UNIVERSITY OF TURKU

THE WHO SURGICAL SAFETY CHECKLIST IN NEUROSURGERY

Marjut Westman

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ABSTRACT

The World Health Organization's surgical safety checklist (WHO SSC) is designed to improve adherence to operating room safety standards. Its use has been shown to reduce surgical morbidity and mortality. Studies on solely neurosurgical patients have been sparse.

The aim of this study was to evaluate the impact of the implementation of the checklist on safety-related issues in the OR and patient outcomes in neurosurgical patients. Safety-related issues in the operating room were assessed based on data collected through a personnel questionnaire. Electronic hospital and patient records were utilised to survey postoperative adverse events before and after the checklist implementation. The hypothesis was that implementing the checklist would enhance safety attitudes in the OR and reduce postoperative adverse events.

The checklist implementation enhances safety-related performance in the OR. Postoperative wound complications and unplanned readmissions were observed to reduce significantly. Data obtained from the hospital-acquired infection register revealed a reduction in early-on surgical site infections, although the overall surgical site infection rate did not decrease. Use of the WHO SSC was associated with reduced the rate of complication-related reoperations, especially preventable infections leading to reoperation. A separate literature review on checklists in neurosurgery also found checklist use to reduce complications and enhance OR safety culture. However, the volume of studies on solely neurosurgical patients is small.

The use of the WHO SSC seems to improve patient safety in neurosurgery through enhanced communication and reduced adverse events, although the amount of evidence is still limited. In the future, technological advancements will raise a requirement to reconsider the contents of checklists.

KEYWORDS: adverse event; communication; complications; HAI register data; hospital-acquired infections; neurosurgery; operating room teamwork; patient safety; postoperative infections; reoperation; surgical checklist; WHO Surgical Safety Checklist

TURUN YLIOPISTO
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TIIVISTELMÄ

Maailman terveysjärjestö WHO:n kirurginen tarkistuslista on suunniteltu yhdenmukaistamaan ja parantamaan kirurgisen hoidon laatua. Tutkimusten mukaan tarkistuslistan käyttö vähentää kirurgisten haittatapahtumien määrää. Tutkimuksia aiheesta neurokirurgisilla potilailla on tehty vähän.

Tutkimuksen tarkoituksena oli selvittää, miten tarkistuslistan käyttöönotto vaikuttaa potilasturvallisuuteen ja haittatapahtumiin neurokirurgisilla potilailla. Henkilökunnan kyselytutkimuksen avulla selvitettiin käyttöönoton vaikutuksia turvallisuusasenteisiin ja kommunikaatioon leikkaussalissa. Sähköisistä potilasaineistoista ja sairaalan rekistereistä saatavista aineistoista selvitettiin haittatapahtumien määrää ennen ja jälkeen tarkistuslistan käyttöönoton. Tutkimusolettamuksena oli, että tarkistuslistan käyttöönotto edistäisi leikkaussalihenkilökunnan potilasturvallisuusasenteita ja vähentäisi leikkauksiin liittyviä haittatapahtumia.

Tarkistuslistan käyttöönoton todettiin parantavan kommunikaatiota sekä turvallisuuskysymysten läpikäymistä leikkaussalissa. Leikkauksen jälkeisten haavaongelmien sekä suunnittelemattomien sairaalaan paluiden todettiin vähenevän. Sairaalainfektiorekisteristä saadun aineiston perusteella aikaiset haavainfektiot vähenivät tarkistuslistan käyttöönoton myötä, joskaan kokonaisuudessaan laskua haavainfektioissa ei todettu. Tarkistuslistan käyttö vähensi infektiokomplikaatiosta johtuvia uusintaleikkauksia. Erityisesti vältettävissä olevat infektiot vähenivät. Kirjallisuuskatsauksessa todettiin tarkistuslistojen vähentävän komplikaatioita ja parantavan potilasturvallisuuskulttuuria leikkaussalissa, vaikkakin neurokirurgisilla potilailla tehtyjä tutkimuksia on vielä vähän ja potilasmäärät melko pieniä.

Kirurgisen tarkistuslistan käyttö näyttää parantavan neurokirurgisten potilaiden potilasturvallisuuttaa parantamalla kommunikaatiota ja vähentämällä haittatapahtumia. Näyttö on kuitenkin vielä rajoittunutta. Teknologian kehittyminen tullee tulevaisuudessa aiheuttamaan tarvetta päivittää tarkistuslistan sisältöä.

AVAINSANAT: haittatapahtuma; kirurginen tarkistuslista; kommunikaatio; komplikaatio; neurokirurgia; potilasturvallisuus; postoperatiivinen infektio; hoitoon liittyvä infektio; sairaalainfektiorekisteri; uusintaleikkaus; WHO Surgical Safety Checklist; yhteistyö leikkaussalissa

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Abbreviations

AE	adverse event
AI	artificial intelligence
ASA	American Society of Anesthesiologists
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CNS	central nervous system
CSF	cerebrospinal fluid
ED	emergency department
ELVIS	Eliminating Ventriculostomy Infection Study
EMBASE	Excerpta Medica Database
EVD	external ventricular drainage
HAI	hospital-acquired infection
ICD	International Classification of Diseases
ICU	intensive care unit
LOS	length of stay
MEDLINE	Medical Literature Analysis and Retrieval System Online or MEDLARS online
MeSH	Medical Subject Headings
NA	not applicable
NS	neurosurgery
NOMESCO	Nordic Medico-Statistical Committee
OECD	The Organisation for Economic Co-operation and Development
OR	operating room
PICO	population, intervention, comparison, outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomised controlled trial
SD	standard deviation
SSC	surgical safety checklist
SSI	surgical site infection
SURPASS	Surgical Patient Safety System
UCLA	University of California, Los Angeles

US	United States
WHO	World Health Organization

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

I Lepänluoma M, Takala R, Kotkansalo A, Rahi M, Ikonen TS. Surgical safety checklist is associated with improved operating room safety culture, reduced wound complications, and unplanned readmissions in a pilot study in neurosurgery. *Scand J Surg*. 2014; 103(1): 66-72

II Westman M, Marttila H, Rahi M, Rintala E, Löyttyniemi E, Ikonen TS. Analysis of hospital infection register indicates that the implementation of WHO surgical safety checklist has an impact on early postoperative neurosurgical infections. *J Clin Neurosci*. 2018; 53: 188-192.

III Lepänluoma M, Rahi M, Takala R, Löyttyniemi E, Ikonen TS. Analysis of neurosurgical reoperations: use of a surgical checklist and reduction of infection-related and preventable complication-related reoperations. *J Neurosurg*. 2015; 123(1): 145-152.

IV Westman M, Takala R, Rahi M, Ikonen TS. The need for surgical safety checklists in neurosurgery now and in the future – a systematic review. *World Neurosurg.* 2019 [In press 8 November 2019]

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1 Introduction

According to estimates, 312.9 million surgical operations are performed globally every year (Weiser et al. 2016). The rate of surgical adverse events varies between 3–22% (Gawande et al. 1999, Griffin et al. 2008, Kable et al. 2002, Nilsson et al. 2016), and of these, up to 64% are theoretically preventable (Gawande et al. 1999, Houkin et al. 2009, Nilsson et al. 2016). Depending on the type of neurosurgical operation, various studies report that adverse event and mortality rates vary between 2–73.5% and 0–2.3%, respectively (Halvorsen et al. 2011, Hammers et al. 2010, Lassen et al. 2011, Street et al. 2012, Wong et al. 2012d, Wong et al. 2012b, Wong et al. 2012c, Wong et al. 2012e). Complications may lead to reoperations with reported incidence of 1.5–4.3% (Lassen et al. 2011, Rolston et al. 2014). According to Houkin et al., most neurosurgical adverse events are predictable if not preventable (Houkin et al. 2009).

The WHO Surgical Safety Checklist is part of the World Health Organization's (WHO) Safe Surgery Saves Lives challenge to improve the safety of surgical care by ensuring adherence to verified standards (WHO Patient Safety). The 19-point Surgical Safety Checklist (SSC) covers the most important safety-related items during the operation. Within years, it has spread all over the world, with over 4,000 registered hospitals of which nearly 1,800 are active users (WHO and Harvard University). The SSC has been studied widely, and its use has been proven to reduce complications and mortality in diverse surroundings and surgical specialties (Bergs et al. 2014, Haugen et al. 2015, Haynes et al. 2009, Jammer et al. 2015, Sewell et al. 2011, van Klei et al. 2012, Weiser et al. 2010) and to have a positive impact on communication and teamwork (Haynes et al. 2011b, Haynes et al. 2009, Takala et al. 2011, Weiser et al. 2010).

In surgery, various checklists have been used before, but the introduction of the WHO SSC has brought more research on their clinical impact. Checklists have been shown to reduce surgical morbidity and mortality in multiple studies, yet the impact in developed countries may have been less than expected (de Vries et al. 2010b, Haynes et al. 2009, Lyons 2010). Also, some studies have shown conflicting results (O'Leary et al. 2016, Santana et al. 2016, Sewell et al. 2011). There are many open questions and lack of high-quality studies on checklist use.

Research on surgical patient safety and checklists on neurosurgical patients is limited. Neurosurgery is different from many other surgical subspecialties because of its delicate nature and the amount of harm in case of a complication. In neurosurgery, a simple wound infection may lead to multiple reoperations and long antibiotic treatments, and hence cause greater costs than infections in other surgical specialties (Parker et al. 2012, Whitmore et al. 2012). The aim of this study was to define the impact of SSC implementation in a neurosurgical patient population and its effect on postoperative adverse events.

2 Review of the Literature

2.1 Surgical adverse events

2.1.1 Terms and definitions

An adverse event is an unintended physical injury or complication caused by medical intervention rather than the underlying disease process of the patient, and may cause prolonged hospital stay, disability or death (Brennan et al. 2004, Corrigan et al. 2000). Adverse events can be further divided into preventable and unpreventable; a preventable adverse event could be avoided with proper execution of a plan or adherence to current standards of care. An example of an adverse event is a surgical site infection or wrong-site surgery.

A medical error is defined as an act of omission or commission that results in deviation from the optimum and may cause or causes harm to the patient (Grober et al. 2005, Stone et al. 2007); for example, errors in medication or error in diagnosis. *A surgical error* is an error or a mistake committed by the surgeon pre- or intraoperatively, for instance error in technique like wrong-site incision, or an intraoperative nerve or vessel injury. or error in judgement when choosing the operative plan (Bosma et al. 2011).

A surgical complication has been defined as any deviation from the normal postoperative course (Dindo et al. 2004), or as in the latest version of Clavien and Dindo "any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure" (Dindo et al. 2008). Surgical complications can be graded according to the severity of the complications or the extent of therapeutic actions needed to correct it. A typical postoperative complication can be induced by the surgery, (e.g. bleeding or surgical site infection), or any other intervention during the hospital stay or the hospitalisation itself (e.g. urinary tract infection or pneumonia) (Dindo et al. 2004).

Errors can be potential adverse events causing harm, whereas adverse events are harm (Rolston et al. 2015). Adverse events can also exist without errors. The terms *adverse event*, *complication* and *error* are used interchangeably in the literature making the comparison of study results challenging.

2.1.2 Common surgical adverse events

Postoperative adverse events may be due to the surgical intervention or unrelated factors. Surgical interventions predispose patients to a wide variety of adverse events that are separate from or unrelated to the surgical procedure. Surgery itself and the immobilisation it occasionally requires are risk factors for deep venous thrombosis and pulmonary embolism. In general surgery, the incidence of symptomatic venous thromboembolism was 0.8% in a large multispecialty surgical study (White et al. 2003). . The surgical operation exposes the patient to risk of decubitus ulcers and nerve compressions due to surgical positioning, especially in operations lasting longer than 3 hours (Primiano et al. 2011, Winn 2004). According to a review, 15% (0.3–57.4%) of surgical patients suffer from pressure ulcers (Chen et al. 2012). After surgery, patients are in risk of surgical site infections from superficial wound infections to deep organ infection with or without surgical implant (see further below). There is also the risk of wound rupture or dehiscence, and wound haematoma or seroma (Doherty 2015). Surgical patients may also be exposed to medical complications, such cardiac arrhythmias or acute stroke. According to a Spanish study, the risk for acute cardiac or cerebrovascular event in surgical patients <40 years of age with intermediate-to-high surgical risk was 4.3% (Sabate et al. 2011) Older patients or patients with memory deficits or psychiatric disorders are easily caught by disorientation or delirium postoperatively, during acute infection or hospitalisation (Schenning et al. 2015). The risk of medication-related adverse events is also present (de Boer et al. 2013, Noguchi et al. 2016).

2.1.3 Hospital-acquired infections

According to a Scottish study, hospital-acquired infections concern 11.2% of surgical patients (Reilly et al. 2008). These hospital-acquired infections can be related or unrelated to the surgical operation itself. In the latter case, infections may be accidental by timing, or caused by the hospitalisation; hospitalisation exposes the patient to the risk of other hospital-acquired infections, such as viral and bacterial diarrhoea, skin infections or upper respiratory tract infections (Klevens et al. 2007, Magill et al. 2014). Immobilisation increases the risk of postoperative atelectasis and pneumonia. Also, mechanical ventilation enhances the risk for pneumonia. Atelectasis can cause fever also without a clinical infection (Doherty 2015). Postoperative pneumonia occurs in 0.18–0.44% of surgical ward patients (Kazaure et al. 2014, Wren et al. 2010). Rates for ventilator-associated pneumonias are higher, 10–20% of ICU patients (Safdar et al. 2005). Overall pulmonary complications (e.g. pneumonia, atelectasis, respiratory failure, bronchospasm) occur in 2–19 % of patient having non-thoracic surgery (Fisher et al. 2002).

