions‡	95 (6.8)	123 (5.3)	0.072	19 (7.4)	0.788	78 (4.5)	0.005

*Intervention (include full use of WHO SSC, partial use of WHO SSC, and noncompliance).
†Bleeding: is postoperative bleedings as recorded from ICD-10 codes.
‡Blood transfusions: are transfusions provided intraoperatively during surgical procedures; *P* value indicates analysis using Pearson's exact χ^2 test.

when adjusted for time effects (variation in process metrics and patient outcomes over time, i.e., per study month).

Postoperative bleeding identified through ICD-10 codes decreased from 2.6% (36/1398) to 1.0% (24/2304) in the intervention arm ($P < 0.001$). In support to this finding, adjusted for patient and procedure characteristics the risk of postoperative bleeding was reduced in the intervention steps (Table 5). Further, evaluating intraoperative blood loss percentiles, there was significant reduction of 750 mL to 1000 mL blood loss (6.0% vs. 4.5%), and increase for no (0–49 mL) or minor bleeding (50–249 mL)—25.2% vs. 28.6% and 21.1% vs. 24.3%, respectively ($P = 0.006$) (SDC 3, http://links.lww.com/SLA/B343). The need of blood transfusion also decreased in the procedures where the SSC had been applied (Table 4). Distribution of blood transfusions with plasma, erythrocytes, and platelets is presented in Figure 2.

Adjusted for patient and procedure characteristics and care process metrics, the risk of having a blood transfusion was reduced when using all 3 parts of the SSC, with OR 0.63 (95% CI, 0.43–0.91). OR was 5.81 (95% CI, 3.34–10.01) in emergency procedures; 1.94 (95% CI, 1.16–3.27) in general anesthesia; 3.07 (95% CI, 2.31–4.01) by

TABLE 5. Results From Logistic Regression Analyses of Complications on Checklist Fidelity in the Stepped Wedge Cluster Randomized Controlled Trial in a Norwegian University Hospital (2009–2010)

			Complications														
	CA	IA	Cardiac			Respiratory			Infections			Wound Rupture*			Bleeding		
SSC Compliance (CA = Reference)	**n**	**n**	**OR**	**95% CI**	***P* Value**	**OR**	**95% CI**	***P* Value**	**OR**	**95% CI**	***P* Value**	**OR**	**95% CI**	***P* Value**	**OR**	**95% CI**	***P* Value**
None used†	1398	256	0.72	(0.41, 1.25)	0.236	0.94	(0.58, 1.54)	0.795	0.51	(0.26, 0.98)	0.044	–	–	0.996	0.45	(0.14, 1.47)	0.185
1 part used†	1398	109	0.67	(0.29, 1.56)	0.351	0.53	(0.21, 1.33)	0.177	0.60	(0.24,1.50)	0.273	–	–	0.996	0.71	(0.17, 2.98)	0.637
2 parts used†	1398	196	0.88	(0.50, 1.57)	0.673	0.47	(0.23, 0.98)	0.044	0.67	(0.34, 1.30)	0.237	–	–	0.995	0.39	(0.09, 1.63)	0.197
3 parts used†	1398	1743	0.56	(0.42, 0.75)	<0.001	0.39	(0.29, 0.54)	<0.001	0.42	(0.30, 0.59)	<0.001	0.16	(0.06, 0.41)	<0.001	0.37	(0.21, 0.67)	0.001
Any parts used†	1398	2048	0.60	(0.45, 0.79)	<0.001	0.41	(0.30, 0.55)	<0.001	0.45	(0.33, 0.62)	<0.001	0.13	(0.05, 0.35)	<0.001	0.39	(0.23, 0.67)	0.001
All cases†	1398	2304	0.61	(0.47, 0.80)	<0.001	0.47	(0.35, 0.62)	<0.001	0.45	(0.33, 0.62)	<0.001	0.12	(0.05, 0.31)	<0.001	0.40	(0.24, 0.67)	0.001
Intervention‡	1398	2304	0.61	(0.44, 0.85)	0.003	0.98	(0.55, 1.76)	0.051	0.52	(0.38, 0.71)	<0.001	0.14	(0.05, 0.34)	<0.001	0.55	(0.32, 0.96)	0.035

P values in the regression models are based on the likelihood ration test.
*For the variable "Wound rupture" there were too few cases to calculate OR and 95% CI for None used, 1 part used, and to 2 parts used.
†Fidelity of "SSC parts used" entered into the logistic regression model I (3 parts used = full checklist compliance).
‡SSC effects adjusted for age, sex, case-mix, comorbidity, anesthesia type, knife time, study time points, and process metrics in the logistic regression model II's final step.
CA indicates control arm; IA, intervention arm; OR, odds ratio.

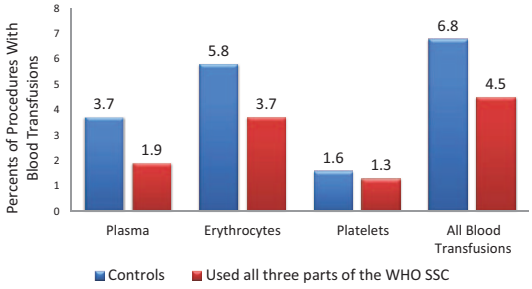

FIGURE 2. WHO SSC Impact on Intraoperative Blood Transfusions—in the Stepped Wedge Cluster RCT, Haukeland University Hospital (2009–2010). All blood transfusions = 1 or more transfusions per surgical procedure.

increasing ASA classification; 1.01 (95% CI, 1.01–1.02) by increasing knife time (minutes); 2.68 (95% CI, 1.26–5.69) in orthopedic procedures; and 0.40 (95% CI, 0.20–0.81) for neurosurgical procedures. Forced air warming blankets were more frequently used in procedures requiring blood transfusions OR 2.68 (95% CI, 1.26 to 5.69).

Costs for blood transfusion units in USD were overall recorded per procedure for all transfusion units of plasma, erythrocytes, or platelets administered to patients. Mean blood transfusion costs in control procedures were USD 46.42 vs. USD 36.39 in the intervention procedures ($P = 0.092$). The cost was USD 28.03 in intervention procedures utilizing the SSC with high fidelity (all 3 parts, $P = 0.007$), representing a 40% cost reduction of blood transfusions.

DISCUSSION

We studied in detail how the quality of the SSC implementation impacts its clinical effectiveness. Our results indicate that better use of the checklist (ie, high-fidelity application) is needed for clinical effectiveness to materialize. Both process metrics and patient outcomes improved when all parts of the checklist were utilized. In line with the UK study on the SSC,[10] our results show that high-fidelity use of the checklist, including all 3 parts of the checklist, provides the lowest rates of odds ratio (Table 5).

Good-quality implementation of the SSC improved both care processes and outcome for patients. The findings correspond well to the clinical improvement model that we hypothesized in Figure 1. The outcome improves as a function of better care processes being in place and due to good actual use of the SSC.

Our results replicate early findings by Haynes et al—the SSC improved safety and process measures (airway evaluation, pulse oximeter use, intravenous catheter, antibiotics, patient identity and site marking, and sponge count), though their process measures were not compared directly to patient outcomes.[11] The WHO recommends monitoring safety and care processes associated with the SSC implementation.[16] This is in accordance with Donabedian's framework for improvement that outlines care structures, processes, and outcomes.[17,23] The strength of this perspective lies within this interrelationship where structure (the SSC in this case) improves the process, and both structure and process then improve outcomes.[16,17] This was especially evident in the use of hypothermia preventing care processes (forced air warming) and timeliness of infection prophylactic antibiotic provided in the operating room.

Even mild hypothermia (34°C to 36°C) is known to increase the incidence of surgical wound infections,[24] blood transfusions,[25] prolonged hospitalization,[24,25] and prolonged recovery from drugs.[26] Hence, to obtain patients' normothermia is of vital importance to prevent intra- and postoperative complications. Ensuring normothermia may be associated with increased use of prewarmed blankets and forced warming air blankets after the SSC implementation (Table 2). Both the use of the SSC and active warming blankets with forced air were significantly related to lower risk of surgical wound rupture and cardiac complications. These results correspond to previous research that indicated a 55% reduction in risk of morbid cardiac events when normothermia was maintained.[27] Hypothermia is well known to increase risk of cardiac complications due to elevations in blood pressure, heart rate, plasma concentrations of catecholamine, and thus myocardial ischemia by turning myocardial oxygen balance into a net deficit.[28] With an increased use of prewarmed intravenous fluid, prewarmed blankets, and forced warming air that correspond to items on the SSC, we find it reasonable to attribute the effect on surgical wound ruptures and cardiac complication to the checklist intervention and improved hypothermia preventing care processes.

Another major finding is the improved timeliness of prophylactic antibiotics provided in operating rooms through good use of the SSC. Antibiotics were administered to patients significantly more frequent before incision and fewer times after incision in the intervention procedures. Our results underline the recommendations on preoperative measures for surgical site infections recently released by the WHO Guideline Development Group. Surgical antibiotic prophylaxis is to be administered within 120 minutes before incision customized to the half-life time of the antibiotics.[29] Optimal timing of antibiotics has been estimated to potential reduce infections in cardiac surgery by 9% to 31%.[30] We identified a significant reduced odds ratio for having a surgical infection, 0.54 (95% CI, 0.37–0.79), when antibiotics were provided before incision rather than no antibiotics given or antibiotics provided after incision. The use of checklists seems to influence on better timing of antibiotics and reduction of surgical infections. The efficacy of antibiotic prophylaxis in preventing surgical site infections has been clearly established,[31] hence antibiotic items on the checklist may optimize and ensure adequate tissue levels of the antibiotic microbial prophylaxis according to the half-life time of the drug at the initial incision.

In a recent randomized controlled trial of a modified surgical safety checklist, surgical wound, abdominal and bleeding-related complications were significantly lowered in the checklist arm of the study.[32] Similarly, we observed a significant reduction in postoperative bleeding from 2.6% to 1.0% and significant improvement of intraoperative bleeding in the SSC intervention procedures. Adding to this, we found a significant reduction in transfusions of plasma, erythrocytes, and platelets in the SSC intervention procedures. The clinical relations between the checklist, intraoperative bleeding, and need of blood transfusion are multifactorial; however, we find the 2 hypothermia preventing items on the checklist to be important. These relations are supported by the improvement seen in use of forced air warming (Tables 2 and 3) and subsequent reductions in bleedings and blood transfusions. A plausible explanation is prevention of hypothermia induced by the checklist intervention.[25]

Implementation of the SSC in US hospitals was estimated to generate cost savings once it prevents at least 5 major complications in hospitals with a 3% baseline rate on major postoperative complications.[33] We observed an approximate 40% cost reduction associated with blood transfusions after implementation of the SSC in our Norwegian hospitals. This result suggests a potential economic benefit of the SSC intervention with improved care processes and patient outcomes.