Urinary tract infections are common in hospitalised patients, 5 % have bacteriuria (Doherty 2015) and 1–1.7% of surgical patients develop a postoperative urinary tract infection (Doherty 2015, Regenbogen et al. 2011, Trickey et al. 2014). The most common cause is the use of urinary catheter due to urinary retention, immobilisation or control of diuresis. 67.7–80% of urinary tract infections of hospitalised patients are catheter-related (Magill et al. 2014, Saint et al. 2003). According to an Italian study, catheter-associated urinary tract infections occur in 4.2% of all hospitalised patients (Marani et al. 2016). In the same study, 9.4% of patients with central venous catheter developed a bloodstream infection (Marani et al. 2016). According to an American point-prevalence study, 25% of healthcare-associated infections were device-related (ventilator-associated pneumonia, catheter-associated urinary tract infection, central-line associated bloodstream infection) (Magill et al. 2014).

Surgical infection complications comprise of infections that are due to the surgical operation. These include, for example, surgical site infections, pneumonia or empyema in thoracic surgery patients, abdominal infection in gastric patients, meningitis or encephalitis in neurosurgical patients.

2.1.3.1 Surgical site infections

A surgical site infection is defined as an infection of the incision and the tissues in the operation area (NICE 2019). *Superficial incisional SSI* affects only the skin and the subcutaneous tissue of the incision, whereas *deep incisional SSI* goes as deep as fascia and muscle of the incision. *Deep organ SSI* consider other, deeper surgical sites manipulated in the operation besides the incision site (Horan et al. 1992). Factors contributing to the risk of SSI can be divided into patient-related factors (e.g. other co-morbidities, age, gender, nutritional status, ASA score), microbial factors (knowledge of local common causative pathogens) and perioperative factors (e.g. antimicrobial decontamination with alcohol swabs, antibiotic prophylaxis, patient warming). In miscellaneous or general surgery patient data, SSIs affected 1.95–8.2% of patients (Astagneau et al. 2001, Barchitta et al. 2012, Boetto et al. 2015, Hawn et al. 2013, Marani et al. 2016).

2.1.3.2 Surgical site infection prevention

Surgical site infections impose a significant burden both on patients in terms of suffering as well as on societies in terms of financial costs. According to a US review on studies with a mixed surgical patient data, more than 50% of SSIs were considered preventable, with potential savings of billions of dollars yearly in the US alone (Umscheid et al. 2011). SSIs are multifactorial with patient-related, microbial and perioperative factors. All factors associated with SSI cannot be influenced. Yet many perioperative and some microbial factors, such as antibiotic prophylaxis, are easily applicable. Broader protocols than the surgical checklist for SSI prevention has been published in recent years covering factors from preoperative to postoperative care. The recommendations include among others decolonisation of Staphylococcus aureus from nasal carriers, hair removal only when necessary and by clipping with scissors, proper surgical site prepping, and patient homeostasis intraoperatively (Allegranzi et al. 2016a, Allegranzi et al. 2016b, NICE 2019)

It has been demonstrated that use of a checklist improves the timing of prophylactic antibiotics (de Vries et al. 2010a, Lingard et al. 2011, Rosenberg et al. 2008). According to prevailing knowledge, antibiotic prophylaxis is more effective in preventing SSI when administered closer to the time of incision (Classen et al. 1992) and most effective when administered 30–59 minutes before incision (Weber et al. 2008). A more recent review by de Jonge et al. did not find support for the 60-minute timeframe and instead stated the relevant timeframe to be 120 minutes before incision (de Jonge et al. 2017). However, some studies have questioned the importance of timing in general finding no correlation with reduced SSI and timing (Hawn et al. 2013, Lee et al. 2013).

2.1.4 Reoperations and readmissions

Reoperations may be pre-planned, but often reoperation is unplanned and due to an adverse event. A pre-planned reoperation (second-look surgery) is done when the patient’s medical condition requires it (e.g. operations for abdominal infections), when performing all certain procedures in one operation (e.g. abdominal traumas) put the patient in an unnecessary risk of complication. Unplanned reoperations are performed due to procedure-specific adverse events, such as leakage of an anastomosis, haemorrhage of the operation area, or infection. In general surgical operations, unplanned reoperations occurred in 1.35–5.9% of operations (Birkmeyer et al. 2001, Froschl et al. 2006, Guevara et al. 2013), and 17.9–32.9% of reoperations were done due to postoperative surgical site infection (Froschl et al. 2006, Guevara et al. 2013). Wound complications were the reason for reoperation in 14.7–23% of operations (Birkmeyer et al. 2001, Guevara et al. 2013). Unplanned reoperations were associated with longer stay in the ICU or hospital (Froschl et al. 2006, Guevara et al. 2013). In a study on orthopaedic and trauma patients, 2.2% of patients went through an unplanned reoperation and over 48% of those were regarded as preventable (Pujol et al. 2015).

Readmissions may also be pre-planned or unplanned. Unplanned readmissions after surgical care are caused by both surgery-related and other, patient-related factors. Surgery-related reasons include adverse events like pain, SSIs, and procedure-specific complications. Two studies on general surgery patients showed a 30-day readmission rate of 4.7–5.9% (Clark et al. 2018, Lee et al. 2018). The study by Lee et al. stated that over 40% of those readmissions, mainly due to SSI or pain, could have been avoided, and that a higher work load was associated with a higher readmission rate (Lee et al. 2018). Major surgery carries a higher risk for readmission than minor operations (Clark et al. 2018).

2.2 Neurosurgical adverse events

2.2.1 Common neurosurgical adverse events

The adverse event rate in neurosurgery varies widely between 3–73% depending on the definition used (Halvorsen et al. 2011, Houkin et al. 2009, Street et al. 2012). Common neurosurgical complications are cerebral oedema, cerebral haemorrhage or infarction after cranial surgery; surgical site infections; neurological deficits, dural tear, and CSF fistula after spinal surgery (Nanda 2018, Winn 2004).

According to a recent series of literature reviews on adverse events after intracranial tumour surgery, the occurrence of neurological deficits was 0–20%, postoperative seizures 1–12%, postoperative oedema of the surgical site 2–10%, and wound infections 1–2% (Wong et al. 2012d). Infections occurred in 3–12% of shunt surgeries, and mechanical malfunction of the shunt occurred in up to 64% of patients (Wong et al. 2012b). Among patients undergoing operation for intracranial tumours, the most common adverse event was deep venous thrombosis varying between 3–26% (Wong et al. 2012d) and even up to 60% of the patients with intracranial malignancy (Marras et al. 2000). The risk factors for venous thromboembolic events include malignant disease, age ≥ 60 years, chemotherapy, leg paresis, surgery ≥ 4 hours (Marras et al. 2000). In the review by Wong et al., other medical complications occurred in 6–7% of neurosurgical patients (Wong et al. 2012d). According to a study by Lieber et al., neurosurgical patient receiving corticosteroids have an increased risk of deep venous thrombosis and pulmonary embolism (Lieber et al. 2016).

In open cerebrovascular surgery, intraoperative rupture risk varied from 7% to 35%, and technical adverse events of aneurysm clipping ranged between 3–18% (Wong et al. 2012c). In endovascular interventions, the most common adverse event was thromboembolic (2–61%) (Wong et al. 2012e). Endovascular treatment of aneurysmal subarachnoid haemorrhage has a morbidity of 4.5% and mortality of 0.2% for procedural complications (Alanen et al. 2018).

2.2.2 Postoperative infections in neurosurgery

According to previous studies on unselected neurosurgical operations, surgical site infection occurs in 0.4–5.1% of operations (Abu Hamdeh et al. 2014, Cassir et al. 2015, Kolpa et al. 2019, Lietard et al. 2008, Ogihara et al. 2015, Olsen et al. 2003). According to a study by Cassir et al., risk factors for SSI include prolonged postoperative stay in the ICU, co-infection and CSF leakage after cranial surgery (Cassir et al. 2015). CSF leakage is a risk factor for postoperative meningitis (Srinivas et al. 2011). ASA score > 2, postoperative intracranial pressure monitoring or ventricular drainage >5 days, reoperation, co-infection and emergency operation have also been found to be risk factors for SSI (Young et al. 2014). Following a spinal surgery, CSF drainage longer than 3 days, revision operation or open operation technique were associated with higher risk of SSI (Cassir et al. 2015, Smith et al. 2011). Also, long operation time (>2 hours) has been reported to enhance risk for SSI (Daley et al. 2015, Ogihara et al. 2015, Young et al. 2014).

A large Polish study on over 10,000 neurosurgical patients observed under a 15-year time span the incidence of HAIs to be 4.6% whereof a third was covered by SSIs. The incidence of pneumonia was 1.1%, urinary tract infection 0.6%, gastrointestinal infections 0.3%, and skin and soft tissue infections 0.08%. Bloodstream infections occurred in 0.9% of which a fourth were catheter-related (Kolpa et al. 2019).

According to some studies on surgical site infections in neurosurgery, there is no direct correlation between prophylactic antibiotics and surgical site infections (Lietard et al. 2008, Raggueneau et al. 1983). By contrast, other studies have shown that antibiotic prophylaxis does significantly reduce surgical site infections after craniotomy (Burnichon et al. 2007, Korinek et al. 2008, Korinek et al. 2005).

2.2.3 Reoperations and readmissions in neurosurgery

Typical adverse events leading to a reoperation in neurosurgery are SSIs or haematoma, brain oedema after intracranial surgery, CSF leakage, or complication with surgical implants after spinal surgery (Halvorsen et al. 2011, Hoover et al. 2012, Lassen et al. 2011, Marini et al. 2012).

Reoperations due to a surgical adverse event vary between 0.6–3.6% (Halvorsen et al. 2011, Hoover et al. 2012, Lassen et al. 2011, Marini et al. 2012, Shimizu et al. 2016). In recent years, unplanned readmissions have become of interest as an indicator of quality of care and surgical patient safety. 3.9–24% of neurosurgical patients are readmitted postoperatively within 30 days, and approximately half of them are readmitted due to a surgical adverse event (Amin et al. 2013, Ansari et al. 2018, Buchanan et al. 2014, McCormack et al. 2012, Moghavem et al. 2015, Shah et al. 2013, Taylor et al. 2016, Vaziri et al. 2014, Wilson et al. 2018). The leading causes are SSIs, other wound-related problems, and CSF shunt problems. In spinal surgery, a third of readmissions are due to postoperative infections (Amin et al. 2013, McCormack et al. 2012).

2.3 Safety procedures to enhance patient safety

2.3.1 Briefing and teamwork training

In a general surgical patient population, 85% of postoperative process failures have been preventable, and more than 50% of process failures and adverse events have been due to communication failures and delays in treatment (Symons et al. 2013). Preoperative checklists and briefings have been reported to improve communication and teamwork in the operating room (OR) (Lingard et al. 2005, Lingard et al. 2008, Makary et al. 2007, Nagpal et al. 2010b, Paige et al. 2008, Papaspyros et al. 2010). Enhanced co-operation among OR personnel correlates with reduced postoperative complications (de Vries et al. 2010b, Haynes et al. 2011a, Lyons 2010, Mazzocco et al. 2009) and mortality (de Vries et al. 2010b, Mazzocco et al. 2009, Neily et al. 2010). Preoperative briefings also correlate with enhanced safety attitude (Allard et al. 2011, Magill et al. 2017). A preoperative time-out is quick to perform but easily distracted (Freundlich et al. 2019). The quality of communication can be perceived differently by nurses and doctors (Makary et al. 2006), but with the use of a checklist, the communication failures are reduced (Takala et al. 2011). Team training enhances teamwork and safety climate experience (Bleakley et al. 2012, Weaver et al. 2010). Interventions combining team training and non-technical skill training with systems interventions (e.g. Lean) have been stated to improve checklist performance more than team training alone (McCulloch et al. 2017).

2.3.2 Safety checklists

According to studies on other than neurosurgical specialties, infection control protocols with interventions throughout the hospital stay and perioperative care reduce SSIs (Barchitta et al. 2012, Graf et al. 2009, Wick et al. 2012). A surgical checklist covering the whole length of the surgical pathway, the Surgical Patient Safety System (de Vries et al. 2010b), was developed in the Netherlands. According to studies, it has optimised antibiotic prophylaxis and it intercepts incidents in all phases of the surgical pathway, pre-, peri- and postoperatively (de Vries et al. 2010a, de Vries et al. 2009, de Vries et al. 2012).

2.3.2.1 The WHO Surgical Safety Checklist

In 2004, WHO founded The World Alliance for Patient Safety to enhance safety and quality of care in its member states. The WHO Patient Safety programme was initiated, comprising of Global Patient Safety Challenges. One of them was Safe Surgery Saves Lives – a campaign to improve surgical safety and reduce surgical deaths and complications. As a way to reach these goals, the WHO Surgical Safety Checklist was developed (WHO Patient Safety). The 19-point checklist covers the operation in three phases: *Sign in* – before induction of anaesthesia; *Time out* – before incision; and *Sign out* – before patient leaves the operating room (see Appendix 1 and 2).

The checklist aims to reduce errors and adverse events and enhance teamwork and communication. The checklist points cover most major important steps and factors affecting the optimal course of the operation and postoperative convalescence. In the *Sign in* phase, the identity of the patient is verified along with the operation side/site markings. Wrong-site surgery is rare but detrimental both to the patient and the caregiver, and considered as preventable (Devine et al. 2010, Hanchanale et al. 2014). According to Makary et al., preoperative debriefings reduce the risk for wrong-site surgery (Makary et al. 2007). Equipment needed for anaesthesia is checked and risk for patient allergies, and risk of difficult airway or major blood loss is discussed. The use of pulse oximetry has been shown to reduce hypoxemia- and anaesthesia-related adverse events, although its impact on morbidity and mortality is controversial (Li et al. 2009, Pedersen et al. 2014). Hypersensitivity reactions for perioperative medication or other agents occur on average with an incidence of 15 per 10,000 operations, and of those, 2 per 10,000 operations suffer from anaphylaxis (Saager et al. 2015). The most common allergenic agents are neuromuscular blocking drugs, antibiotics, chlorhexidine, dyes, latex and anaesthetic agents (Di Leo et al. 2018, Low et al. 2016, Sadleir et al. 2013). During *Time out*, the team members introduce themselves, confirm the patient and the operative plan, and go through anticipated critical events. Communication failures and errors in the operating room are common (Lingard et al. 2004, Nagpal et al. 2010b, Nagpal et al. 2010a), however, communication and information exchange can be enhanced with preoperative briefings (Lingard et al. 2005, Lingard et al. 2008, Paige et al. 2008). In the *Sign out*, the operation performed is verified along with the plan of further treatment on the ward. The aim is to transfer important information from the surgeon and anaesthesiologist to the personnel responsible of the care after the surgery itself;

uncertainty and patient-related problems are associated with low-quality postoperative patient handovers (Reine et al. 2019).