Strengths and Limitations

The use of a stepped wedge cluster randomized controlled methodology has been described as a robust study design for quality improvement clinical trials.[9] It prevents extraneous influences as it has controls and intervention steps across the same time periods, and offers the possibility for modeling the effects of time on the effectiveness of the SSC intervention.[19,22] However, our study has some limitations. Routinely collected data may be hampered by random errors or inaccuracy regarding data quality. In our study, data on SSC compliance were prospectively recorded on paper forms. These data were validated against concurrent electronic registrations of checklist utilization.[12] Use of routine data may also have been of some benefit, as it made it possible to leave the healthcare personnel involved unaware of the specific data of interest to the study. This also applied to process data, as well as outcome measures. In our study we did not have access to care process metrics associated with every single item of the SSC, which is a limitation of our study. Items that did not have corresponding metrics could also have improved the care processes and may have contributed further to improvement of the outcomes. There were no changes in how routine data were recorded in the study period. Random errors would most likely be equally present both before and after the intervention steps.

Intraoperative bleeding was significantly lower in procedures where the SSC had been utilized. The size of this reduction does perhaps not seem clinically relevant when presented as average group values, and might need further exploration. However, the finding was strengthened by a significant reduction of blood transfusions in the SSC procedures. Another possible limitation was that the process metric ''forced air warming'' increased the odds ratio for having a blood transfusion. Initially, this might seem contradictory, but preventing hypothermia to prevent further blood loss, might render forced air warming more frequently used in patients with large bleedings.[24,25] Thus, this offer a clinical explanatory mechanism to the seemingly increased likelihood of bleeding by ''forced air warming.''

Another limitation was lack of patients' core temperature as a parameter. However, due to incomplete data as temperature measures for all surgical procedures at the time of the study, and to avoid introducing competing interventions, we omitted use of patients' core temperature as process metric. Further, for other important items like the team briefing and different risk assessments there were no available metrics. This might represent a limitation for our study as these items also may have contributed to the improved outcomes, however difficult to measure.

Between control and intervention steps there were no differences in patient characteristics. However, we acquired a larger proportion of orthopedic procedures and regional anesthesia in the intervention part of the study, due to the stepped wedge design, as following random allocation the intervention started in orthopedic surgery (with largest number of procedures). Variation in elective and emergency procedures may have been influenced by the intervention itself, as we previously reported a drop in unplanned returns to the operating room from 1.7% to 0.6%, $P < 0.001$.[12] To control for these indifferences from control to intervention procedures we used logistic regression analysis to adjust for case mix and possible confounding effects. In surgical quality service improvement trials it is difficult to control for complexity and all possible factors that may influence or explain outcome.

Future Research

Our study sheds some light in what may be defined as clinical ''micro-processes'' within the operating room. The need remains to better understand how the complexity in hospital organization, safety culture, team cohesion, and communication impact on how well surgical improvement interventions are introduced and implemented, and how in turn care processes and patient outcomes improve as a result.[34] Further studies are necessary to establish quantitative relationships between specific checklist items and related care processes and complications.

CONCLUSION

This study successfully applied Donabedian's improvement framework of clinical structures, processes, and outcomes as a clinical causal model for the SSC intervention. Use of SSC improved operating room care processes; subsequently, high-quality SSC implementation and improved care processes led to better patient outcomes.

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II

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Investigation of perioperative work processes in provision of antibiotic prophylaxis: a prospective descriptive qualitative study across surgical specialties in Norway

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ABSTRACT

Objective Surgical site infections are known postoperative complications, yet the most preventable of healthcare-associated infections. Correct provision of surgical antibiotic prophylaxis (SAP) is crucial. Use of the WHO Safe Surgical Checklist (SSC) has been reported to improve provision of SAP, and reduce infections postoperatively. To understand possible mechanisms and interactions generating such effects, we explored the underlying work processes of SAP provision and SSC performance at the intersection of perioperative procedures and actual team working.

Design An ethnographic study including observations and in-depth interviews. A combination of deductive and inductive content analysis of the data was conducted.

Setting Operating theatres with different surgical specialities, in three Norwegian hospitals.

Participants Observations of perioperative team working (40 hours) and in-depth interviews of 19 experienced perioperative team members were conducted. Interview participants followed a maximum variation purposive sampling strategy.

Results Analysis identified provision of SAP as a process of linked activities; sequenced, yet disconnected in time and space throughout the perioperative phase. Provision of SAP was handled in relation to several interactive factors: preparation and administration, prescription accuracy, diversity of prescription order systems, patient-specific conditions and changes in operating theatre schedules. However, prescription checks were performed either as formal SSC reviews of SAP items or as informal checks of relevant documents. In addition, use of cognitive reminders and clinical experiences were identified as mechanisms used to enable administration of SAP within the 60 min timeframe described in the SSC.

Conclusion Provision of SAP was identified as a complex process. Yet, a key element in provision of SAP was the given 60 min. timeframe of administration before incision, provided in the SSC. Thus, the SSC seems beneficial in supporting timely SAP administration practice by either being a cognitive tool and/or as a cognitive intervention.

Strengths and limitations of this study

- This study builds on previous work investigating the impact of the WHO Safe Surgical Checklist implementation on perioperative work processes including provision of antibiotic prophylaxis.
- It shows perspectives on provision of antibiotic prophylaxis by all members represented in the multidisciplinary perioperative team, using purposive sampling strategy in selecting participants for single, in-depth interviews.
- It provides detailed, first-hand observations of everyday work processes on antibiotic prophylaxis across different surgical specialties, including the WHO Safe Surgical Checklist antibiotic items.
- The extent to which identified elements in the work processes of antibiotic prophylaxis can be influenced and further lead to improved provision of prophylaxis remains to be tested.
- The findings might not be generalisable across countries due to organisational and cultural differences.

INTRODUCTION

Surgical site infections (SSIs) are associated with substantial morbidity and mortality, prolonged hospital stay and increased costs.[1–3] Although SSI incidence is higher in low-income and middle-income countries,[4] SSIs remain the most common healthcare-associated infections in the USA, and the second most frequent in Europe.[5 6] The efficacy of surgical antibiotic prophylaxis (SAP) in preventing SSIs is well established. Timely administration of appropriate SAP is considered one of the most effective SSI prevention strategies[5] as recommended in the WHO global guidelines for prevention of SSIs.[7]

Successful SAP requires administration of one or more antimicrobial agents at appropriate time-points to achieve effective

antibiotic concentrations at the surgical site at time of incision and throughout surgery. Pharmacokinetic properties determine administration forms and correct timing and intervals of antibiotic(s).[5] Actual delivery of antibiotics for surgical prophylaxis is commonly carried out within operating theatre (OT) premises. Provision of optimal SAP may be influenced by a number of factors before, during and after surgery. Lack of clarity concerning responsibility for the choice, dose, timing and duration of antibiotics influences decision-making and proper prescription of SAP.[8] Unresolved issues of workflow and role perceptions have also been reported as obstacles to properly timed SAP.[9] As a consequence, SAP may be administered too early,[10–12] too late or not at all,[13–16] causing unnecessary patient risks. Guidelines do not recommend prolonged SAP administration for preventing SSI. However, prolongation of SAP for >24 hours remains prevalent.[17 18]

Within the OT setting, the WHO Safe Surgical Checklist (SSC)[19] includes evidence-based items for prevention of SSI. Use of the SSC has been reported to reduce mortality and complications, including postoperative infections.[20 21] In a previous study investigating changes in perioperative care processes following WHO SSC implementation, we found significant improvements in timely SAP provision preoperatively, within 60 min before incision.[22] This was further associated with reduced risk of infections and wound ruptures postoperatively. We aimed to understand possible mechanisms and interactions contributing to these effects, in order to further improve SAP provision. The aim of this study was therefore to outline work flow of SAP provision, including SSC performance of SAP items at the intersection of preoperative procedures and actual team working. The following research questions were addressed: (1) How can SAP work processes be described? (2) What are the key elements in these work processes that influence provision of SAP?

METHODS

Design

An ethnographic design was used, where multiprofessional perioperative teams were observed in action in OTs, followed by face-to-face interviews of key informants. This design is well suited to capture 'everyday' routine behaviours in their natural settings.[23 24]

Study setting

The study was conducted in three hospitals in one Regional Health Authority in Norway; surgical activity and hospital characteristics are described in table 1.

The hospitals operate within separate organisational structures, and perioperative routines vary accordingly. However, SAP use should be compliant with the implemented Norwegian national guidelines of antibiotic use in hospitals.[25] Furthermore, the WHO SSC had been implemented formally at all sites at the time of the study.

Data collection

Data triangulation was used in collection of data across time, hospital settings and professions to capture a more complete and contextualised portrait of the studied settings and to validate conclusion of findings.[26 27] Data collections were limited by available time frames for both the observation and interview time, although saturation of data was met in relation to responsibility of prescription, preparation and administration of SAP.

Perioperative observations

Data were collected through 40 hours of non-participant observations of perioperative teams in OTs, and through individual interviews of members of these teams (surgeons, OT nurses, anaesthesiologists and nurse anaesthetists). Observations aimed to map routine behaviours on: (1) antibiotic management and (2) team reviews of antibiotic items in the WHO SSC. All team observations took place within local OTs, and followed the entire perioperative phase from the patient arrival in the OT to postoperative delivery. Data were collected from one

Table 1 Characteristics of hospitals in the study of surgical antibiotic prophylaxis work processes in Norway, 2015–2016

Hospitals (n=3)	Hospital size*	Surgical activity†	Teaching status	Hospital level	Medical service	Organisational structure
1	1066	33 584	University hospital	Tertiary referral hospital	National and Regional referral hospital for medical and surgical care	22 specialised units
2	149	4769	Residency training approval	Secondary care hospital	General medical and surgical care	3 specialised units
3	244	7887	Residency training approval	Secondary referral hospital	General medical and surgical care	2 specialised units

The Regional Health Authorities have overall responsibility for the specialist health service. Hospital #1 and #3 are organised in two separate health trusts, while hospital #2 is a private, non-profit hospital on contract with the Regional Health Authority.
*2016 Occupancy rate (Statistics Norway)=bed days/available bed days.
†2016 Reported surgical hospital stays with one or more surgical procedure, based on the classification system of the Norwegian diagnosis-related groups (N-DRG, Norwegian Patient Registry).

hospital at a time, with team observations taking place prior to interviews. The observations covered scheduled surgical procedures at dates agreed upon beforehand with the service managers and teams. Three different surgical specialties/subspecialties were included in order to cover different SAP regimes. Observations of team interactions and communications were noted and reviewed by the research team. These field notes were used to develop the interview guide.