In a pilot study conducted in eight hospitals across the world, the SSC improved compliance with standards and reduced morbidity and mortality (Haynes et al. 2009). In that study, consisting of more than 7,500 non-cardiac surgical patients, inpatient complications and death rate declined by a third after the implementation of the checklist. Especially the rate of surgical site infections and unplanned reoperations decreased (Haynes et al. 2009). A sub-analysis of urgent patients showed a decrease in complication rate by a third and the death rate declined by two thirds (Weiser et al. 2010).

The checklist was launched in Europe in 2009, and in Finland its use was encouraged by the recommendation of Managed Uptake of Medical Methods program in 2010 based on a review article in the Finnish Medical Journal (Pauniaho et al. 2009). A Finnish pilot study on checklist implementation showed enhanced communication and enhanced awareness of patient-related issues (Takala et al. 2011).

In a more recent international multicentre study (Abbott et al. 2018) and a European point prevalence study (Jammer et al. 2015), SSC use was associated with reduced mortality, but not with reduced complications. In a study on gastric surgery patients, the overall rate of risk-adjusted surgical morbidity was reduced during a 30-day follow-up after SSC implementation, yet wound complications or SSIs did not show statistically significant decrease or decrease at all (Bliss et al. 2012). In contrast, in a British study on orthopaedic patients, the use of the checklist did not have a significant effect on mortality, complication rates, surgical site infections or reoperations (Sewell et al. 2011). Likewise, in a Canadian study on a mixed surgical patient selection, SSC implementation did not significantly reduce mortality or complications, however the rate of unplanned returns to the OR decreased significantly (Urbach et al. 2014). A study on paediatric surgical patients found no difference in perioperative complications after checklist implementation (O'Leary et al. 2016). Still, a systematic review and meta-analysis on mixed surgical patients on SSC effects on postoperative complications found a statistically significant reduction in any complication, SSI and mortality (Bergs et al. 2014). A Spanish study with multiple surgical specialties found no statistically significant reduction in overall adverse events, yet the rate of infectious adverse events decreased (Rodrigo-Rincon et al. 2015). When adapted to plastic surgery, the SSC did not reduce complications (Biskup et al. 2016). In a recent study by Australians, the SSC implementation on multispecialty surgical patient data reduced postoperative mortality, decreased the length of hospital stay and reduced mortality significantly in a 2–3 years post-implementation period (de Jager et al. 2019).

In a multinational pooled data on laparotomies the checklist was used more often in emergency operation than in elective surgery in high-income countries, and vice versa in low-income countries. The checklist use was associated with lower postoperative mortality (GlobalSurg Collaborative 2019). The most recent study by Ramsay et al. on a Scottish surgical multispecialty data showed a reduction in inpatient mortality and reduced return to the theatre with checklist implementation (Ramsay et al. 2019). Studies have shown the SSC implementation to enhance safety consciousness in the OR (Ayabe et al. 2017, Cabral et al. 2016), and a Japanese study found the checklist to shorten operation time, instead of lengthening it (Ayabe et al. 2017). The use of a surgical checklist is simple and cheap, and could indirectly save money (Semel et al. 2010), reduce excessive work and diminish the suffering of patients. There is a need for a surgical checklist in all surgical specialities (McConnell et al. 2012), and especially in neurosurgery (Wong et al. 2012a).

2.3.2.2 Neurosurgery checklists

In neurosurgery, various, mainly local, checklists have existed for years (Table 1). At Mayo Clinic, Lyons et al. developed a short checklist for neurosurgical operations to improve quality and surgical patient safety. In an 8-year follow-up, no wrong-side or wrong-patient operations was detected (Lyons 2010). In Germany, an advanced perioperative checklist with team time-out similarly resulted in no errors after implementation (Oszvald et al. 2012). In spine surgery, checklists have reduced infections (Ryan et al. 2014) and wrong-level operations (Vachhani et al. 2013). More procedural specific checklists have been developed, aiming to reduce ventricular drainage associated infections (Hommelstad et al. 2013, Kestle et al. 2016, Kubilay et al. 2013, Lee et al. 2018). However, in a previous study the impact of the checklist was not significant when the combination of checklist and antibiotic-impregnated catheters and interventions were assessed separately (Harrop et al. 2010). A checklist for endovascular interventions adapted from the WHO SSC reduced adverse events, such as wrong item opened at the beginning of the procedure or excessive radiation exposure to the patient or staff, and enhanced communication (Fargen et al. 2013). A checklist for deep-brain stimulation operations reduced errors, such as incomplete pin set and failure to run simulation prior to cannulisation, during one-year follow-up (Kramer et al. 2012).

Table 1. Checklists in neurosurgery.

Author, year	Aim of the checklist	Intervention	Number of patients	Main outcomes
Harrop et al. 2010	To reduce ventriculostomy-related infections	A standardised catheter insertion protocol with antibiotic-impregnated catheters	1,961	Protocol alone did not significantly reduce infections yet the use of antibiotic-impregnated catheter did reduce infections significantly
Lyons 2010	To develop a tool to maintain and improve patient safety in the operating rooms	An operative site checklist	6,345	No wrong-site, wrong procedure or wrong patient events with the checklist
Kramer et al. 2012	To improve error rates in deep brain stimulation surgery	Deep brain stimulation surgery checklist	28	The checklist significantly reduced minor and major errors (e.g. incomplete pin set, failure to relax x-coordinate, failure to run simulation prior to cannulisation, failure to have appropriate x-translation)
Oszvald et al. 2012	To implement and analyse the effects of an advanced perioperative checklist with a "team time-out”	Advanced perioperative checklist	12,390	With perioperative checklist 2 wrong-sided operations; No errors occurred during the advanced perioperative checklist
Fargen et al. 2013	To improve communication and reduce adverse events during neurointerventional procedures	A neurointerventional procedural checklist	131	Checklist improved the perceived communication and reduced the total number of adverse events (e.g. wrong item opened at the beginning of the procedure, access obtained before ‘ time out’ performed, excessive radiation exposure to the patient or staff, creatinine not checked, heparin dose delayed or accidently not given)
Hommelstad et al. 2013	To determine the efficacy of a protocol in reducing shunt infection rate	A perioperative protocol	901	The infection rate of children aged <1 year did reduce statistically significantly, yet the overall infection rate of the study patient population did not

Vacchani et al. 2013	To assess the effect of the Universal Protocol on wrong-site surgery in neurosurgery	The Universal Protocol	22,743	After the protocol, there was statistically significantly less wrong-site surgery events, and no wrong-procedure or wrong patient events
Kubilay et al. 2013	To decrease ventricular catheter-associated infections	A ventriculostomy placement bundle including an antimicrobial-impregnated catheter	2,928	The external ventricular drainage infection rate decreased statistically significantly throughout the study period
Ryan et al 2014	To reduce instrumented spine infection rate in paediatric patients	The Texas Children's Hospital spine surgery protocol	168	A significant reduction in surgical site infections with the protocol
Kestle et al. 2016	To reduce cerebrospinal fluid shunt infection rate	A Hydrocephalus Clinical Research Network protocol wit antibiotic- impregnated catheters	1,670	The use of antibiotic-impregnated catheters with the checklist did not markedly reduce infections compared to checklist use alone
Lee et al. 2018	To implement a shunt surgery checklist and evaluate its impact on shunt infection rate	A paediatric shunt surgery checklist	NA (1,813 procedures)	A significant reduction in shunt infections with the checklist

2.3.2.3 Main concerns with checklists

Any organisational or procedural change may cause resistance among employees. Proper introduction and good leadership support the success of the implementation of a new procedure (Fourcade et al. 2012, Haugen et al. 2019a, Russ et al. 2015b, Treadwell et al. 2014). The checklist, or any safety procedure, should be executed because of its purpose and the benefit it will provide, not just for the sake of executing it and "ticking boxes". The checklist should fill a need for a change of acting (Thomassen et al. 2011). Historically, surgeons have been known for their "surgeon egos", and arrogant and overconfident behaviour, posing challenges to the implantation of changes and effective of teamwork (Myers et al. 2018).

Hospital staff have encountered difficulties with implementing and complying with the WHO checklist (Fourcade et al. 2012, Russ et al. 2015b, Vats et al. 2010). In addition, the WHO checklist has been noticed to be more beneficial in developing than developed countries (GlobalSurg Collaborative 2019). This discrepancy has been suggested to be caused by the differences in implementing the WHO SSC and with the higher rate of baseline complications in developing countries, however these discussions and conclusions are merely speculative (de Jager et al. 2016)

It has been discussed that if the appropriate use of checklists could hinder all preventable errors, the potential postoperative complications would be reduced only by about 50% (Kable et al. 2002). This 50% decrease is achieved with enhancing teamwork and communication and with proper timing of the checklist use. Yet, it remains unclear how the rest of unwanted surgical side effects in the surgical field could be prevented. In a Canadian study on neurosurgical patients and in two British studies on multiple surgical subspecialties, checklist compliance has been noticed to be suboptimal (Gagne et al. 2016, Pickering et al. 2013, Russ et al. 2015a). However, proper implementation, constant supervision and encouragement, and using an electronic checklist can lead to better results (Gitelis et al. 2017, Hannam et al. 2013, Jelacic et al. 2019, Saturno et al. 2014, Sendlhofer et al. 2015). Checklist use has been seen to lower postoperative complications, especially with full checklist completion (Mayer et al. 2016, van Klei et al. 2012). User driven modification and cutting down the checklist enhanced checklist use with better implementation results (Yu et al. 2017). Using a large wall-mounted poster SSC and sharing the responsibility of going through the checklist phases among the OR team (migrated leadership) enhanced compliance and checklist completion (Ong et al. 2016). Staff insecurity, negative attitude towards the checklist and lack of teamwork have been reported to decrease adherence to SSC use (Schwendimann et al. 2019). Using a checklist is experienced differently by team members in the OR, and all those aspects should be considered to succeed in checklist implementation and use (Thomassen et al. 2010).

3 Aims

The aims of this study were

I) to study the impact of checklist implementation on safety-related issues in the operating room, and on postoperative adverse events in neurosurgical patients;

II) to analyse surgical site infections (SSI) after neurosurgical operations, and to determine whether the checklist implementation would have an impact on the reported SSIs;

III) to assess whether the use of the WHO Surgical Safety Checklist would have an impact on the number and causes of reoperations due to surgical complications in neurosurgery;

IV) to systematically review the current state of literature on surgical checklists in neurosurgery.

4 Materials and Methods

The study protocol was reviewed by the Ethics Committee of Hospital District of Southwest Finland (285/2009) and accepted by the Chief of Operative Group of Turku University Hospital (15/09, 49/09, O16/12), and the registry database was formed following national legislation in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

4.1 Study design, patients and methods

4.1.1 Pilot study (I)

In 2009, the WHO Surgical Safety Checklist was implemented in four Finnish hospitals in a prospective pilot study: a structured multiple-choice questionnaire was directed to surgeons, anaesthesiologists and circulating nurses (Appendix 3.) in consecutive operations during a six-week period before and after the implementation of the surgical safety checklist. Between the two study periods, an interim of two weeks was held, during which the checklist was introduced to all surgical team members. The original checklist was translated with minor changes in order to suite the Finnish OR environment. All original steps of the checklist were maintained. Participation in the study was voluntary in emergency operations. The results of the questionnaire on multispecialty surgical patient data, and a subanalysis in otorhinolaryngology patients on communication and attitudes of the personnel are reported elsewhere (Helmio et al. 2011, Takala et al. 2011).

Adverse events of neurosurgical patients operated in Turku University Hospital, who were in the neurosurgical subgroup of the pilot study, were retrospectively analysed from electronic patient records. Altogether 228 neurosurgical procedures were performed during the study period. Of these, the personnel answered the questionnaire in 162 procedures. The patients involved in these procedures were tracked down and included in an adverse event analysis. Children were excluded. The operations included in the analysis were the first operations of each hospital stay. These criteria excluded three children and eight procedures on same patients. One procedure was excluded due to inadequate operation information. The total number of patients studied was 150: 83 before and 67 after the checklist implementation (Figure 1).

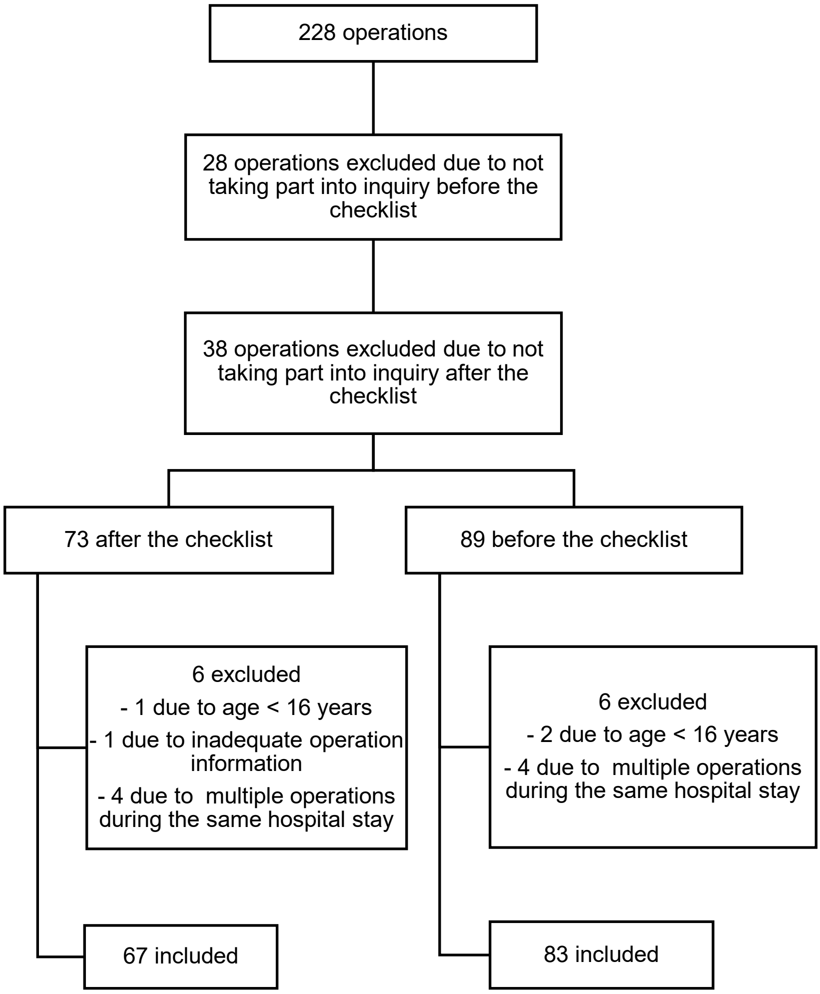


Figure 1. Exclusion and inclusion of neurosurgical patients into the adverse event analysis from the operations performed during the questionnaire pilot study period.

The length of hospital stays and predetermined adverse events were systematically collected from the electronic patient records. The durations of hospital stay and stays in the intensive care unit postoperatively, and time periods between first operation, unplanned reoperation, discharge and unplanned readmission were monitored. In order to be included in the analysis, the reasons for an unplanned reoperation or readmission needed to be related to the primary operation. Furthermore, the electronic patient records were compared with the electronic OR records to assess the consistency and accuracy of recorded diagnoses and procedure codes.

After the primary operation, adverse events were monitored for 30 days, and after reoperation or readmission for 120 days. The monitored adverse events were: stay in the ICU longer than 24 hours; decreased level of consciousness longer than 24 hours in the ICU; mechanical ventilation longer than 48 hours; readmission to the ICU; unplanned reoperation; acute renal failure; sepsis; septic shock; systemic inflammatory response syndrome; myocardial infarction; pulmonary embolism; intracranial haemorrhage; cerebral infarction; meningitis; pneumonia; blood loss of 500 ml or more during the operation, or bleeding requiring the transfusion of at least four units of red blood cells; cardiac arrest requiring cardiopulmonary resuscitation; deep-vein thrombosis; wound disruption; surgical site infection; surgical site haematoma or seroma; cerebrospinal fluid leakage from the wound; cerebrospinal fluid deposit of the surgical site; pressure ulcer; peritonitis caused by shunt infection; paresis; urine retention; unplanned readmission, and death. Urinary tract infection was not considered as a complication. Diagnosed infections and suspected infections treated with antibiotics, excluding urinary tract infections and upper respiratory tract infections, were all monitored.

4.1.2 Hospital-acquired infection study (II)

The HAI register of the Turku University Hospital was searched for SSIs reported on neurosurgical patients operated on between January 1, 2007, and December 31, 2011. The infection categories were: superficial or deep incisional SSI, organ/space SSI such as intracranial abscess, bacterial or fungal meningitis, ventricular shunt infection, spinal abscess or discitis, infection of an orthopaedic implant of spine, and other surgical infection. Infections were considered as HAIs if they occurred within 30 days after surgery or within one year, when foreign material was involved.

The validity of the HAI register was evaluated by an infection control nurse, who compared the reported infections in 2007–2011 to positive microbiological cultures, laboratory test results and the usage of antibiotics found from electronic patient records of all neurosurgical ward patients, and to the annual infection prevalence results. Yearly, 35–74 cases missing from the HAI register were evaluated, and 3–14 additional wound infections (superficial or deep incisional SSI, deep organ SSI) per year were found. All non-reported infections were added to the HAI register and included in this analysis. Thus, the reporting coverage of the neurosurgical ward of all infections was 71–88%.

The search resulted in 239 infections in 217 patients who underwent 236 operations, representing 4.0% of the total amount of neurosurgical operations (N=5,943) during the study period. The electronic patient records were then manually examined by an independent reviewer not directly involved in the treatment of neurosurgical patients (M. Westman) and by an infectious disease consultant (H. Marttila). After reviewing the data, the infection category was changed if applicable. Two infections of two patients were excluded, as they appeared not to be surgical infections in more careful examination. Lumbar drainage of cerebrospinal fluid and duplicates of infections reported twice with different infection categorisation were excluded. These criteria led to the exclusion of 13 infections. Thus, the number of infections in 2007–2011 was 226.

The years included in the study period were divided into three tertiles (January through April; May through August; September through December). The WHO Surgical Safety Checklist (Appendix 2. (Takala et al. 2011)) was introduced and implemented in the beginning of May 2009. The study period was divided into two based on this date. The patients and infections were divided into these two groups according to the operation date. The second tertile in 2009 was considered as a ‘grey area’ regarding the use of the checklist and was therefore excluded, excluding 10 infections from the study. In order to balance the number of patients before and after the implementation of the checklist, the third tertile in 2011 and its 17 infections were excluded, resulting in 199 infections (Figure 2). Eventually, the compared study periods were January 2007–April 2009 and September 2009–August 2011 with 95 and 104 infections, respectively. The final data comprised of 187 individual patients. Before the checklist implementation, there were 90 individual patients, of which six patients had two separate infections. After the implementation, the corresponding figures were 103 and two patients, respectively. One patient was represented twice in the group before and once in the group after the implementation. Three patients were represented once in both groups. The total numbers of neurosurgical operations during the two study periods were 2,342 before and 2,336 after the checklist implementation, respectively.

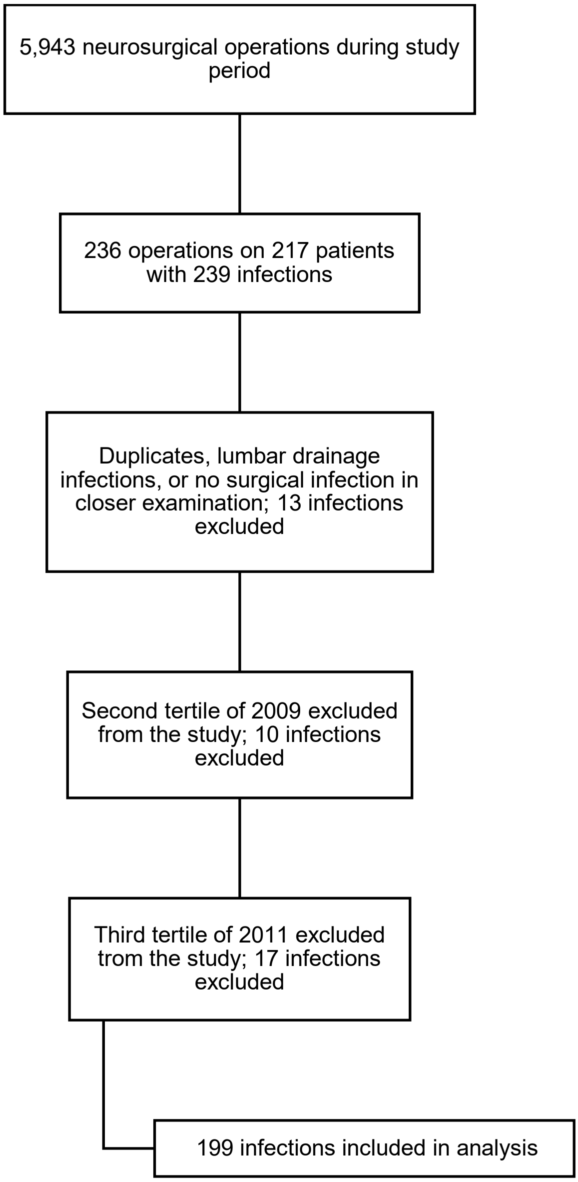


Figure 2. Exclusion and inclusion of neurosurgical patients into the adverse event analysis from the operations performed during the questionnaire pilot study period.

4.1.3 Reoperation study (III)

We searched the discharge data and the hospital registry for operations and procedures of Turku University Hospital from January 2007 to June 2011 in order to specify neurosurgical primary operations leading to a reoperation due to a neurosurgical complication. Predetermined ICD-10 diagnosis codes (G00, G03, G04, G06, I20-I22, I46-I50, J15, J16, T80, T81, T84, T85, T88) and surgical procedure codes based on Nomesco classification (AAF20, AAF25, AAF90, AAMxx, AAUxx, AAWxx, ABWxx, AWxxx, NAC92, NAG99, NASxx, NAT20, NAWxx, PAUxx, PAWxx, ZSA00, ZSN00, ZST00) were searched from the registries to identify all neurosurgical complication-related reoperations. The search gave 291 hits on 249 complication-related reoperations. Electronic patient records for all identified patients were examined, and reoperations that were not associated with a neurosurgical complication or preceding neurosurgery were excluded. In addition, two reoperations were excluded as the preceding neurosurgical operation took place more than 10 years before. These criteria led to the exclusion of 54 reoperations. Of the remaining 195 reoperations, 20 were excluded as the preceding neurosurgical procedure was performed before January 2007. This resulted in 175 reoperations defining the included complication episodes and primary operations; a complication episode was regarded to start from the preceding neurosurgical procedure (later: primary operation), which led to the complication-related reoperation.

The study period (January 2007–June 2011) was divided into two periods based on the date of the primary operation and the implementation of the WHO surgical safety checklist: January 2007–April 2009 was defined as the period before the checklist and May 2009–June 2011 as the preriod after the checklist. There were 103 episodes before and 72 after the checklist implementation (Figure 3). The groups consisted of 100 patients before and 70 patients after the checklist. Two patients in both groups had two separate complication episodes. Another two patients were included in both groups: one patient had two separate complication episodes before and one after the checklist, and another patient had one episode before and one after the checklist. Thus, the total number of patients in the data is 166. However, each complication episode was analysed separately, and the total number of studied episodes was 175.

The electronic patient records were manually checked for predetermined adverse events by an independent reviewer not involved in the treatment of neurosurgical patients (M. Westman). Considered adverse events were infection, bleeding, cerebrospinal fluid leakage, shunt complications, error (in diagnosis, in treatment or during surgical procedure), and delay in diagnosis and/or treatment. Also, the diagnosis of the primary operation and the time span from the primary operation to the complication-related reoperation were recorded.

The complications of each complication episode leading to reoperation were retrospectively analysed and categorised to theoretically preventable and unpreventable events based on a consensus of two experienced specialists in neurosurgery (M. Rahi and A. Kotkansalo). An infection was considered as preventable if the contamination or the clinical factors enabling the infection could have been prevented by proper sterile precautions or antibiotic prophylaxis. Other adverse events (bleeding, cerebrospinal fluid leakage, error, delay) were considered preventable when due to suboptimal human action assessed by two neurosurgeons. If the time period between the primary operation and the onset of complication leading to a reoperation was longer than 4 years, infections and shunt-related complication were considered unpreventable. Infections of patients prone to infections, or complications due to contributory factors (e.g. arm of spectacles) leading to skin erosion and exposure of the shunt system were considered as unpreventable. All cases were individually analysed.

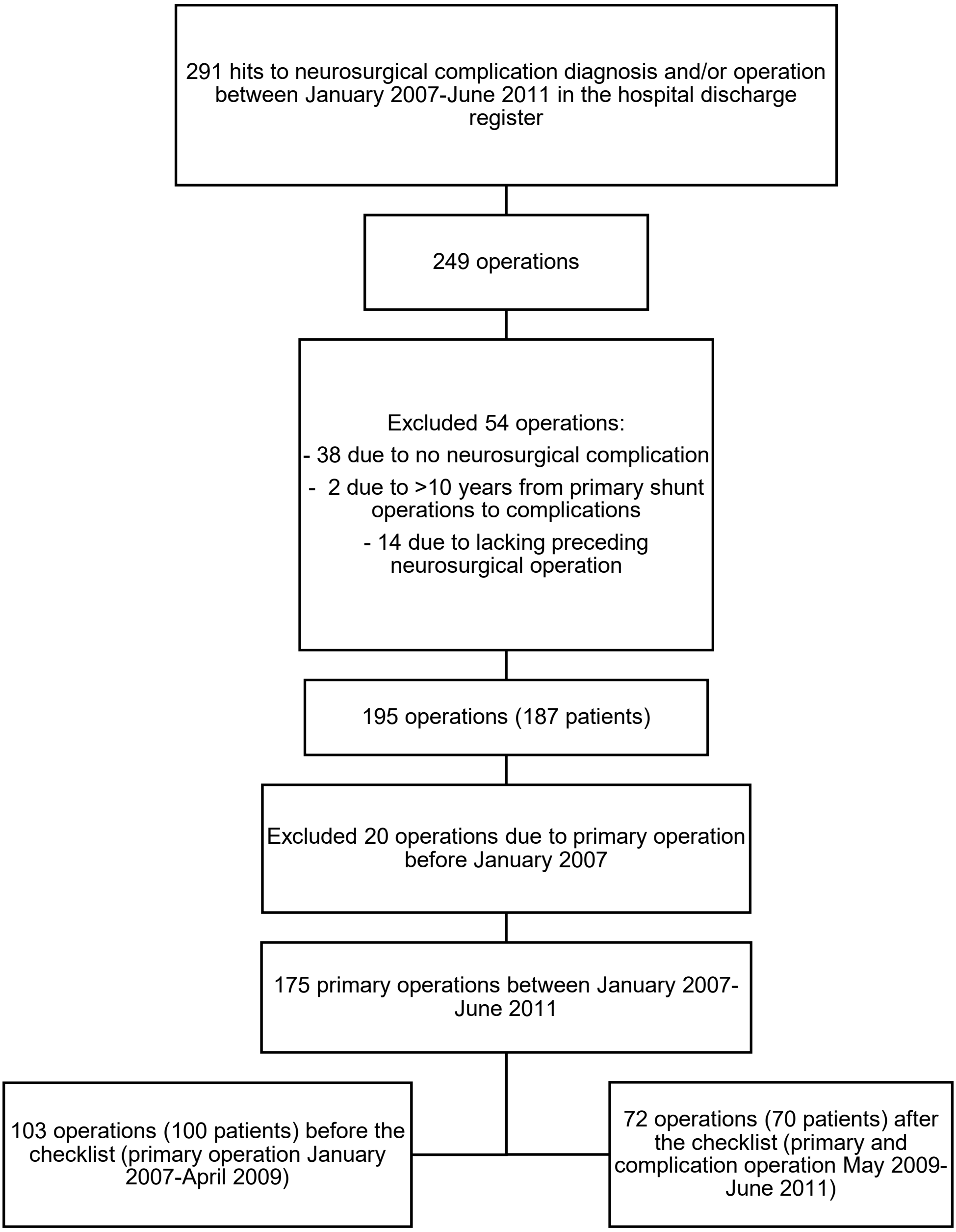


Figure 3. Exclusion and inclusion of the neurosurgical complication-related reoperations to the comparison analysis.