Mapping work processes of how antibiotics were managed in a variety of surgical contexts was essential. By 'work processes' we included both the formal documentation for standard procedures of antibiotic prophylaxis as well as the organisational roles and responsibilities, together with informal roles and lines of communication. All observations and interviews were performed by HVW (nurse anaesthetist, trained in qualitative research). ASH (senior nurse anaesthetist, trained in qualitative research) also participated in some of the initial observations (6 hours). Observation notes were compared and discussed between the two observers to validate findings.

Interviews with members of the perioperative team

Nineteen interviews were performed lasting from 27 to 48 min in duration, with a median length of 33 min. The interview guide covered three topics: (1) antibiotic management, (2) use of the WHO SSC (with specific focus on SAP items) and (3) teamwork experience (interview guide in online supplementary file 1). All healthcare personnel in the perioperative teams were considered key informants. Hence, a maximum variation purposive sampling strategy was used to elicit all perspectives in the provision of SAP in the OTs.[28] Invitations to participate were initially reviewed and approved by the Directors of the Departments of Research and Development at the respective study hospitals. Participants were recruited by the local managers. Professionals with variable length of perioperative work experience were targeted for sampling; their characteristics are described in table 2.

The interviews were conducted between November 2015 and November 2016, and were conducted in the OT departments, in areas free from distractions (eg, meeting rooms). Each participant was interviewed once. The interviews were audiotaped, transcribed verbatim and transferred to NVivo Pro V.11.4 computer software (QSR International ABN 47006357213) for coding.

Analysis

Data from observations and interviews were analysed using a content analysis approach, combining deductive and inductive analysis elements. First, to identify the perioperative work process of SAP, a deductive approach was applied using directed content analysis as described by Hsieh and Shannon.[28] The Norwegian national regulation framework for medication management was applied as coding frame. This regulation framework requires healthcare personnel to adhere to defined responsibilities in the three domains of medication prescription, preparation and administration to ensure that the right medication and dose is administered correctly to the right patient at the right time.[29] The deductive analysis investigated specific SAP work processes in relation to these three domains of the medication regulation framework, which is also a compulsory part of the curriculum and training for nurses and physicians in Norway. HVW, ASH, ES (consultant anaesthesiologist) and SH (consultant in infectious diseases) participated in the preliminary analysis using group consensus to strengthen coherence of the findings.[30] Second, to further explore the underlying work processes, an inductive approach was applied with a thematic analysis according to Graneheim and Lundman.[31] This qualitative content analysis comprises descriptions of the manifest content close to the text as well as interpretations of the latent content

Table 2 Characteristics of informants in the study of surgical antibiotic prophylaxis work processes in Norway, 2015–2016

Participant profession	Number n=19	Work—experience years qualified in profession—range	Sex female/male	Participant work place		
				Secondary care hospital	Secondary referral hospital	Tertiary referral hospital
Nurses*	12	5–30	11/1	4	4	4
Nurse anaesthetist/operating theatre nurse						
Physicians†	7	3–30	0/7	0	4	3
Consultant anaesthesiologist/consultant surgeon/surgeon						
Total	19	3–30	11/8	4	8	7

Authorisation requirements in Norway: 3-year bachelor degree in Nursing-180 ECTS+either a 1.5-year Specialist education program-90 ETCS, or a 2-year Master's program-120 ECTS at a College University degree.
†Authorisation requirements in Norway: 6-year cand. med. degree, 360 ECTS*+6.5 years of specialist training before qualification as consultant.
ECTS, European Credit Transfer and Accumulation System credits.

distant from the text, yet still close to the participants' experiences.[30] Statements, observations and interpretations that reflected participants' conditional actions and interactions were identified. The following steps were used: HVW, ASH and SH read the transcribed interviews forming units of analysis. HVW identified and coded transcript sections into 'meaning units', followed by relating categories and theme, constituting the manifest content.[31]

Observational data were used to support the interview data analysis, contributing to the formation and interpretation of emerging themes. ASH and SH reviewed the coding and interpretations. Preliminary themes, subthemes and quotes were then discussed among the authors (HVW, ASH, ES, SH). In addition, KA and SW (safety scientists, trained in qualitative methods) also participated in finalising analysis of the latent content, the underlying meaning of the text and concluding themes. The finalised dataset is reported in categories and subthemes constituting the overarching descriptive theme, with verbatim quotes from the interviews, and summarised field notes from the observations to support and illustrate each category.

Patient and public involvement statement

There were no direct patient or public involvement in this study, although the object of study and its relevance to patients have been discussed on several occasions with Head of Patient Involvement Committee in the Western Norway Regional Health Authority. Both observers had previously worked in OTs. The local managers informed all OT staff prior to case observations, and cases where any staff member or the patient withheld consent were excluded.

RESULTS

Analysis of observations and interviews identified provision of SAP as a process of linked activities, sequenced yet disconnected in time and space during the perioperative phase. The process involved interactions of the multidisciplinary team members before, under and after surgery. The deductive analysis identified the 'who', 'where' and 'when' in relation to initial and follow-up prescription, preparation and administration of SAP. These three domains, as described in the Norwegian regulation framework, constituted the formal steps of the work process. Participants described these steps in relation to the entire perioperative phase, although timing administration of SAP prior to incision was a target.

The inductive analysis identified several challenges of competing demands and varying conditions, in the process of timing administration of SAP within the given timeframe of 60 min prior to incision. The overarching theme describes provision of SAP as 'a complex process of balancing timeliness while considering and responding to multiple, interacting factors'. The balancing of timeliness and interacting factors were further characterised by three subthemes interpreted from nine categories, which were derived from codes of the deductive and inductive analysis, presented in table 3. In the following section, the three subthemes and corresponding categories are presented in detail with representative illustrating verbatim quotes.

Handling surgical antibiotic prophylaxis when considering multiple interacting factors

The formal work processes included participants' perception of roles, responsibility, location and timing of performance related to prescription, preparation and administration of SAP. Prescription of SAP (drug of choice, dosage and duration) was as a rule ordered by the surgeon before the surgical procedure, although verbal prescriptions might also occur during surgery. The surgeon then had to confirm the SAP prescription by signing the anaesthesia and/or postoperative record. This prescribing responsibility was acknowledged by all members of the team. However, diverse prescription order systems with different prescription practices were observed. Some units used electronic surgical planning systems with embedded preoperative standardised SAP prescriptions with default settings.

> **Nurse anaesthetist:** SAP is to be prescribed in the patient's medication chart by the surgeon, if there is an indication. Sometimes, SAP is prescribed in the electronic surgical planning system as well.

> **Surgeon:** As long as the patient belongs to this department SAP is to be prescribed in the medication chart. In case it is not written in the medication chart, then it [the antibiotic] is not prescribed properly.

Other units had written pre-authorised standardised SAP protocols for certain types of surgery, and patient-bound signed preoperative medical paper forms of SAP prescription for others. The different preoperative SAP prescription systems varied not only between sites, but also between surgical wards at one of the study hospitals. Nurse anaesthetists also described variations in prescription accuracy, particularly in cases with unclear prescriptions or lack thereof. Sometimes the anaesthesiologist might also be involved in prescription orders such as in endocarditis prophylaxis or when the anaesthesiologist was personally responsible for an interventional procedure, for example, subcutaneous venous port implantations.

> **Anaesthesiologist:** Formally, the surgeon is in charge of the SAP prescription orders, no doubt of that! Within the premises of the operating theatres, I only prescribe SAP to patients if I'm in charge of the procedure, that is, subcutaneous venous port implantations.

Preparations of all SAP infusion(s) or injection(s) were done by nurses. The medication infusions were mainly prepared in the OTs by nurse anaesthetists, but for surgery involving combinations of two antibiotics, infusions were prepared in the surgical ward.

Table 3 Main findings from the study of surgical antibiotic prophylaxis (SAP) work processes in Norway, 2015-2016

Theme	Provision of SAP as a complex process of balancing timeliness by considering and responding to multiple interacting factors							
Subtheme	Handling SAP in consideration of multiple, preoperative interacting factors				Timing SAP administration in relation to knowledge and clinical experience		Performing formal and informal checks	
Category	Perceptions of antibiotic prophylaxis work processes (work as imagined)	Prescription accuracy	Diverse prescription order systems	Patient-specific conditions	Changing schedules in operating theatre	Cognitive work task reminders	Importance of knowledge and clinical experience	Performance variety of Surgical Safety Checklist	Indirect and direct prescription validity checks
Codes	– Roles – Responsibility – Location of performance – Time	– Unclear prescriptions – Lack of prescriptions – Standardised prescription – Electronic default settings	– Electronic surgical planning system – Electronic medication chart – Paper-forms – Wall poster in operating theatre – Oral prescription – Pre-authorised prescription protocols	– History of allergies – Type of surgery – Adjusting dosage in relation to age – Adjusting dosage in relation to weight (body mass index)	– Order of scheduled patients – Deviations from scheduled patient order – Deviations from information in operating planning system – Timing of incision – Approximate time estimations	– After patient transport – When positioning the patient – During placements of electrocardiography electrodes – When entering the operating theatre – After induction of anaesthesia	– Local prescription systems – Surgeons' preferences – Surgical procedures – Selection of antibiotics according to procedures – Alternative antibiotics	– Interruption of workflow – Unclear responses of antibiotic item – Performance challenges – Responsibility – Identifies missed SAP administration	– Paper documents – Electronic medication chart – Electronic surgical planning system – Prescribing signature – Calling surgeons – Paging surgeons – Approaching in person

Nurse anaesthetist: For orthopaedic surgery, and for some of the abdominal, like the inguinal hernia repairs, we prepare the SAP ourselves, although sometimes it gets a bit messy, due to suboptimal localities… For some of the other abdominal surgeries…. i.e. cancer surgery, the SAP is prepared as 500 mL or 1000 mL infusions, and both preparations are made at the ward, and brought to the OT along with the patients.