4.1.4 Systematic review (IV)

The study question was formulated according to PICO (population, intervention, comparison, outcome) principles (Figure 4).

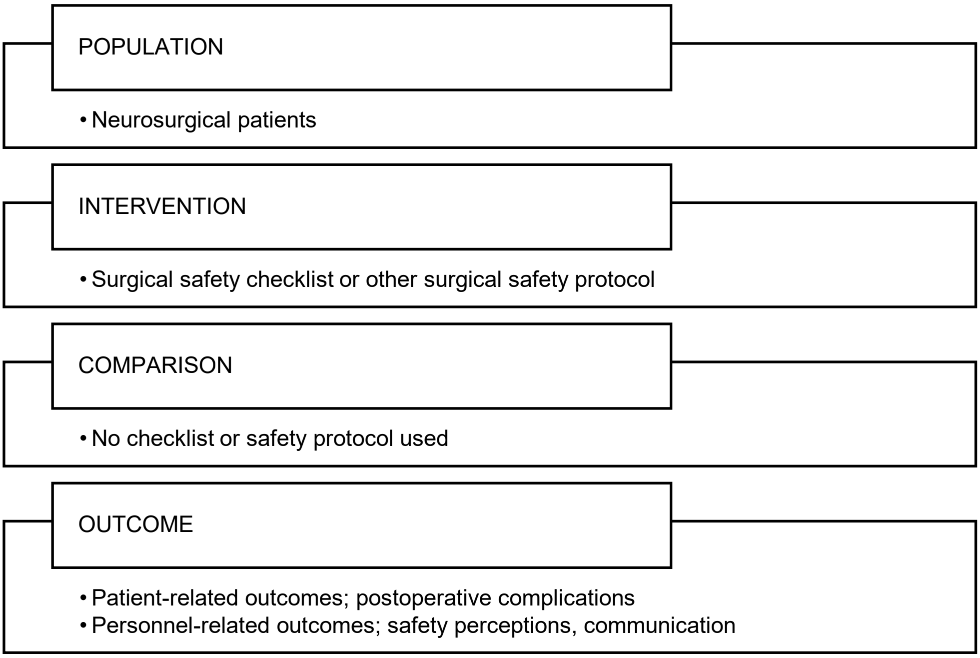


Figure 4. Formulation of the study question of the systematic review.

Search criteria for systematic PubMed search

A systematic PubMed search for articles published between 1 January 2008, and the search date 30 November 2015 was carried out using medical subject heading (MeSH) terms and keywords describing postoperative complications and surgical adverse events, neurosurgery, spine surgery and central nervous system surgery, surgical checklist, patient safety and protocol.

Eligibility criteria and results of search

Studies in English language on both paediatric and adult patients were included. Studies that included a mixed surgical patient population with a subgroup of neurosurgical patients were included. Neurovascular procedures were also included. Articles with incorrect intervention were excluded. Studies including major patient safety procedures besides the checklist other than infection prophylaxis were excluded. The features of the materials used in the surgical procedures, such as antibiotic impregnated sutures of catheters, were not regarded as an intervention itself. In addition, studies not including postoperative infections or patients in their data were also excluded. After the removal of duplicates, all references were screened based on the title and abstract by one of the authors (M. Westman), and the results on inclusion and exclusion were controlled by a colleague author (T. Ikonen). The search gave 1,243 hits, of which 4 original articles and 1 review met the inclusion criteria.

Another systematic search and results

To map out more studies and reviews, another systematic search on Cochrane Database of Systematic reviews and Cochrane Central Register of Controlled Trials, EMBASE and MEDLINE was carried out by an information specialist in June 2016 with the same search and eligibility criteria as in the first systematic search. The keywords used included the following: neurosurgery, neurosurgical procedures, orthopaedics, orthopaedic procedures, general surgery, surgical procedures, and checklist. This search gave 474 hits on original studies and 44 reviews. Two new original articles were found; one new article on patient-related outcomes and one on personnel-related outcomes. Seven reviews met the inclusion criteria. Reviews that described the literature search in specific enough detail were included (Figure 5).

Additional searches on PubMed and on authors' own reference libraries were carried out along the process, latest being carried out in January 2019. Altogether, these searches resulted in 16 new articles meeting the inclusion criteria: 10 articles on patient-related outcomes, 3 articles on personnel-related outcomes, and 3 reviews.

Details from articles meeting the inclusion criteria were collected and systematically filed in three tables: studies with patient-related outcomes, studies with personnel-related outcomes, and systematic and other reviews. The data was then cross-checked by the authors. A meta-analysis was not carried out as the data in the original articles was not specific enough.

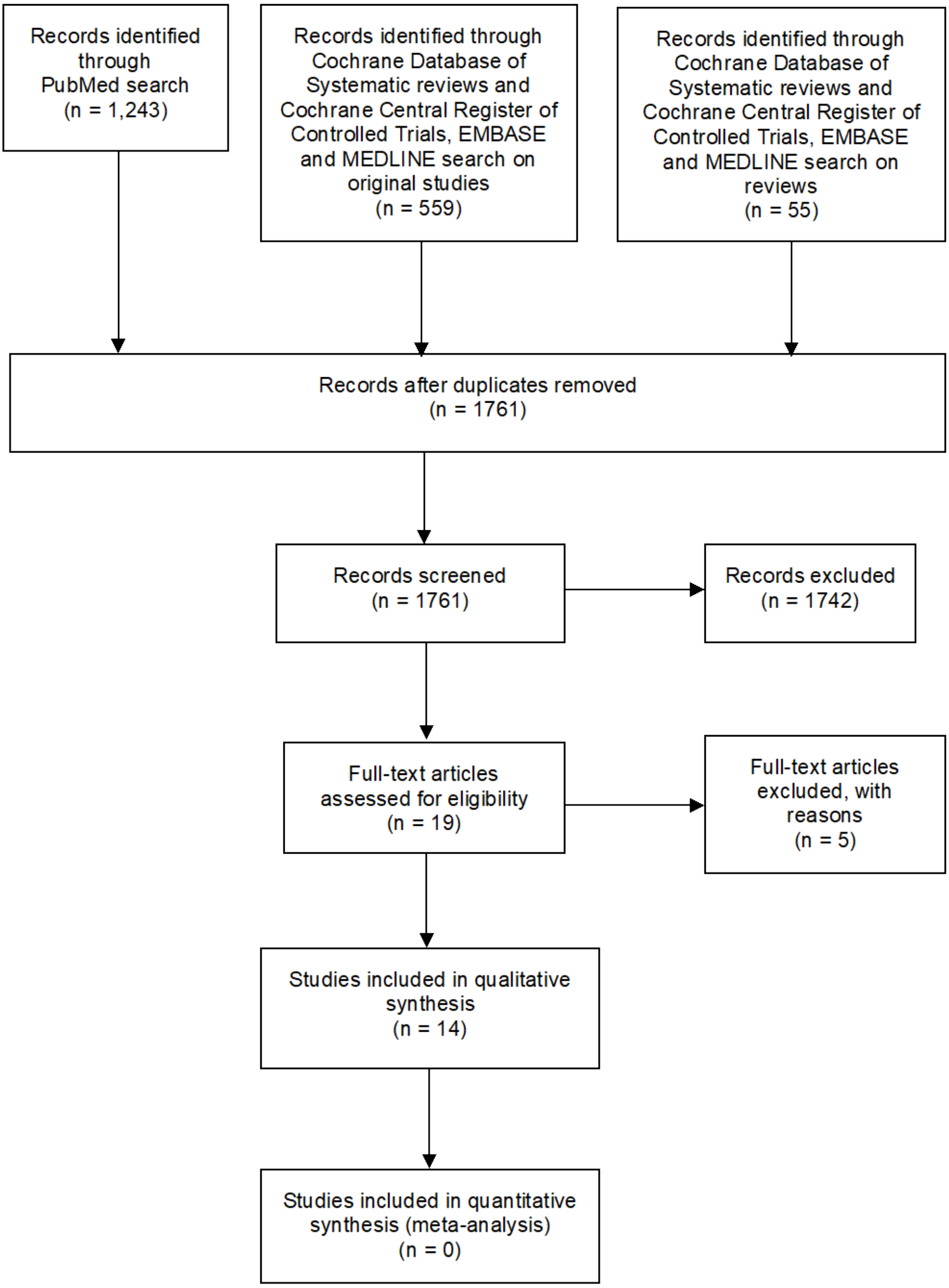


Figure 5. Exclusion and inclusion of articles to the review from the systematic searches.

4.1.5 Statistical analysis or analysis methods

Categorical data are described as counts and proportions. For proportions, 95% confidence intervals (CIs) were calculated. Numerical data is summarised with mean and standard deviation.

For numerical variables, the normality of the distributions of the variables was tested with the Kolmogorov—Smirnov test. If normality assumption was met (age), comparison between groups before and after checklist implementation was performed with the independent sample t-test and of non-normally distributed numerical variables (durations and periods, average complication rate) using a nonparametric Mann—Whitney U-test. Association between categorical variables between groups was tested using the Pearson's chi-square test.

Similarly, baseline characteristics in hospital-acquired infection study (gender, age, time between operation and infection) and reoperation study (gender, age at the time of primary operation, age at the time of complication, time between primary operation and complication-related reoperation) were compared before and after checklist implementation using Fisher’s exact test or Chi-square test (categorical variables), one-way analysis of variance (normally distributed variables), the Mann—Whitney U-test or the Kruskal-Wallis test (non-normally distributed variables). Time to infection from operation before and after checklist implementation was compared with the Wilcoxon test and presented with the Kaplan-Meier curve. Fisher’s exact tests were also performed to study association between infection subgroup and microbe findings, timing and urgency of the operation, and the level of experience of the operator, and also between infection subgroup and the implementation of the ‘time out’ phase of the checklist was performed or not. Fisher’s exact test was also used in reoperation study when proportions before and after checklist use were compared with primary operation, diagnosis, complications and preventable adverse events.

Even though data included some patients with two separate adverse events, all adverse event episodes were considered as independent observations.

A p-value less than 0.05 (two-tailed) was considered statistically significant. The statistical analysis was performed with SPSS 17.0 for Windows or using SAS software (version 9.3 for Windows).

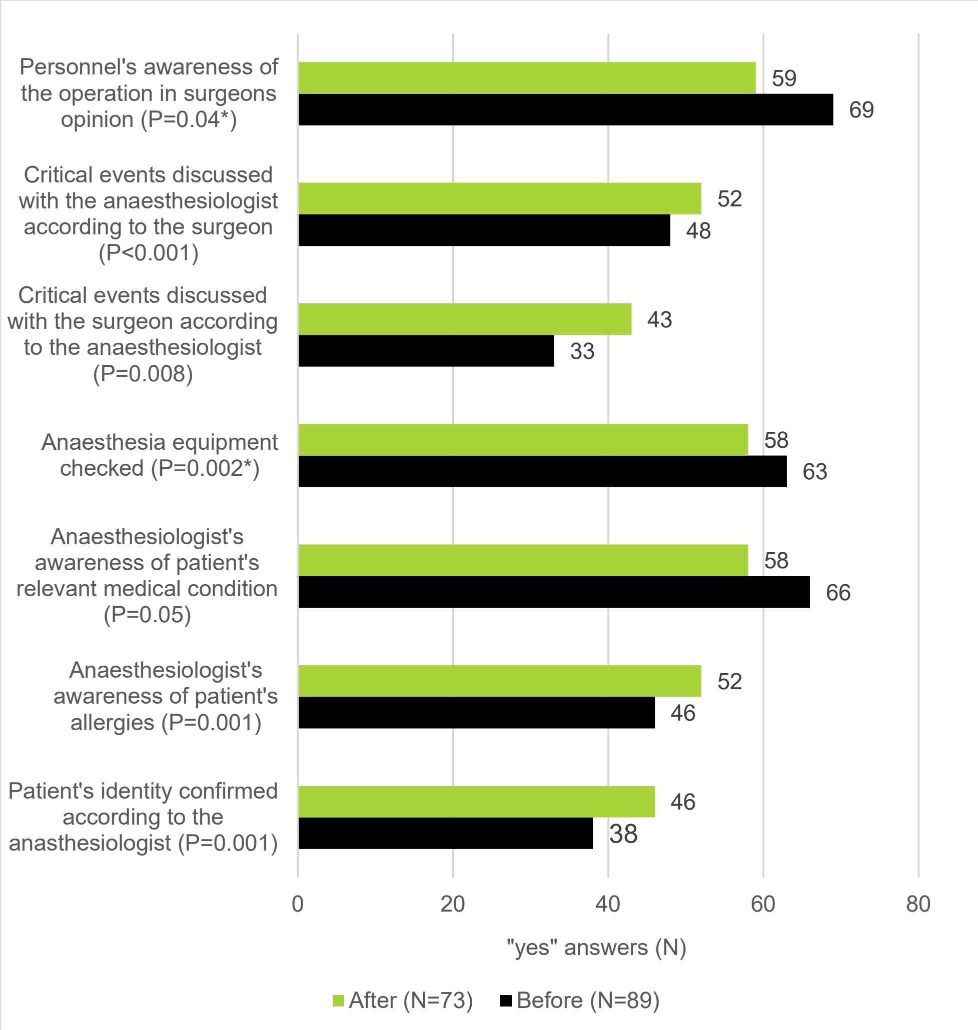
The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed in reporting the results of the systematic review.

5 Results

5.1 Pilot study (I)

Personnel outcomes

The statistically significant results of the questionnaire study are presented in Figure 6. Missing answers were included in the analysis, representing 3%–16% of answers per question. When regarding the “yes” answers of all the answered questionnaires, the possible critical events during the operation were discussed more often after the checklist implementation according to both surgeons (“yes” answers 54% versus 71%, $p<0.001$) and anaesthesiologists (37% versus 59%, $P=0.008$). The anaesthesiologists confirmed the patient’s identity more frequently when the checklist was used, and the awareness of patient’s allergies and relevant medical condition improved. When the checklist was used, the anaesthesia equipment was checked more frequently, and the surgeons’ opinion of other OR personnel’s awareness of the operation increased. The checklist did not significantly improve the confirmation of the sterility of instruments (98% versus 95%) or the checking of the availability of cross-matched blood products when a blood loss of over 500 ml was expected (54% versus 67%). The checklist did not change the awareness of the names and roles of each team member, the awareness of the procedure or the procedure side, or the giving of postoperative prescriptions or instructions, nor did it improve the perceptions of the successfulness of communication in the OR. The proper timing of the antibiotics failed both before and after the checklist implementation on average in every third operation (27% versus 37%).



* Fischer’s exact test

Figure 6. Percentage of anaesthesiologists’ and surgeons’ “yes” answers in the questionnaire regarding safety-related issues in the operating room in neurosurgical operations.

Patient outcomes

During the first 6 weeks of the study period, that is, before the checklist, the number of patient days on the neurosurgical ward was 1,165, and during the 6 weeks when the checklist was used, the number was 1,061.

The rate of unplanned readmissions was 25% before and 10% after the checklist implementation (P=0.02). The readmissions consequent on the primary operation were 11% and 3%, respectively (P=0.07). Number of patients with wound complications decreased from 19% to 8% (P=0.04). The durations of hospital stay or stay in the ICU or the other recorded time periods did not show a statistically significant difference between the patient groups. Table 2 presents the occurrence of recorded adverse events perioperatively and postoperatively.

There were no events of acute renal failure, sepsis or septic shock, systemic inflammatory response syndrome, pulmonary embolism, myocardial infarction, or cardiac arrest requiring cardiopulmonary resuscitation in either of the patient groups. A total of 4 (5%) patients before the checklist implementation and 1 (2%) patient after the implementation had a postoperative stroke. None of the deaths (2 patients before and 1 patient after the checklist implementation, respectively) were related to a recorded complication. The overall adverse event rate was 58% before and 46% after the checklist implementation (P=0.16). On average, patients who had complications had 1.78 adverse events before and 1.25 adverse events after the checklist (P=0.12).

The use of the checklist improved accuracy in the documentation of the diagnosis and the procedure of the operation. Before the checklist, the diagnoses recorded were missing or discordant in 33% of the cases, whereas with the checklist, there was a discrepancy between the two diagnosis records in 19% (P=0.07). Between the procedure records, the discrepancy declined from 18% to 6% (P=0.03), respectively.

Table 2. Adverse events in neurosurgical patients included in the adverse event analysis before (N=83) and after (N=67) the implementation if the checklist.

Adverse event	Before the checklist; N(%)	After the checklist; N (%)	P-value
Perioperative adverse events			
Blood loss of ≥ 500 ml during the operation and/or bleeding requiring transfusion of at least four units of red blood cells	12 (14.5)	8 (11.9)	0.625
Decreased level of consciousness > 24 h in the ICU (natural)	2 (2.4)	0 (0.0)	0.502
Decreased level of consciousness > 24 h in the ICU (sedation)	10 (12.0)	7 (10.4)	0.759
Mechanical ventilation > 48 h	9 (10.8)	5 (7.5)	0.479
Stay in the ICU > 24 h	13 (15.7)	10 (14.9)	0.901
Unplanned postoperative events			
Readmission to the ICU	2 (2.4)	1 (1.5)	1.000
Unplanned reoperation[1]	16 (19.3)	6 (9.0)	0.076
Unplanned readmissions, within 30 days postoperatively	15 (18.1)	5 (7.5)	0.057
Unplanned readmissions, all[2]	21 (25.3)	7 (10.4)	0.020
Wound complications			
Wound complications combined[3]	16 (19.3)	5 (7.5)	0.038
Wound dehiscence	3 (3.6)	0 (0.0)	0.254
Surgical site infection	8 (9.6)	3 (4.5)	0.347
Other wound complication[4]	8 (9.6)	2 (3.0)	0.186

Other adverse events (within 30 days posteoperatively)			
Any infection (≥1)[5]	11 (13.3)	9 (13.4)	0.974
Meningitis	6 (7.2)	6 (9.0)	0.698
Pneumonia	4 (4.8)	2 (3.0)	0.692
Deep vein thrombosis	1 (1.2)	0 (0.0)	1.000
Intracranial haemorrhage, during the hospital stay	4 (4.8)	3 (4.5)	1.000
Miscellanneous[6]	8 (9.6)	2 (3.0)	0.186

[1] Period between primary operation and unplanned reoperation 7.19 ± 8.479 before and 6.22 ± 6.591 days (mean± SD) after the checklist ($p = 0.771$)

[2] Period between primary operation and unplanned readmission 15.73 ± 8.111 before and 14.00 ± 8.093 days (mean ± SD) after the checklist ($p = 0.684$)

[3] A patient may have more than one wound complication

[4] Includes haematoma or seroma of the surgical site, cerebrospinal fluid from the wound, and cerebrospinal fluid deposit of the surgical site

[5] Includes treatment of diagnosed and suspected infections

[6] Includes pressure ulcer, peritonitis caused by shunt infection, paresis or hemiparesis, error during the operation, and urine retention

5.2 Hospital-acquired infection study (II)

The analysis of the HAI register consisted of 199 neurosurgical postoperative surgical site infections in a data of 4,678 neurosurgical operations between 2007 and 2011. The percentage of SSIs was 4.1% (N=95) before and 4.5% (N=104) after the checklist implementation, in populations of 2,342 and 2,336 operations, respectively. The difference was not statistically significant.

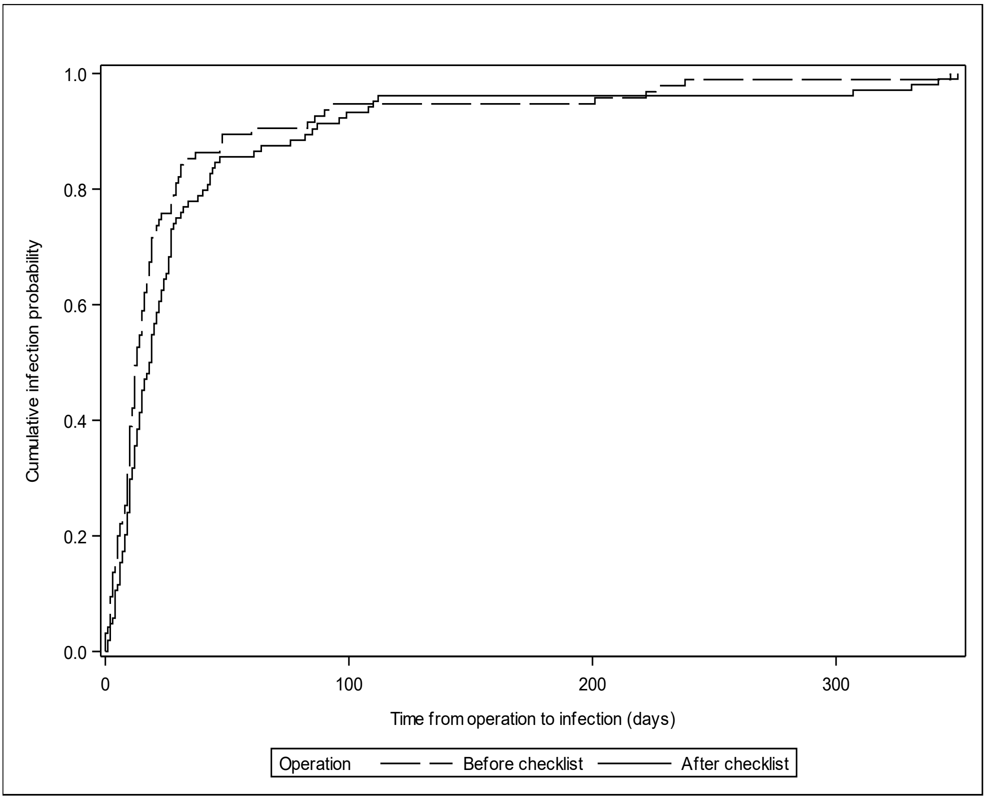


Figure 7. Time to infection from the operation as days before (N=95) and after (N=104) the checklist implementation (P=0.0394, Wilcoxon rank sum test).

Figure 7 presents the time from operation to infection for patients with a registered SSI before and after checklist implementation. The postoperative infections occurred earlier before the checklist implementation than after implementation (P=0.039). Figure 8 presents the time distribution of SSIs before and after checklist implementation, indicating the difference in the occurrence of SSIs within 30 days postoperatively. The distribution of SSIs in

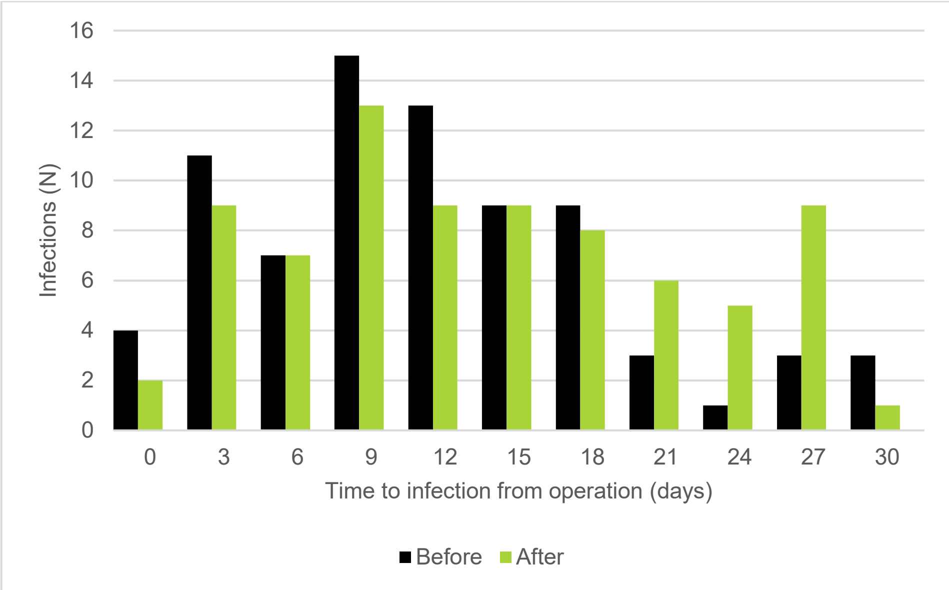


Figure 8. Number of infections before (N=78, 82% from N=95) and after (N=78, 75% from N=104) within 30 days postoperatively.

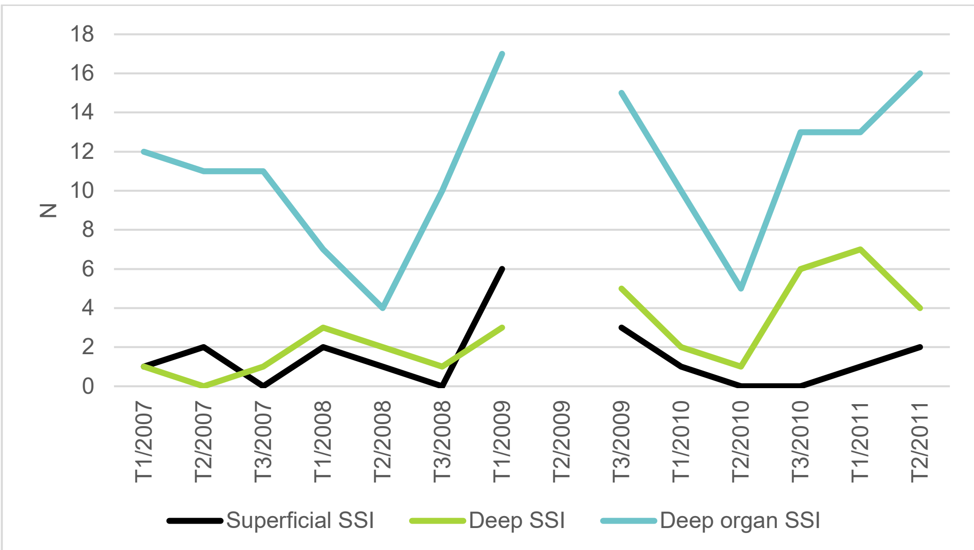


Figure 9. Number of infections per tertile in 2007–2011.

tertiles is presented in Figure 9. During the whole observation period, there was considerable variation in the numbers of infections by tertiles. No association of infection rates to seasonal variation, inpatient occupancy rate, or the number or occupational status of the operating neurosurgeon was noticed. Table 3 shows the infections before and after the checklist implementation categorised in subgroups. There were no statistical significances. When proportioned to the total number of neurosurgical operations during the study period, the number of deep organ SSIs was rather the same.