Administration was then started in the surgical ward or the operating holding area: the ward nurse handed over the double controlled and signed infusion containers to the nurse anaesthetist if the infusions were not completed before patient handover. SAPs with short half-lives were both prepared and administered to patients by nurse anaesthetists within the OT. Dosages and time points were documented in the patients' anaesthetic records, registered at a precise time point (injections) or an explicit 'start' and 'stop' time (infusions).

Operating theatre nurse: The anaesthesia team is responsible for SAP administration. Medications, anaesthesia,… this is their responsibility.

Considering patient-specific factors was also described as important when handling SAP. When in need of alternative antibiotic(s) due to patient allergies, adjustments in timely administration of SAP had to be reconsidered, according to the pharmacokinetic property of the alternative antibiotics, especially half-lives. This was not always clarified prior to the patient's arrival in the OT. Clarifications on the precise SAP dosages in cases of elder, paediatric, and/or adipose patients were also reported by informants as important, yet time-consuming considerations in the planning or preparation of SAP.

The type of surgery initially determined the SAP regimes. Hence, the OT scheduling of patients also influenced SAP work processes. The scheduled order of the different surgical procedures in the OT with corresponding specific SAP regimes generated fluctuating SAP work processes throughout the day. With the exception of the first patient admitted to the OT, the timings of incision for the remaining scheduled patients were based on approximate time estimations with SAP being administered according to these estimations.

Nurse anaesthetist: It is much easier to provide right timing of SAP to the first scheduled patient of the day, because we have an exact point of time scheduled for this patient. Throughout the day, it gets more complicated, because it is difficult to predict the time of arrival and administration of SAP, for the next patients.

Participants described cases where information in the operating planning system, including SAP prescriptions, deviated from agreed (or perceived as agreed) on perioperative standards. Furthermore, abrupt changes in preoperative scheduling, lack of signed preoperative

prescriptions and uncertain SAP indications also caused variations in the preparations and administration of SAP.

Timing administration of surgical antibiotic prophylaxis using clinical knowledge and experience

The participants described how specific preoperative work tasks served as cognitive reminders for SAP administration within the preferred timeframe. This was explained as particularly helpful for the anaesthesia team as both preparation and administration of SAP might easily be influenced by concurrent tasks, distracting them in timely provision of SAP. This was confirmed through observations, especially during induction of anaesthesia. The anaesthesia team explained how linking SAP administration concurrently to other specific work tasks made it easier for them remembering to administer SAP within the recommended timeframe of 60 min. Such work tasks included patient transport, patient positioning or electrocardiography electrodes placement.

> **Nurse anaesthetist:** For orthopaedic patients, they are first transported to anaesthetic room, for application of anaesthesia. Then, there is a timespan where SAP may be administered, before the patient is transported into the OT.

SAP administration was also emphasised to be carried out at specific points of time in the preoperative phase such as when entering the OT, when positioning the patient or after induction of anaesthesia.

> **Anaesthesiologist:** As a routine, I believe that the SAP is administered during induction of anaesthesia, just after we have inserted the central venous catheter.

Use of the WHO SSC, with the item for specified timeframe of SAP provision within 60 min prior to incision, was also described as a reminder. Most of the nurse participants reported that the WHO SSC implementation had made them more aware of this timeframe. Knowledge and experience on surgical routines and workflow in the OTs, in addition to the local SAP regimes, were also highlighted as important among the participants. This was described as being experience gained on the standardised surgical procedures and the types of antibiotics used as standard prophylaxis for the different procedures performed at their surgical unit. In addition, participants emphasised the need to have knowledge on alternative SAPs used in cases of identified antibiotic allergies.

> **Nurse anaesthetist:** When you have some experience, you know which type of surgeries that requires SAP, and which types of surgeries that do not, because you recognise the indications, even though prescriptions are not clear.

Performing formal and informal checks

Both formal and informal SAP checks were carried out in the preoperative phase as illustrated in figure 1, which outline the workflow for SAP including different checkpoints. The Safe Surgical Checklist constituted the formal, compulsory check. Prior to incision, the perioperative teams paused and performed a 'time-out' according to the WHO SSC with items questioning whether SAP had been provided read aloud. Varying team-briefing responses as to these SSC SAP items were observed. Some team responses concentrated on the timing of SAP administration, some reviewed if prescribed dosages correlated to the actual administered SAP and some left responses to the SSC items out completely. During performance of the formal SSC, and specifically when addressing SAP items during the SSC team briefings, some of the OT nurses were reluctant, because they felt like questioning aloud whether the anaesthesia team had performed their job or not. If the anaesthesia team failed to respond, repetition of these SSCs items was then ignored.

> **Operating theatre nurse:** My only worry—personally—is to ask the anaesthesia team whether they have done their job or not. I really struggle with this checklist item (SAP). I get this awkward feeling … It's like poaching on somebody's preserve.

The informants also described episodes where surgeons did not wait (but carried on with incision) despite the 'time-out' briefings having identified missing or delayed SAP administration. This was also confirmed by observations.

> **Surgeon:** No, I don't think that I have ever experienced to stop and await incision, in cases where SAP has not been fully administered.

The physicians' responses were explained by an overall concern of delay causing surgical programme flow disruptions and prolonging time of anaesthesia. However, in cases where surgery required application of a tourniquet, surgeons delayed incision in order to let the SAP work appropriately.

> **Operating theatre nurse:** No, the surgeons do not await incision if SAP is missing. Only if the tourniquet is already applied, then they have to wait.

Informal SAP checks were performed by the anaesthesia teams to clarify which antibiotic to administer, the dosages and duration. For the SAP to be administered by the nurse anaesthetists in the OT, SAP prescription orders should have been documented and signed preoperatively according to local prescription systems involved, that is, written paper orders, electronic orders or orders in the patient medical chart. The informants emphasised that SAP prescriptions also had to be checked to ensure validity of the prescription order, as default settings in the electronic surgical planning system might cause an unintentional or incorrect SAP prescription.

> **Nurse anaesthetist:** Well, if SAP is not prescribed initially, and the surgeon arrives in theatre and announces that we need to administer antibiotic prophylaxis….Then, I need to make the surgeon sign

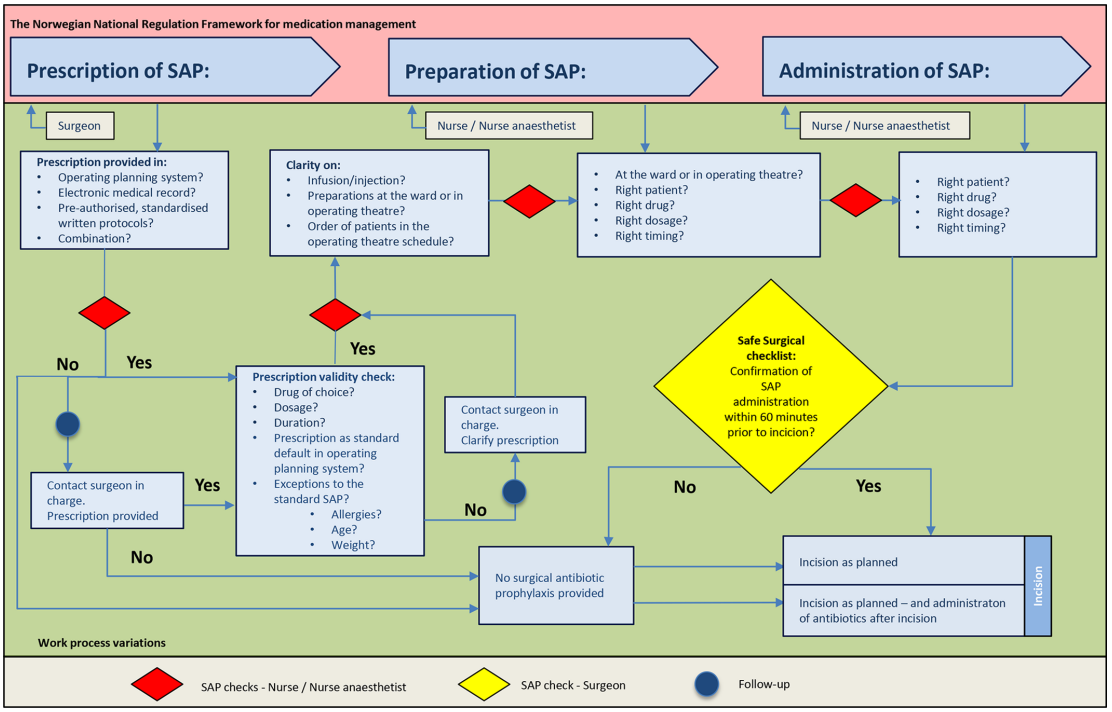

Figure 1 The clinical pathway of surgical antibiotic prophylaxis (SAP): an outline of the workflow for SAP in perioperative care.

the patient's medical record. I present the medical record to the surgeon and then…sign here, please!

The surgeons in charge were contacted in cases of partial or missing SAP prescription orders, or if anyone in the anaesthesia team was in doubt of whether or not to administer the SAP. Surgeons were contacted by phone or pager or by approaching them when they entered the OT. These actions were taken by members of the anaesthesia team themselves or by the OT nurses on behalf of the former.

Anaesthesiologist: Normally, the nurse anaesthetist calls the surgeon if SAP prescriptions are missing.

DISCUSSION

This study has identified provision of SAP as a complex process of balancing timeliness by considering and responding to multiple interacting factors. Our findings of the multiple considerations and compensating mechanisms used particularly in the preoperative phase, highlight the real-world balancing of professional judgements regarding patient, antibiotic and surgery-related factors as well as coordinating the OT scheduling and workflow for SAP to be administered in due time before incision. Even though perceptions of responsibility in relation to SAP prescription, preparation and administration were consistent among team members, our results indicate ambiguities in ownership for SAP. This was seen especially at intersections of prescription transfers to providers, where suboptimal use of the prescription order systems or poorly completed SAP orders may provide unclear indications for SAP to its actual providers. In addition, the team performances on the WHO SSC including reviews of antibiotic items varied during the 'time-out' part of the SSC, also with a reluctance to address SAP items, described by the OT nurses. The nurse anaesthetist, surgeon and anaesthetist each seem to have self-perceived defined roles in provision of SAP, and yet these roles did not seem to be aligned or sufficiently understood through shared decision-making. Consequently, possible risks of SAP failures were poorly understood or defined at each step in the preoperative planning of surgery.