Table 3. Neurosurgical postoperative infections before (N=95) and after (N=104) the checklist implementation.

	Before the checklist			**After the checklist**		
Infection subgroup	**N (%)**	**Proportion of all neurosurgical operations (N=2,342)**	**95% Confidence Intervals (%)**	**N (%)**	**Proportion of all neurosurgical operations (N=2,336)**	**95% Confidence Intervals (%)**
Superficial SSI	12 (12.6)	0.51	0.27-0.89	7 (6.7)	0.30	0.12-0.62
Deep SSI	11 (11.6)	0.47	0.23-0.84	25 (24.0)	1.1	0.69-1.6
Deep organ SSI	72 (75.8)	3.1	2.4-3.9	72 (69.3)	3.1	2.4-3.9

5.3 Reoperation study (III)

The primary operations leading to complication-related reoperations represented 3.9% (N=103) and 2.6% (N=72) of 2,665 and 2,753 neurosurgical operations, before and after the checklist, respectively. Of the studied complications, 85% (N=88) and 75% (N=54) were categorised as preventable before and after the checklist, respectively (P=0.12). When proportioned to the total number of neurosurgical operations during the study period, the preventable complications leading to reoperation were significantly lower after the checklist implementation, 3.3% (CI 2.7–4.0%) before vs. 2.0% (CI 1.5–2.6%) after.

Classified diagnoses of all complication-related reoperations are presented in Table 4A, and according to their preventability in Table 4B. Most frequently, the reoperations were caused by wound infections. There was no statistically significant difference between the groups in any individual diagnosis. However, the rate of wound infections as a cause for reoperation was significantly higher before (N=47) than after (N=28) the checklist, representing 1.8% and 1.0% of the total number of neurosurgical operations, respectively (P=0.02) (Table 4A). Also, the proportion of preventable wound infection diagnoses decreased significantly from 1.7% (N=44) to 0.8% (N = 23) (P=0.0067) after the implementation of the checklist (Table 4B).

The reoperations were categorised into preventable (N=142) and unpreventable (N=33) according to the preventability of the complication leading to the reoperation. When examining the distribution of clinical diagnoses (Table 4B), there was a significant difference in preventability (P=0.01). The majority of the operations with wound infection diagnosis were categorised as preventable (67 vs. 8) and they represent higher proportion of preventable than unpreventable complications (47% preventable vs. 24% unpreventable). On the other hand, complications of spinal or other implants (11 vs. 12 operations) were relatively more frequently unpreventable than preventable (8% preventable vs. 36% unpreventable). These results support the internal validity of the assessment of individual patient charts concerning preventability.

Table 4A. Comparisons of complication-related reoperations after primary operations before and after the checklist implementation for all reoperations classified by diagnosis codes of the complication-related reoperation or hospital stay.

Diagnosis	**All complication-related reoperations**	
	Before the checklist (N=103) **N (%)**	**After the checklist (N=72)** **N (%)**
Meningitis	2 (1.9)	0 (0.0)
Empyema/abscess of CNS	3 (2.9)	3 (4.2)
Haemorrhage or haematoma complicating a procedure	14 (13.6)	18 (25.0)
Disruption of wound	11 (10.7)	9 (12.5)
Wound infection (excl. septicaemia)	47 (45.6)	28 (38.9)
Foreign body or substance left following procedure	1 (1.0)	1 (1.4)
Other/Unspecified postoperative complication	7 (6.8)	3 (4.2)
Complications of spinal implants or other implants (excl. septicaemia)	15 (14.6)	8 (11.1)
Other complication of surgical or medical care	3 (2.9)	2 (2.8)
P-value (Fisher's exact test)	0.65	

Table 4B. Comparisons of complication-related reoperations caused by preventable and unpreventable complications classified by diagnosis codes of the complication-related reoperation or hospital stay.

Diagnosis	**Reoperations caused by preventable complications (N=142)**		**Reoperations caused by unpreventable complications (N=33)**	
	Before the checklist (N=88) N (%)	**After the checklist (N=54) N (%)**	**Before the checklist (N=15) N (%)**	**After the checklist (N=18) N (%)**
Meningitis	2 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)
Empyema/abscess of CNS	2 (2.3)	3 (5.6)	1 (6.7)	0 (0.0)
Haemorrhage or haematoma complicating a procedure	12 (13.6)	13 (24.1)	2 (13.3)	5 (27.8)
Disruption of wound	11 (12.5)	6 (11.1)	0 (0.0)	3 (16.7)
Wound infection (excl. septicaemia)	44 (50.0)	23 (42.6)	3 (20.0)	5 (27.8)
Foreign body or substance left following procedure	1 (1.1)	1 (1.9)	0 (0.0)	0 (0.0)
Other/unspecified postoperative complication	6 (6.8)	3 (5.6)	1 (6.7)	0 (0.0)
Complications of spinal implants or other implants (excl. septicaemia)	7 (8.0)	4 (7.4)	8 (53.3)	4 (22.2)
Other complication of surgical or medical care	3 (3.4)	1. (1.9)	0 (0.0)	1 (5.6)
P-value (Fisher's exact test)	0.77		0.15	

When comparing the before and after groups, there were no statistically significant difference between the groups in absolute numbers of adverse events (Table 5). Yet, when proportioned to the total number of neurosurgical operations per study period, before or after checklist respectively, there was a significant change in infection prevalence. The rate of infection-related reoperations decreased significantly after the checklist implementation (2.5% vs. 1.6%, before and after, respectively, P=0.02; Figure 10A). Even stronger association was found when comparing preventable infection complications leading to neurosurgical reoperations (2.2% vs. 1.2%, before and after, respectively, P=0.006) (Figure 10B).

Other adverse events (bleeding, cerebrospinal fluid leakage, shunt complications, error in diagnosis and/or treatment, delay in diagnosis and/or treatment) did not indicate statistically significant differences before and after the introduction of the checklist, but the number of events was small (Table 5). There were no significant differences in the occurrence of different complications when using the checklist (Table 6).

According to the operating room records (October 2009–June 2011), the average adherence to perform 'time out' (at least the 'time out' phase performed) was 78% for all neurosurgical operations after the checklist implementation. At least one of the three phases of the checklist was used in 68% (N=49) of the studied primary operations since the checklist introduction in May 2009 (N=72); All phases ('sign in', 'time out', 'sign out') were performed in 73% (N=36) of these operations, and in additional 24% (N=12) of the operations, at least 'time out' was performed, resulting in a 67% (N=48) compliance rate with performing 'time out'. In the primary operations leading to a preventable complication, any phase of the checklist was used in 70% (N=38) of the operations; all phases were performed in 76% (N=29) of the operations, and at least the 'time out' phase was performed in additional 9 operations. Thus, the overall compliance with performing 'time out' was 70% (N=38) in primary operations preceding a preventable complication.

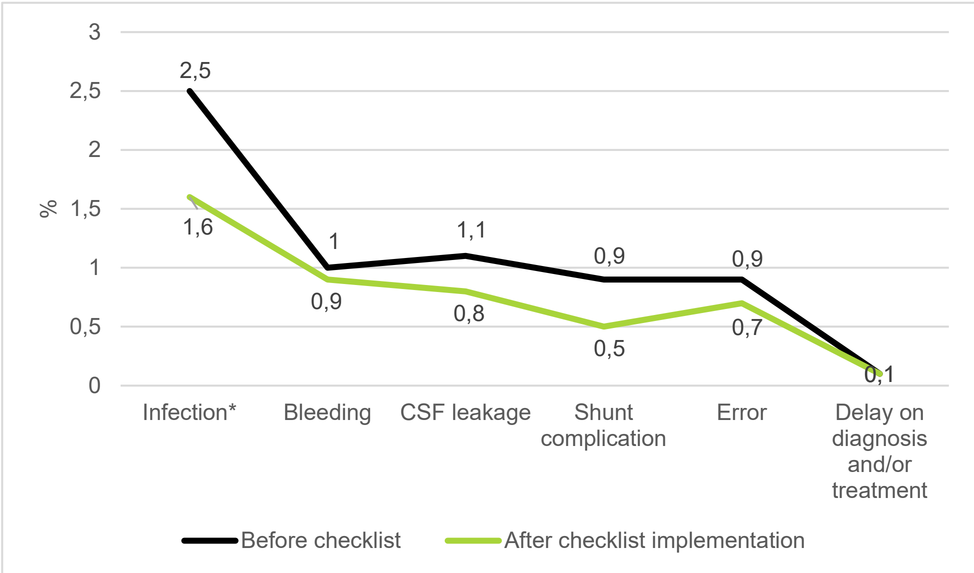


Figure 10A. All complication-related reoperations proportioned to the total number of neurosurgical operations. Change in infections before and after checklist implementation statistically significant, P=0.02*

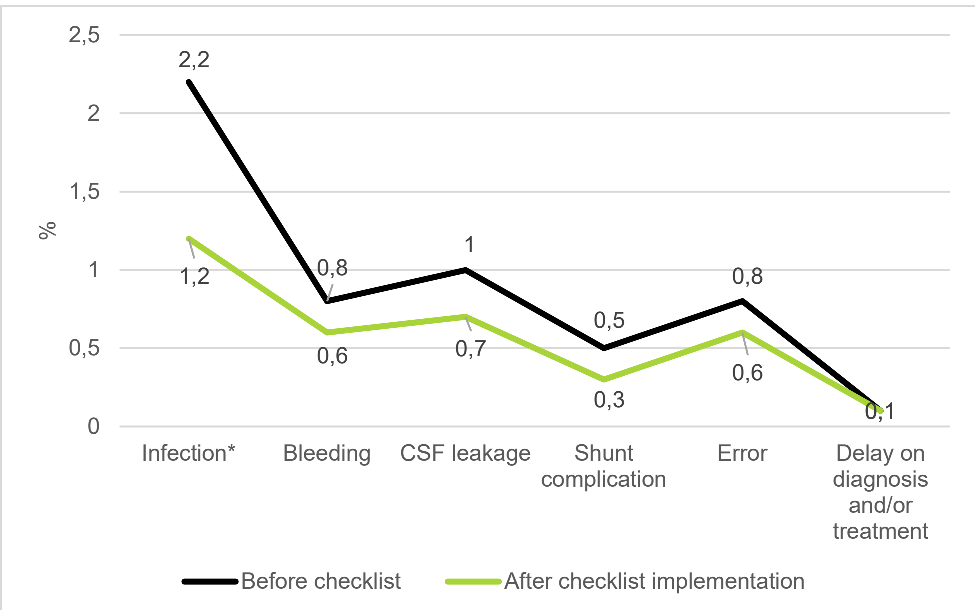


Figure 10B. Reoperations caused by preventable complications proportioned to the total number of neurosurgical operations. Change in infections before and after checklist implementation statistically significant, P=0.006*.

Table 5. Fisher's exact test comparison of adverse event groups following primary operations before and after the checklist implementation for all complication-related reoperations and reoperations caused by preventable complications.

	All complication-related reoperations			**Reoperations caused by preventable complcations**		
	Before the chceklist (N=103) **N (%)**	**After the checklist (N=72)** **N (%)**	**P-value**	**Before the chceklist (N=103)** **N (%)**	**After the checklist (N=72)** **N (%)**	**P-value**
Infection						
Yes	66 (64.1)	43 (59.7)	0.64	59 (89.4)	34 (79.1)	0.17
No	37 (35.9)	29 (40.3)		7 (10.6)	9 (20.9)	
Bleeding						
Yes	26 (25.2)	26 (36.1)	0.13	21 (80.8)	18 (69.2)	0.52
No	77 (74.8)	46 (63.9)		5 (19.2)	8 (30.8)	
CSF leakage						
Yes	29 (28.2)	23 (31.9)	0.62	27 (93.1)	20 (87.0)	0.64
No	74 (71.8)	49 (68.1)		2 (6.9)	3 (13.0)	
Shunt complication						
Yes	23 (22.3)	14 (19.4)	0.71	13 (56.5)	9 (64.3)	0.74
No	80 (77.7)	58 (80.6)		10 (43.5)	5 (35.7)	
Error						
Yes	23 (22.3)	19 (26.4)	0.59	22 (95.7)	17 (89.5)	0.58
No	80 (77.7)	53 (73.6)		1 (4.3)	2 (10.5)	
Delay in diagnosis and/or treatment						
Yes	3 (2.9)	4 (5.6)	0.45	3 (100.0)	4 (100.0)	-
No	100 (97.1)	68 (94.4)		0 (0.0)	0 (0.0)	

Table 6. The use of the WHO surgical safety checklist in the primary operation compared with each of the categorised adverse events after checklist implementation.