Existing surgical workflow systems have previously been identified by surgeons and anaesthesiologists as an obstacle to proper timing of SAP, also with work processes of SAP being of low priority among their many perioperative responsibilities.[9] Yet, studies investigating predictors for appropriate antibiotic use found that patients were more likely to receive an effective and timely first SAP dose when preoperative orders were written and implemented in the OTs.[32 33] We identified a number of interacting considerations that might help to understand factors and situations influencing timely provision of SAP. One contributor to delayed SAP administration was ignored identification of patients' allergies, or the lack of such being properly addressed. This

has also been reported by others, with administration of an effective first prophylactic dose being less likely when a patient had a beta-lactam allergy, increasing the risk of SSI.[33] Another identified contributor to delayed SAP administration was the need to clarify the precise SAP dosages in cases of elder, adipose or paediatric, especially neonate, patients. As these subgroups of surgical patients (age <60 weeks and >75 years, obesity with body mass index (BMI) >30, morbid obesity with BMI ≥40) are reported to have an increased risk of developing SSIs based on their physical status, delayed SAP administrations adds to these risks.[25 34] The classification of patients' physical status (America Society of Anesthesiologists classification) has previously been identified as a significant predictor of SSIs.[35] Patients with an impaired physical status should therefore be given extra attention during the planning and prescription of SAP. Although our findings describe the surgeons as being responsible for SAP prescriptions, the anaesthesiologists have responsibility for patient assessments as to potential allergies and physical status. This imbalance of responsibilities might contribute to unclear SAP prescription orders with risks of delayed SAP administrations.[36] Furthermore, our findings indicate that suboptimal use of the prescription order systems or poorly completed SAP orders may provide unclear indications for SAP to its actual providers. Especially the nurse anaesthetist performed additional informal SAP checks, and the surgeons were contacted when in doubt of SAP indication or the validity of the prescription order. Nevertheless, the need to spend crucial minutes in the OTs to clarify prescription orders as illustrated in figure 1, inadvertently leaves a narrower timeframe for the nurse anaesthetist to administer SAP on time (60 min prior to incision). A narrower timeframe in itself, in turn, increases risk of SAP administration delays. A comparison on the risk of SSI with different timing intervals of SAP was addressed in a recent meta-analysis.[37] The analysis showed that the risk of SSIs almost doubled when SAP was administered after incision compared with before incision, and resulted in 25 more infections per 1000 treated patients.[37]

This study builds on previous research which reported significant improvements in timely SAP provision preoperatively before incision following implementation of the WHO SSC.[22] The key novelty of our findings show how implementation of the SSC may facilitate resilient mechanisms within the team, in relation to specific work processes of SAP. This is supported by how timing administration of antibiotics was performed. We found that this was executed mainly by nurse anaesthetists, in relation to their knowledge and clinical experience of workflow in surgery, and the performance of prescription checks at different time points before incision (figure 1). A key element that seems to drive tasks and behaviours related to SAP administration was the given timeframe of 60 min prior to incision as provided in the SSC. This suggests that the SSC might serve as a cognitive tool to drive SAP administration to take place prior to incision. In addition, by being aware of the timeframe the providers of SAP were able to respond to regular and irregular variabilities in prescriptions by questioning uncertainties and adjusting timing of SAP administration according to disturbances in the OT workflow.

However, the identified various team responses during the 'time-out' part of the SSC as well as a reluctance to address SAP items, indicates a lack of SSC quality performance at full length. In a previous study, we have identified how nurses used a variety of strategies to adjust team involvement when encountering resistance to the SSC from members of the surgical team.[38] This included avoiding completing the checklist entirely, or selectively completing some items with specific team members. Both strategies resulted in decreased quality of the SSC process. This shows that obstacles stemming from the SSC apply to the content and to psychological ownership.[39] Moderate compliance rates of SSC utilisation as well as poor performance quality have also been identified in previous studies.[40–42] Furthermore, we found that identification of missing or delayed SAP prescription or administration during SSC Time-Out reviews, seldom resulted in delays of incision, although this is recommended in guidelines.[43]

Our findings indicate that the SSC is likely to identify missed SAP administrations, yet does not prevent surgical incision to take place before SAP administration. However, having established focus on the timeframe of completing SAP administration within 60 min prior to incision through SSC use might have influenced SAP administration practise indirectly. The nurse anaesthetist more likely responds in a prompt manner to unclear prescriptions, and adjusts timing of administration in accordance with the SSC recommendations. To strengthen SSC use as a safety barrier to minimise risk of SSI, we suggest that SAP prescription checks should also be done by the nurse anaesthetist at the SSC Sign-In in addition to the surgeons' already established controls of SAP administration at Time-Out (figure 1). This should also reduce risk of interfering with the time point for incision and possible delays in OT schedules. Such clarifications via preoperative team briefings have previously been associated with improved clinical practice of timely SAP administration.[44]

Recommendations and further research

Antibiotic stewardship programmes are of particular importance to surgical specialties due to their prominent role in prophylactic antibiotic usage and management of surgical infections, and may serve as suitable frameworks to address correct provision of SAP.[45] Multidisciplinary team roles and pathways specifying timing and sequence of responsibilities are recommended to influence team-level communications and workflow.[46] Based on our findings we advocate that objectives and measures of antibiotic stewardship programmes in surgery must include both nurse providers of SAP as well as the surgeon prescribers. Our findings illustrate how nurses, particularly nurse anaesthetists, are important stakeholders in SAP provision when responding to unclear prescriptions and adjusting time of SAP administration according to

the timeframe provided in the SSC. Nurses' role in antibiotic stewardship practices in hospitals have previously been emphasised.[47] To our knowledge, their role and responsibility of SAP in the perioperative period has not been described before.

Further research should investigate how the roles and responsibilities of nurses and nurse anaesthetists regarding SAP management for surgical patients could be expanded. In addition, antibiotic stewardship programmes in surgery should test SAP delivery interventions, and measure performance indicators of timely SAP administrations as well as prescription adherence to guidelines. We suggest that education of SAP indications and the pharmacokinetic properties of the antibiotic used as prophylaxis may further support SAP providers to target SAP timing according to the half-life of the prescribed antibiotic. Also, providing feedback on timeliness of SAP administration as performance indicator will allow nurses and nurse anaesthetists to take ownership in improving provision of timely SAP.[46]

Study limitations

This study was conducted in surgical settings in Norway. Recommendations of SAP regimes were based on the Norwegian national guidelines of antibiotic use in hospitals. The identified work processes and mechanisms might therefore be limited to reflect practice in Norway. However, international recommendations indicate that SAP should be initiated within 60–120 min prior to surgical incision, based on its pharmacokinetic property.[5]

In order to achieve credible information on the SAP work processes, data triangulation was used by collecting data across time, hospital settings and professions.[26] Also, combinations of individual interviews and observations of team interactions in the OTs, made it possible to collect data showing actual behaviours in their natural settings.[23 24] Although all members of the multidisciplinary surgical team were represented, interview selection bias was a possibility. Despite our maximum variation purposive sampling strategy,[28] a majority of the informants turned out to be experienced clinicians (table 2), which likely reflected and limited the range of responses compared with if junior team members had been involved. By use of the ethnographic approach, possible risks of SAP failures and possible explanations of their occurrence have been identified. Larger follow-up studies on procedures, work practices and measures of SAP provision are required to achieve more generalisable findings.

CONCLUSION

This study has explored SAP work processes in the preoperative period and outlined how the multitude of considerations in handling SAP may influence, and delay its administration. Yet, a key element to proper SAP that supports timely provision is the given timeframe of administration, focused on by SSC use. Thus, the introduction of SSC, emphasising SAP administration 60 min prior to incision, is likely to have influenced administration practice through the following mechanisms: (1) as a cognitive tool, in helping the nurse anaesthetist to remember timing of SAP administration, (2) as an educational intervention, facilitating resilience by making SAP providers able to respond promptly when in need of clarifications of prescriptions, to ensure SAP administration before incision.

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to participate prior to the interviews, and could withdraw from the study at any time.

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III

How does the WHO Surgical Safety Checklist fit with existing perioperative risk management strategies? An ethnographic study across surgical specialities in Norway.

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ABSTRACT

Background

The World Health Organization (WHO) Surgical Safety Checklist (SSC) has demonstrated beneficial impacts on a range of patient- and team outcomes, though variation in SSC implementation and staff`s perception of it remain challenging. Precisely how frontline personell integrate the SSC with pre-existing perioperative clinical risk management remains underexplored – yet likely an impactful factor on how SSC is being used and its potential to improve clinical safety. This study aimed to explore how members of the multidisiplinary perioperative team integrate the SSC within their risk management strategies.

Methods

An ethnographic case study including observations (40h) in operating theatres and in-depth interviews of 17 perioperative team members was carried out at two hospitals in 2016. Data were analysed using content analysis.

Results

We identified three themes reflecting the integration of the SSC in daily surgical practice: 1) Assessing utility; implying an intuitive advantage assessment of the SSC`s practical utility in relation to relevant work; 2) Customising implementation; reflecting performance variability of SSC on confirmation of items due to precence of team members; barriers of performance; and definition of SSC as performance indicator, and 3) Interactive micro-team communication; including formal- and informal micro-team formations where detailed, specific risk communication unfolded.

Conclusion

When the SSC is not integrated within existing risk management strategies, but perceived as an “add on”, its fidelity is compromised, hence limiting its potential clinical effectiveness. Implementation strategies for the SSC should thus integrate it as a risk-management tool and include it as part of risk-management education and training. This can improve team learning around risk comunication, foster mutual understanding of safety perspectives and enhance SSC implementation.

Keywords

Surgical Safety Checklist, Patient Safety, Ethnography, Quality Improvement, Health Services Research

INTRODUCTION

The World Health Organization`s (WHO) Safe Surgical Checklist (SSC) (1) has been advocated globally, and in some cases mandated as a surgical safety intervention, aiming to improve information exchange within the perioperative team, and to critically review specific safety items.(2) Clinical effectiveness studies have demonstrated beneficial impact of the SSC implementation on a range of patient- and team outcomes, including mortality rates, complication rates, length of in-hospital stay, teamwork, and adherence to safety processes.(310) Also, high-fidelity use of the SSC, i.e. suitable use of all three parts of it, has been shown of crucial importance in order to achieve improved outcomes.(11) The evidence thus supports that high quality implementation of SSC is required for positive effects to be attained.(12)

Studies on the implementation of the SSC, however, have had mixed results.(13, 14) Further, research shows that the SSC is sometimes used patchily, and that SSC implementation quality

differs among hospitals, surgical specialities, surgical staff members, and among specific items and parts of the checklists.(15-18) In addition, longitudinal implementation studies of the SSC have offered only modest, sustained impacts on staff attitude- and satisfaction, and surgical team perspectives.(19-22) Instead, conflicting findings and failings to link the SSC to improved outcomes are causing some at least scepticism around its true potential as a patient safety intervention.(15) Questions on how lack of SSC compliance might actually introduce new risks not present before have also been raised,(23) prompting calls for the reconsideration of policies mandating the SSC as an organisational safety practice.(24)

Although variations in SSC fidelity of use have been documented, there is limited understanding of why such variations occur.(25-28) Safety interventions, their implementation and the clinical and organisational context within which they are applied are intertwined and mutually interacting, thus influencing how such interventions actually work in practice (or not).(29) Structural changes in operating staff workflow and their perceptions of the SSC and patient safety are reccomended to improve SSC implementation.(25) Ulitmately, the reduction of risk SSC aims to achieve is not achieved by 'ticking off' checklist items, but by the actions and behaviours of the perioperative team the SSC calls for.[27] A knowledge gap still remains of how perioperative staff integrate (or not) the SSC into their pre-existing risk management strategies and tools; and how their risk perceptions are impacted by the use of the SSC. Studies that seeks to understand the role of adaptive, human and social practices in safety efforts such as the SSC are therefore called for.(30-32)

Reflecting on the purpose of the SSC, we propose that for a safety intervention aiming at human behaviour, it is essential that all team members share an understanding of clinical risk and risk management strategies; and that the intervention is actually embedded effectively and efficiently into existing safety practices. Thus, the aim of this study was to explore how the

multidisiplinary perioperative team members integrate the SSC as part of their risk management strategies in perioperative care.

METHODS

Design

This is a prospective ethnographic study. Multidisciplinary perioperative teams were observed during performance of the SSC in operating theatres (OTs), followed by face-to-face interviews of key informants. While focusing on description and analysis of "everyday" routine practice in their natural settings, this design is well suited to capture both participants` use of SSC and risk communication patterns, as well as their perceptions of patient safety challenges.(32, 33)

Study setting

The study was conducted in two hospitals, a tertiary teaching hospital and a central community hospital, within the Western Norway Regional Health Authority. The hospitals operate within separate organisational structures, and perioperative routines vary accordingly. One surgical unit at each hospital was included in the study. These hospital units served as surgical study-clusters in a large stepped wedge, cluster randomised control trial of the WHO SSC`s impact on patient outcome, and were therefore recruited.(8) The adapted Norwegian version of the WHO SSC had been implemented at both the surgical units, following an educational program with standardised lectures and dissemination events.(22) Following initial introduction, SSC utilisation was monitored by both the local hospitals and the Western Regional Health Authority, as part of the Norwegian Patient Safety Programme: In Safe Hands, commissioned by the Norwegian Ministry of Health and Care Services.(34) The observed SSC utilisation indicator was defined as: number of surgeries where the SSC was used over total number of performed surgeries.(34) Longitudinal monitoring of SSC

compliance data from 2014-2016, showed differences between the two hospitals (Figure 1), such that compliance was lower for hospital 1 compared to hospital 2. SSC registrations generating the compliance rates for both hospitals, were performed by the operating theatre staff. The SSC compliance reports were presented on a monthly basis to the surgical unit managers, and the reports were available electronically to all OT staff.

Data collection

Data collection involved non-participant observations and interviews together with longitudinal SSC compliance rate reports derived from administrative data systems (described in detail below). Data triangulation was used across time, hospital settings and professional groups, to capture a contextualised 'portrait' of the SSC within the studied settings.(35, 36)

Perioperative observations

We observed 6 complete surgical cases at each of the study sites. Observations took about one week per site, and covered specialities of general- and highly specialised surgery. The observations (40h) covered scheduled surgical procedures at dates agreed upon beforehand by the service managers. All cases were elective, done under general anaesthesia during normal working hours, and covered both complex cases and day-surgeries. Cases where any staff member or the patient withheld consent were excluded. The observations aimed to map routine behaviours of "work as done" of SSC team performance. Data were collected in 2016 at one hospital at a time, with team observations taking place prior to interviews, starting at the central community hospital (hospital 2 in Table 1). Observations of team interactions and communications were noted and reviewed by the research team. These field notes were used to develop the interview topic guide and inputs to the data analysis.

Interviews

Interviews were carried out with 17 members of the perioperative team (surgeons, operating theatre nurses, anaesthesiologists, nurse anaesthetists, and cardiovascular perfusionists). Interview topics covered SSC use, team-work and communication patterns (interview guide in Additional file 1). All healthcare personnel in the perioperative team were considered key informants. Hence, a maximum variation purposive sampling strategy (37) was used to elicit professional perspectives on SSC utilisation in the OTs. Invitations to participate were initially reviewed and approved by hospitals managers at the respective study hospitals. Participants were recruited by the surgical unit managers. Professionals with variable length of perioperative work experience were targeted for sampling; their characteristics are described in Table 1. All interviews were conducted in the OT departments, in areas free from distractions (e.g., meeting rooms). Each participant was interviewed once. The interviews lasted between 28 and 47 minutes, with median length 36 minutes. The interviews were audiotaped, and transcribed verbatim for analysis.

All observations and interviews were performed by HVW (MSc, senior nurse anaesthetist, trained in qualitative research). A second researcher, ASH (PhD, senior nurse anaesthetist, trained in qualitative research) participated in 6 hours of the observations to ensure trustworthiness of the findings.

Table 1. Hospital and interviewee characteristics

HOSPITAL CHARACTERISTICS					INTERVIEWEES CHARACTERISTICS					
	Size*	**Surgical hospital stays****	**Level**	**Organisational structure**	**Number** N = 17	**Nurses**[1] Nurse anaesthetist/ Operating theatre nurse	**Physicians**[2] Consultant anaesthesiologist/ Consultant surgeon/Surgeon	**Cardiovascular perfusionist**[3]	**Sex** female/ male	**Work – experience** years qualified in profession - range
Hospital 1:	1066	33584	Tertiary referral hospital	22 specialised units	9	4	3	2	4/5	5-32
Hospital 2:	244	7887	Secondary referral hospital	2 specialised units	8	4	4	0	3/5	3-30
Total	1310	41471	-	-	17	8	7	2	7/10	3-32

***Size:** 2016 Occupancy rate (Statistics Norway) = bed-days/available bed-days. ****Surgical hospital stays:** 2016 reported stays with one or more surgical procedure, based on the classification system of the Norwegian diagnosis related groups (N-DRG, Norwegian Patient Registry. [1]Authorisation requirements in Norway: 3-year bachelor degree in Nursing-180 ECTS[§] + either a 1,5-year Specialist education program-90 ETCS, or a 2-year Master`s program-120 ECTS at a College University degree. [2]Authorisation requirements in Norway: 6year cand. med degree, 360 ECTS + 6,5 years of specialist training before qualification as consultant. [3]Authorisation requirements in Norway: 3-year bachelor degree in Engineering or Nursing180 ECTS + a 2-year Master`s program-120 ECTS at a College University degree. [§]European Credit Transfer and Accumulation System (ECTS) credits.

Analysis

Data from observations and interviews were analysed using an inductive, content analysis approach.(38) The following steps were used: HVW, ASH, SW (senior safety scientist, trained in qualitative methods), and SH (quality manager and senior scientist), read the transcribed interviews forming units of analysis. HVW identified and coded transcript sections into ‘meaning units’, followed by relating categories and themes, constituting the manifest content.(38) Observational data were used to support the interview data analysis and contribute to the formation and interpretation of the latent content, and emerging themes. ASH, SW and SH reviewed the coding and interpretations. Preliminary themes, subthemes and quotes were then discussed amongst all authors, using group consensus to strengthen coherence of the findings.(39) The finalised dataset is presented in emerging themes.

RESULTS

Analysis of observations and interviews identified three major themes: (1) Assessing utility, (2) Customising implementation, and (3) Interactive micro-team communication. In the following sections, each of the themes are presented in detail. The identified themes and corresponding categories are presented in table 2, with representative verbatim quotes and observation notes (in italics) to illustrate the findings.

Assessing utility

Participants expressed various views related to SSC`s practical utility. The anaesthesia team (nurse anaesthetists and anaesthesiologists) perceived the SSC to lack practical value, especially the "Sign-In" part, which was perceived as not adding anything new to reduce anaesthetic risk. They reported that they had good control of procedures and tasks before induction of anaesthesia. Existing checking mechanisms and protocols were considered sufficient, as pre-anaesthetic patient risk assessments; e.g. difficult airways, medications, allergies were performed in advance, and safety tests and -checks of the anaesthesia machine, - equipment and -medications, were incorporated in existing routines and reviewed prior to induction of anaesthesia. Checks performed by the anaesthesia team during the preoperative phase were aligned with their roles and responsibilities, acknowledged by both the anaesthesia team and other perioperative members. In addition, some anaesthesiologists expressed a need of retrieving surgical information regardless of the SSC, which in their opinion made reviews of SSC "Sign- In" items superfluous. Yet, some anaesthesiologists expressed a need for more time to review and handle high-risk patients together with the nurse anaesthetists, during a pre-anaesthesia briefing.

Interestingly, however, other staff-members described situations where they experienced the

SSC as being particularly useful i.e.; by confirmation of patient identity, as a reminder-list of important safety checks, especially for procedures that might vary according to types of surgeries, or patient specific conditions such as administration of surgical antibiotic prophylaxis. OT nurses described how surgical equipment reviews during "Time-Out" were advantageous, as well as tissue-sample labelling double checks at "Sign-Out". SSC was also highly valued in order to provide predictability in the OT, e.g., logistics in OT scheduling, timing of anaesthesia, and for preparation and reports to post-anaesthesia ward. Nurses in particular, reported an ease of workflow when everybody in the team knew the surgical plan. In addition, the "Sign-Out" provided a sum-up of the surgery, which were reported being of help to understand exactly what procedures that had been performed. This was considered helpful in correct surgical procedure codings. Introduction of the team members during SSC "Time-Out" was also described by some surgeons as unifying the team to structure their focus before incision. This was especially useful for new and/or unexperienced team-members.

Customising implementation

Observations identified variations in how different items and parts of the SSC were carried out – and also in how the electronic registration of the SSC was done (the latter is important as it is used to provide national compliance rates). Policy for hospital 1 mandated specific registration of each of the three parts of the SSC (so 3 separate registrations) whereas policy for hospital 2 mandated one SSC registration including all three parts (so 1 registration in total).

SSC utilisation varied across different SSC items and participants` perception of challenges of actual use. Observations showed that induction of anaesthesia done in the OT in both units silenced and concentrated the team members present in OT. Yet, performance of the SSC

"Sign-In" only few minutes earlier did not have at all the same effect: it failed to concentrate the teams' attention.

Participants described how verbal SSC briefings rushed through the items, forgetting to include the whole team. Lack of team focus- and concentration during SSC performance was also described. When SSC checks interfered with existing workflow, the SSC was often partly or poorly performed, delayed, or left out as a result. Resistance within the team and verbal disturbances also influenced performance. As a result, SSC registration was often described as a "tick-off exercise", which some of the participants vocally worried about its impact on safety.

Presence of the different team members in the OT also influenced how- and by whom the SSC items were checked. While nurse anaesthetists and OT nurses were present during all three parts of SSC, surgeons and cardiovascular perfusionists were not present in OT during "Sign-In". Cardiovascular perfusionists also described being haphazardly included or not during "Time-Out", unless they actively initiated communication themselves about specific items or equipment in use. Anaesthesiologists described that their presence in OT during "Time-Out" and "Sign-In" was more relevant in complex surgical cases, and for high-risk patients.

Interactive micro-team communication

Risk communication and critical information exchanges during perioperative care were performed in multiple, formal and informal micro-team constellations. The team members` individual and professional perception of identified or potential patient safety challenges influenced SSC utilisation, and how, when, and to whom information on risk was passed in

the perioperative phase of surgery. Their perceptions of safety challenges also influenced how the team members viewed and exerted influence on risk communication within the team.

In one of the study sites, according to participants, formal team constellations featured preoperative morning meetings where the surgical schedule of the day was presented by the surgeons in charge. Relevant safety issues were discussed amongst the present team members. Team members who had been present at the meeting then disseminated information of importance to their respective colleagues. Some of the interview participants described this information exchange as a "sub-optimal, second hand ad-hoc information transfer". Instead, they would have preferred that team briefings were better structured prior to surgery, involving the actual team members scheduled for that specific surgical procedure. Aligning the SSC items and reviews according to specific risks related to the individual patients and their specialities was also suggested.

The local SSC version was scaled down to cover a minimum of items. This was explained by physicians in charge as being sufficient, partly due to factors such as strong organisational structures, a limited variety of surgical procedures and standardised operative environment with few OTs. Moreover, the required competencies, professional experience and good interstaff relationships were also cited as elements justifying the reduction of SSC content. This was emphasised in terms of the highly qualified and experienced multidisciplinary perioperative team members and local practice of one-to-one relationship between the anaesthesiologist and the patient, throughout the perioperative pathway.

The formal planning of surgery and anaesthesia was performed by the respective surgeons and anaesthesiologists in charge. If somehow concerns about the patient needed to be discussed more thoroughly, i.e.; clarifications about the procedure, required equipment, laboratory tests,

blood products, or patient medications, the different health care personnel directly contacted the responsible professionals. This form of patient specific communication and information exchange within micro-team constellations was observed throughout the perioperative phase – such that:

- the anaesthesia team reported to have an on-going dialogue about the patients` risks, necessary equipment, fluids and medications.
- the OT nurses and surgeons had a continuing dialogue on maintaining a sterile field, possible risks and lack of equipment, specimen labelling and compress counts.
- cardiovascular perfusionists, anaesthesiologists and nurse anaesthetists had an ongoing dialogue on collaboration of the haemodynamic controlling.
- the anaesthesiologist had also ongoing dialogue with the surgeon in charge.

These interactive patterns of micro-team communication and information exchange clearly dominated and superseded any SSC checks.

Table 2: Themes and categories with illustrative participant quotes and observation notes (in italics)

THEME	CATEGORY	ILLUSTRATIVE QUOTES FROM PARTICIPANTS (Observation notes in italics)
Assessing utility	Lack of practical utility	**Anaesthesiologist:** Before I anaesthetise the patient, I know all the parameters for my patients, I check their circulation, and I know about their vascular occlusions and specific arterial stenosis, and I feel I have complete control of the patient, so…. It is hard to think that the checklist will provide extra safety for me. **Anaesthesiologist:** Patient safety is part of our training as anaesthesiologists from the very beginning! Eh-check of the anaesthesia machine, instruments, the patients, and practically checks of everything we do! Double control of every blood products provided, medications, everything! In addition to assessing the patient in person and talking to them prior to surgery. We have always performed these items; it is part of the standardised pre-operative anaesthesia assessment and preparations. **Nurse anaesthetist:** The anaesthesia machine is not due to any variation, it should be checked prior to every anaesthesia. We do not admit patients into the OT unless the anaesthesia machine is OK. **Surgeon:** Well, the SSC has a function, in a very simplistic way, but it does not have a proper control function, the way it is supposed to, because we have so many checks and control mechanisms incorporated. So, I don`t think that the SSC is as important to us, as to other surgical departments, which have other pre-operative assessment routines. We have so many points of assessment, where our patients are discussed and evaluated.
	Perceived utility	**Operating theatre nurse:** The SSC is useful as a reminder of double checks of labelling tissue samples, and to make sure the right surgical equipment is present. Surgical routines are complicated when you are a beginner… **Nurse anaesthetist:** I value how the SSC may contribute in aligning the surgical and anaesthesia plan for the entire team. **Surgeon:** The team introduction is a nice way to start team working; the "Time-Out" is in a way a mental team-calibration.

THEME	CATEGORY	ILLUSTRATIVE QUOTES FROM PARTICIPANTS (Observation notes in italics)
Customising implementation	Review and confirmation of items	**Cardiovascular perfusionist:** And occasionally, I may have to call out if there is something I believe is required or something has been omitted, i.e. that the patient has low haemoglobin levels, and I need to take action. In addition, during haemodilation, I avoid infusing too much fluid in the machine. Then I tell the surgeon and anaesthesiologist what I intend to do, to make them understand what I intend to do. **Operating theatre nurse:** Some surgeons that are more reluctant than others, they just start to mumble through the SSC as soon as they enter the OT, and then proclaim to have performed time-out. Then, it is required from an OT nurse to be determined and speak up, and say, «no, this is not good enough! Everybody needs to know what you just said! » Sometimes I have to add: «No, this was not loud enough, you have to repeat the SSC! » However, to speak up requires some years of work experience. **Operating theatre nurse**: I think the SSC is a good thing, but I miss team concentration during its performance Things have improved, from the beginning until now, but there is still too much disturbance during SSC performance. I really miss that everybody stops and pays attention. Due to the workflow in the OT, there is always someone who pursuits some kind of work, and does not stop. In addition, you need to pay full attention for the SSC to be advantageous. **Nurse anaesthetist:** But it is obvious, the SSC performance is totally depending on the physicians participation. As soon as they became more involved, both performance and compliance increased.
	Presence of team members	**Nurse anaesthetist:** Personally, I prefer to perform the sign-in with the anaesthesiologist being present in the OT, I think it is embarrassing to repeat the questions and items I have asked the patient previously, upon arrival in the OT. So I have almost stopped to ask the patients about their potential allergies, and so on. The anaesthetist repeats everything when they arrive in OT anyway. ***Observation:*** *The team compositions varied during the different parts of the SSC performance; The nurse anaesthetist, operating theatre nurse and anaesthesiologist were present during "Sign-In". The nurse anaesthetist, operating theatre nurse, surgeon(s) and anaesthesiologist (occasionally) were present during "Time-Out". The nurse anaesthetist, operating theatre nurse, surgeon(s) and anaesthesiologist (occasionally) were present during "Sign-Out".*
	Barriers of performance	**Nurse anaesthetist:** Well, you don`t want a conflict within the OT, you're in a way a bit tired of that, so you try once more to perform the SSC, and if you do not receive any attention, you just let it go and tick off the box, even though it has not been performed. **Nurse anaesthetist:** It is so important to keep the SSC short, because it does in a way disturb our workflow.. You are about to start induction of anaesthesia, and then; «No, no, we have to stop and perform the SSC! » Our workflow is interrupted, and it is very disturbing and frustrating. **Operating theatre nurse:** The anaesthesia team is responsible for the anaesthesia, medications…. It is their responsibility**.** Questioning them about this is like questioning them whether they have done their job or not. ….
	Registration practices	***Observation:*** *At the surgical units in hospital 2, SSC performance was ticked off either after "Sign-In", or the "Time-Out" part. There was only one box that needed to be ticked off electronically, in order for the SSC to be registered as performed. At the surgical unit at hospital 1, all three parts of the checklist had to be ticked off as three separate boxes in order for the SSC to be registered as performed.*
THEME	**CATEGORY**	**ILLUSTRATIVE QUOTES FROM PARTICIPANTS (Observation notes in italics)**
Interactive micro-team communication	Patient specificrisk communication	**Anaesthesiologist:** In general, we have contact with the cardiovascular perfusionist prior to surgery, to inform them about patient specific details such as medications, because they don`t read the patient records the same way we do. **Operating theatre nurse:** …. And if bleeding is involved, we need to notify the anaesthesia team about the estimations of blood volume collected in the surgical suction, before other fluids are added.
	Selected communication of risks	**Cardiovascular perfusionist**: … and these preparations are being discussed between the surgeon and the cardiovascular perfusionist prior to surgery. **Operating theatre nurse:** In most cases, we have direct communication with the anaesthesiologist during induction of anaesthesia, and ask permission to start our preparations, such as positioning the patient, or inserting the urinary tract catheter. **Anaesthesiologist**: … and then, the surgeons talk about the details of the surgery they have performed, while rushing out of the OT, right? And then you have to talk with them afterwards anyway, due to potential considerations post-operatively, like the follow-up antibiotic prophylaxis. Then you have to initiate contact anyway, because certain things require a follow-up.

DISCUSSION

This study explored in detail how the perioperative team integrates use of the SSC as part of their risk management strategies in real time during patient care. The individual and professional "cost-benefit" assessments of practical usefulness of the SSC influenced which checks were given attention and by whom. Existing patterns of micro-team risk communication clearly took precedence over formal SSC utilisation.

Our findings correspond to the results of a global survey among medical professionals regarding the SSC.(40) Among the 6269 respondents, perception of usefulness (67%) was the main factor associated with the SSC usage.(40) The perceived (un)importance of checklist items influencing SSC use, was also found in a Canadian study.(41) How team members perceive SSC sense making in practice has further been related to the relevance of specific SSC items, and possibilities of tailoring SSC content to local context.(25, 27, 42, 43)

Anaesthesiologists have previously been identified as being the least positively disposed towards SSC completions, when compared with surgeons and nurses.(44) We found that nurse anaesthetists and anaesthesiologists in particular reported that their existing safety protocols and procedures such as the pre-anaesthetic patient risk assessment were sufficient. The "Sign-In" review was seen as redundant, coinciding with former arguments of SSC performance being double checking routines.(17, 41) Still, this perspective raises the concern of overlooking other team-members' possible information needs. It might also indicate that "perception of risk" is primarily concerned with a narrow view of active failures associated with one's own professional role, rather that wider underlying conditions that impact upon the entire perioperative team.(17) Whilst the SSC is designed to reduce risk perioperatively, for it to work as a team-based intervention a shared understanding among all team members of this simple aim is important. In a previous study, we have reported that improved patient

outcomes have been associated with improved care processes due to high quality use of the SSC.(11) This indicates the importance of ensuring that i.e., risk of hypothermia- and responsibilities of corresponding, preventative actions such as antibiotic prophylaxis is communicated with the team as a whole. If team members` perceptions of risk are solely concerned with their professional perceptions of active failures instead of including underlying conditions, such as risk of developing surgical site infections, important safety aspects of the team communication are neglected.(17, 45)

In addition to the narrower and wider risk perceptions, we found that SSC utilisation is also a function of how it is incorporated into team members` workflow schedules in OT, and how much effort has been spent reducing practical barriers within the team.(46) This finding corroborates previous investigations.(18, 25, 41, 43) However, we identified that the two study hospitals had different policies for how the SSC performance was registered and measured. This may explain some of the observed variation between the two hospitals. Also, variation in style of checklist implementation between the hospitals, the presence of local champions, differences in safety culture, the support and involvement of management, might account for the variation.(18, 47) In terms of these impactful factors, we suggest that SSC performance variations might offer distinct opportunities to address risk management at the intersection of perioperative procedures and actual team working. Figure 2, based on the model by Rudolph and colleagues(48) illustrates how the invisible perceived utility of the SSC influences actions of customising SSC implementation, and further results in visible performance variations in an ongoing process. If hospital managers fail to regard the SSC as a complex, social intervention and instead exert demands for high compliance rates of SSC performance as a top-down approach, this can lead to workarounds and outright resistance, and cause for the checklist to be used as a tick-box exercise to meet management requirements.(25, 49)

Strengths and limitations

The use of an ethnographic design is well suited to capture "everyday" routine behaviours in their natural settings.(32, 33) By combining observations and interviews, participants were given opportunity to identify and share insights into observed practices of SSC performances that deviated from the norm. However, this study was limited to explore team perception of risk management strategies in relation to the three parts of the SSC, rather than each specific SSC item. How team members consider use of the SSC to match their perception of patient safety challenges in perioperative care, might therefore be limited to reflect local roles and responsibilities of teamwork practice. In order to achieve credible information, data triangulation was used by collecting data across time, hospital settings and professions.(35) Although all members of the multidisciplinary surgical team were represented by maximum variation purposive sampling strategy, interview selection bias remains a possibility.

Practical implications and future directions

When well applied, the SSC is an effective intervention. It has been associated with relative risk reduction of 0.42 (95% confidence interval (CI), 0.33–0.50) of surgical complications, and significant reduction in length of in-hospital stay in a randomised trial.(8) A recent population cohort study from Scotland documented a reduction of 36.6 % (95% CI 55.2-17.9) in mortality.(50) Whilst the clinical effectiveness has been shown, study of implementation strategies to address influential barriers to SSC usage is needed, coupled with studies of the implementation process and local contexts.(25) Our findings indicate that how the perioperative team members perceived SSC as a risk reducing intervention, has considerable impact on the execution of the SSC and risk communication around it. We therefore propose that the SSC needs to be explicitly integrated into the risk management toolkit of perioperative care. An incident analysis from one of the study hospitals recently reported that

a patient had wrong surgery despite use of the SSC. One of the causes contributing to the adverse event was lack of team response to detected departures from planned care when the SSC was done.(51) This incident demonstrates that we need to move beyond use of SSC as a symbolic safety check; like other safety interventions, the SSC is vulnerable to meaningless application.(23) When the SSC is seen as an "add-on", or more commonly conseptualised as an external "thing"(31), the challenge of its integration into perioperative work remains.

How does the SSC become better integrated as a perioperative safety strategy? We propose that the SSC needs to be formally established as one (and only one) element of our toolkit of standardised perioperative safety mechanisms. This will contribute to the development of a shared mental model within perioperative teams,(52) such that the SSC becomes owned by them and applied in conjunction (and not in addition to) all other safety mechanisms in the OT, and indeed also pre- and post-operatively. This proposal follows on from recent policy developments in perioperative safety. For example, the national standard for the safe practice of anaesthesia, and the Helsinki declaration on patient safety in anaesthesiology(53) have established normative guidelines for everyone who provides anaesthesia care.(54) The observed behaviours related to induction of anaesthesia, reflect a sense of situation awareness amongst the team members, which might stem from a common understanding of this safety standard. In the UK, the National Safety Standards for Invasive procedures have been developed to set out the key steps necessary to deliver safe and common care standard for surgery, including the SSC but also many other checks and tools.(55) We believe that such a normative standardisation would contribute to establishing a shared mental model for the SSC globally. Of course further implementation strategies are required to translate standards into practice – including educational interventions, regular dissemination and updating of the standards based on emerging evidence.(56)

CONCLUSION

This study showed that when the SSC is perceived as an "add on" and not integrated as a risk management tool or part of the multidisciplinary risk management strategy, its fidelity is low. Strategies to enhance patient safety in surgery should focus on a multidisciplinary approach to foster shared mental models of safety standards in the OT. Aligning risk-assessment in SSC staff education where the SSC is part of a safe surgical risk assessment system, might provide an improved sense of value to all OT personnel, improve team learning of risk communication, and foster mutual understanding of safety perspectives.

LIST OF ABBREVIATIONS

WHO: World Health Organisation

SSC: Surgical Safety Checklist

OT: Operating theatre

CI: Confidence interval

DECLARATIONS

Ethics approval and consent to participate

The study was reviewed and approved by the hospital management and the data privacy ombudsman for research (DPO) prior to data collection, following prior approval by the Regional Ethics Committee, REK Vest, of the Western Norway Health Region (2015/1741). All study participants received written information about the study purpose and researchers involved, gave informed written consent to participate prior to the interviews, and could withdraw from the study at any time.

Consent for publication

Not applicable

Availability of data and material

The datasets generated and analysed during the current study are not publicly available due to risk of compromising individual confidentiality, but minimal dataset can be made available (in Norwegian) from the corresponding author on reasonable request, and with permission of DPOs at the respective hospitals.

Competing interests

NS is the Director of London Safety and Training Solutions Ltd, which provides quality and safety training and advisory services on a consultancy basis to healthcare organisations globally. The other authors declare that they have no competing interests.

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Authors' contributions

HVW, ASH, ES, SW and SH conceived of and designed the study. HVW carried out the data collection, ASH participated in some of the observations. HVW, ASH, SW performed preliminary analysis, and HVW wrote the first draft. All authors agreed on the final analyses, participated in interpretation of the study results, assisted in manuscript revision, and approved the final version of the manuscript.

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Additional files:

Additional file 1: Semistructured interview guide (Appendice II in the PhD Thesis)

Additional file 2: The COREQ checklist (Appendice V in the PhD Thesis)

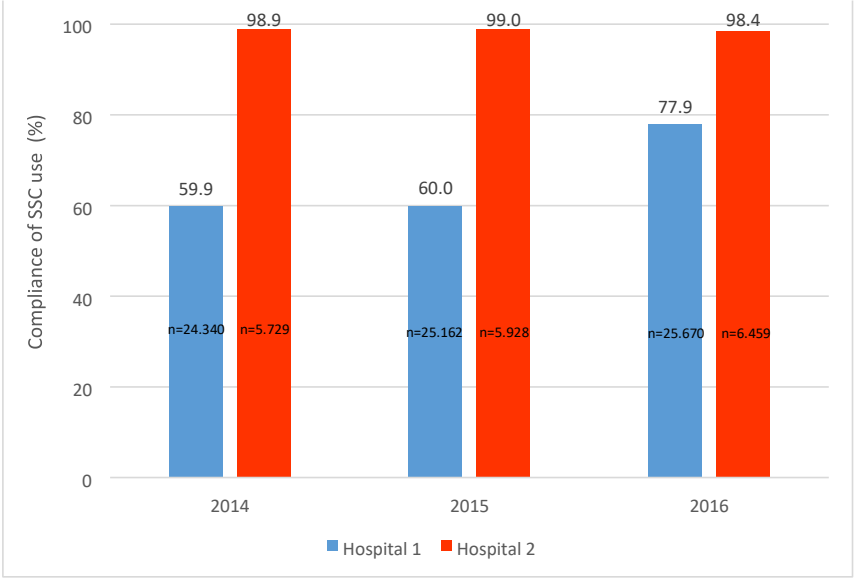

Figure 1. Longitudinal monitoring of SSC compliance rates in surgical procedures (n=total numbers of procedures/hospital/year) performed between 2014 and 2016 for study hospital 1. (tertiary teaching hospital) and study hospital 2. (central community hospital)

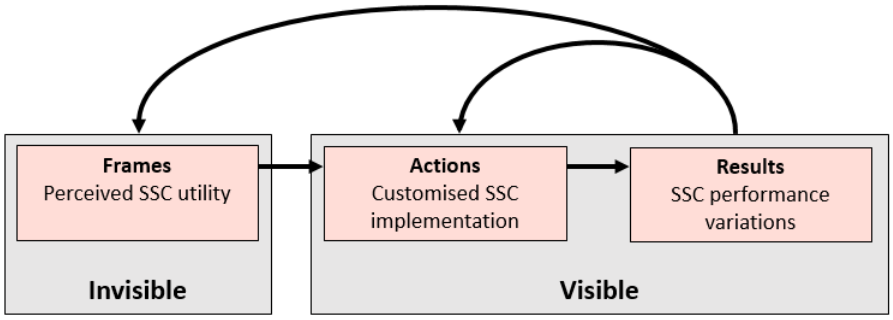

Figure 2. Illustration of how invisible perceived utility of the SSC influences actions of customising SSC implementation, and further results in visible performance variations in an ongoing process.
Revised model based on: Rudolph J, et al. Simul Healthcare 2006;1:49–55.

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