	Use of the checklist in the primary operations after the checklist implementation		
	Yes (N=49) **N (%)**	**No (N=23)** **N (%)**	**P-value***
Infection			
Yes (N=43)	30 (69.8)	13 (30.2)	0.80
No (N=29)	19 (65.5)	10 (34.5)	
Bleeding			
Yes (N=26)	14 (53.9)	12 (46.1)	0.068
No (N=46)	35 (76.1)	11 (23.9)	
CSF leakage			
Yes (N=23)	18 (78.3)	5 (21.7)	0.28
No (N=49)	31 (63.3)	18 (36.7)	
Shunt complication			
Yes (N=14)	10 (71.4)	4 (28.6)	1.00
No (N=58)	39 (67.2)	19 (32.8)	
Error			
Yes (N=19)	10 (52.6)	9 (47.4)	0.15
No (N=53)	39 (73.6)	14 (26.4)	
Delay in diagnosis and/or treatment			
Yes (N=4)	2 (50.0)	2 (50.0)	0.59
No (N=68)	47 (69.1)	21 (30.9)	

* Fisher’s exact test

5.4 Systematic review (IV)

All three studies of this thesis, the pilot study (I), the hospital-acquired infection study (II) and the reoperation study (III), are included in the review (Lepanluoma et al. 2015, Lepanluoma et al. 2014, Westman et al. 2018).

Patient-related outcomes (Table 7)

The search found only one RCT, and the rest of the studies were observational. After screening, we included fifteen studies covering over 58,000 patients in total, of which at least 32,400 were neurosurgical patients. Thirteen of the studies concerned on neurosurgical, neuroradiological or spine surgery patients (Belykh et al. 2019, Fargen et al. 2013, Flint et al. 2013, Harrop et al. 2010, Hommelstad et al. 2013, Kubilay et al. 2013, Lee et al. 2018, Lepanluoma et al. 2015, Lepanluoma et al. 2014, Oszvald et al. 2012, Rahman et al. 2012, Ryan et al. 2014, Westman et al. 2018), and two had a mixed surgical specialty patient population, also including neurosurgical patients (Haugen et al. 2015, O'Leary et al. 2016). In the RCT study, the WHO SSC was implemented in two Norwegian hospitals in five surgical subspecialties, one of them being neurosurgery (the number of patients was not specified) (Haugen et al. 2015). Six studies concerned the WHO Surgical Safety Checklist (Belykh et al. 2019, Haugen et al. 2015, Lepanluoma et al. 2015, Lepanluoma et al. 2014, O'Leary et al. 2016, Westman et al. 2018). Three studies focused on paediatric patients (Lee et al. 2018, O'Leary et al. 2016, Ryan et al. 2014), reporting on 2,956 patients altogether. One study examined neurointerventional endovascular patients (number not reported) (Fargen et al. 2013). Eleven of the fifteen studies had statistically significant findings. The follow-up time in the studies varied between 30 days and 4 years. Excluding the paediatric studies, the patient groups were rather similar in terms of patient-related factors, such as age.

Hospital-acquired infections were reduced in all studies when assessed (Belykh et al. 2019, Flint et al. 2013, Haugen et al. 2015, Hommelstad et al. 2013, Kubilay et al. 2013, Lee et al. 2018, Lepanluoma et al. 2015, Lepanluoma et al. 2014, O'Leary et al. 2016, Rahman et al. 2012, Ryan et al. 2014, Westman et al. 2018). Harrop et al. found a reduction in SSI only when a protocol included an antibiotic impregnated shunt catheter (Harrop et al. 2010). According to the RCT study by Haugen et al., the use of a surgical safety checklist led to a significant reduction (from 6.0% to 3.4%, $P<0.001$) in overall infections, including sepsis, SSI, urinary tract infections, and other infections. When examined separately, the reduction in SSIs was not statistically significant, from 2.2% to 1.5% ($P=0.149$). The number of surgical wound ruptures, on the other hand, reduced significantly (from 1.2 % to 0.3%, $P<0.001$) (Haugen et al. 2015). In the study by O’Leary et al., the reduction was rather marginal and there was no difference in the overall complication rate between the groups before and after checklist implementation (O'Leary et al. 2016). However, Fargen et al. and Haugen at al. found a significant reduction in overall complication rates (Fargen et al. 2013, Haugen et al. 2015); complications were reduced from 19.9% to 11.5% ($P<0.001$) in the RCT (Haugen et al. 2015).

Reoperation rates and reoperations due to infectious complications were assessed in one study showing a statistically significant reduction (Lepanluoma et al. 2015). In the same study, preventable complication-related reoperations were reduced. In another study by the same group, unplanned readmissions were found to reduce significantly (Lepanluoma et al. 2014). In a study by Oszvald et al., there was one wrong-sided cranial operation and one wrong-sided spinal operation before the perioperative checklist and none after its implementation (Oszvald et al. 2012). The RCT by Haugen et al. did not find a significant reduction in mortality or in the length of hospital stay (Haugen et al. 2015).

Compliance with the surgical safety checklist process was reported to vary between 63.7% and 97% (Lee et al. 2018, Ryan et al. 2014), and according to Ryan et al., non-compliance with the checklist process was associated with a higher infection rate (Ryan et al. 2014).

Table 7. Surgical Safety Checklists in Neurosurgery: Original studies with patient-related outcomes.

Author, year	Target population; study design	Intervention; number of patients	Control intervention or control group; number of patients	Inclusion and exclusion criteria	Aim of the study	HAI	Other outcomes	Follow-up time
Belykh E et al., 2019	Posterior spinal fusion surgery patients; Retrospective; Observational	Surgical Protocol for Infections (including WHO SSC), Nonhealing Wound Prophylaxis, and Analgesia; 113 patients	Procedures before protocol implementation ; 35 patients	Patients undergoing posterior or posterolateral spinal fusion during 1-year period	To reduce the risk of SSIs and the incidence of poor wound healing and postoperative pain	Minor SSIs 34% vs. 10% before and after protocol	Protocol use did not increase surgical time; Study patients required less pain medication and pain severity within first 72 hours was lower; earlier active rehabilitation in study group; Positive personnel effects (not reported numerically)	3 months
Lee R et al., 2018	Paediatric shunt surgery patients; Retrospective, Observational	Shunt checklist; 889 shunt procedures	Procedures before the shunt checklist; 924 shunt procedures	All shunt procedures excluding external ventricular drains	To introduce an evidence-based shunt surgery checklist and evaluate its impact on the rate of shunt infections	Pre-checklist infection rate 3.03%, post-checklist 1.01%; absolute risk reduction 2.02%, relative risk reduction 66.6%	Average compliance rate to checklist 97%	12 months

Westman M et al., 2018[1]	NS; Retrospective, Observational	WHO SSC; 104 infections in 2,336 patients	Procedures before SSC implementation ; 95 infections in 2,342 patients	Postoperative infections in neurosurgical patients reported in the HAI register	To determine if the SSC implementation would have impact on reported SSI's	Overall HAI incidence 4.1% vs 4.5% before and after SSC introductions	A reduction in early postoperative infections yet not in the long run	30 days postoperatively, one-year post-operative if foreign material was implanted
O' Leary J et al., 2016	Paediatric surgical patients, mixed; Retrospective, Observational	Modified WHO SSC; 14,314 patients of which 3.1% neurosurgical (N=440)	Procedures before checklist implementation ; 14,458 patients of which 3.0% neurosurgical (N=436)	Children over 28 days of age admitted to hospital to undergo a surgical procedure as primary reason; neonates excluded	To determine whether surgical safety checklists are associated with reduced 30-day all-cause mortality and perioperative complications in children	SSI 1.68% vs.1.63% before and after checklist implementation , respectively	Perioperative complications did not significantly differ between groups; 4.08% before vs. 4.12% after checklist implementation	30 days post-operatively
Haugen AS et al., 2015	Mixed; RCT	WHO SSC; 2,263 patients	Procedures without SSC; 2,212 patients	Cardiothoracic, neurosurgery, orthopaedic, general, and urologic surgical procedures in 2 hospitals; All age groups and elective or emergency surgery; Procedures not involving all 3 parts of	To evaluate the impact of the WHO SSC on morbidity, mortality and LOS	Pneumonia 3.7% vs. 1.9% (P<0.001) before and after SSC introduction; Infections (sepsis, surgical site infection, urinary tract infection, other infection) 6.0% vs. 3.4% (P<0.001)	Overall complication rate (respiratory complications, cardiac complication, infections, surgical wound rupture, nervous system complication, bleeding, embolism, mechanical implant complication,	30 days post-operatively

				the checklist (i.e., γ-knife treatment or donor surgery) were excluded			complication, anaesthesia complication, all other complications, unplanned return to operation theatre, in-hospital death) 19.9% vs. 11.5% (P<0.001); Mortality 1.6% vs. 1.0% (P=0.151); LOS reduced from 7.8 to 7.0 days	
Lepän-luoma M et al., 2015[2]	NS; Retrospective, Observational	WHO SSC; 2,753 NS patients, 72 complication operations	Procedures before SSC implementa-tion; 2,665 NS patients, 103 complication operations	Neurosurgical complication-related reoperations, excluding reoperations not associated with a neurosurgical complication or preceding neurosurgery; preceding neurosurgical operation taken place more than 10 years previously or before January 2007	To determine if the implementation of the WHO surgical checklist had an impact on the occurrence and causes of reoperations due to surgical complications in neurosurgery; to detect whether there was a connection between complications	Wound infections as a cause for reoperation 1.8% vs. 1.0% of the total number of neurosurgical operations (P=0.02); Infection-related reoperations 2.5% vs. 1.6% (P=0.02); preventable infection complications leading to neurosurgical reoperations 2.2% vs. 1.2% (P=0.00)	Preventable complication-related neurosurgical reoperations 3.3% (95% CI 2.7%–4.0%) vs. 2.0% (95% CI 1.5%–2.6%)	NA

					and compliance with using the checklist			
Lepän-luoma M et al., 2014[3]	NS; Retrospective, Observational	WHO SSC; 67 patients	Procedures before SSC implement-tation; 83 patients	Patients of neurosurgical procedures where personnel answered a patient safety-related questionnaire; excluding children	To assess the impact of the implementation of the checklist on postoperative adverse events in neurosurgery	Wound complications 19% vs. 8% (P=0.04)	Unplanned readmissions 25% vs. 10% (P=0.02); the consistency of documentation of the diagnosis and the procedure improved	30 days postoper-atively
Ryan S et al., 2014	Paediatric spine surgery; Prospective, Observational	Texas Children's Hospital spine surgery protocol; 267 procedures	Procedures before protocol implement-tation; NA	All children undergoing complex instrumented spine surgery	To develop and implement a standardised protocol to reduce complex spine infection rate within 12 weeks of surgery	Infection rate 5.8% vs. 2.2% before and after protocol implementation , respectively	Overall compliance rate 63.7%; noncompliance with data collection form associated with higher infection rate on surgeon level	Minimum 12 weeks postoper-atively
Fargen KM et al., 2013	Neurointerventi onal procedures; Prospective, Observational	Neurointer-ventional endovascu-lar safety checklist; NA, 60 procedures	Procedures before checklist implementation ; 71 procedures, NA	Diagnostic or treatment neurointer-ventional procedures	Improve communication and reduce adverse events during neurointerventi onal procedures	-	Total number of adverse events in nine categories (pregnancy not addressed in woman of childbearing age; wrong item opened at beginning of	4 weeks before and after checklist imple-mentation

								procedure; creatinine not checked in patient 50+ or high risk; heparin dose delayed or accidently not given; maximum contrast dose exceeded; access obtained before 'time out' performed/ signed; access obtained with wrong or no patient name in computer; excessive radiation exposure to patient or staff; time delay due to poor communication) reduced from 35.2% to 10.0% (P=0.001) after the checklist implementation	
Flint AC et al., 2013	NS; External ventricular drain; Retrospective, Observational	EVD infection control protocol; 119 patients	Procedures before infection control protocol introduction; 143 patients	EVD placement performed in the ICU in 2005 to 2007 and 2009 to 2011; excluding	To determine whether the introduction of an evidence-based EVD infection control protocol could	CSF culture positivity 9.8% vs. 0.8% (P=0.001); ventriculitis 6.3% vs. 0.8% (P=0.02)	-	NA

				patients with pre-existing central nervous system infection, and patients who had an EVD that was placed outside ICU	reduce the rate of EVD infections			
Hommel-stad J et al., 2013	NS; Shunt surgery; Retrospective, Observational	A periopera-tive protocol; 607 patients	Patients before perioperative protocol; 294 patients	Patients undergoing shunt surgery	To determine the efficacy of a perioperative protocol in reducing shunt infection rate	The infection rate of children aged <1 year reduced from 18.4% to 5.7% (P=0.016), the overall infection rate did not reduce statistically significantly (6.5% vs. 4.3%)	Significant risk factors for shunt infection were age < 1year, premature birth, CSF leakage and high ASA score	12 months
Kubilay Z et al., 2013	NS; External ventricular drain; Retrospective, Observational	Ventricu-lostomy placement bundle; 2,928 patients of which 588 checklist-monitored	Infection rate before bundle implementa-tion; NA	Neurological surgery patients requiring ventricular drainage catheter placement admitted to the Neurointen-sive Care Unit	To study whether a ventriculostom y placement bundle implemented prospectively by a single institution with continuous feedback would decrease the	Infection rate before bundle implementation 9.2%; during the study period the rate decreased quarterly down to 0%; overall EVD infection rate was 0.46% after bundle implementation	-	4 years

					ventricular catheter–associated infection rate			
Oszvald A et al., 2012	NS; Retrospective, Observational	Advanced perioperative checklist with team time-out; 3,595 patients	Procedures before checklist advancement; 6,322 patients	All elective neurosurgical procedures	To demonstrate the implementation of an advanced perioperative checklist and to analyse its effect; to evaluate the feasibility of the checklist as well as the safety of the procedure and the occurrence of perioperative errors	-	With perioperative checklist there was 1 wrong-sided bur hole in an emergency case and 1 wrong-sided lumbar approach in an elective case; using the advanced perioperative checklist no error occurred	NA
Rahman M et al. 2012	NS; External ventricular drain; Retrospective, Observational	ELVIS-protocol, EVD checklist; 2,911 patients	Procedures before checklist implementation; 217 patients	Neurosurgical patients requiring ventricular drainage catheter placement	To decrease EVD-related infections	EVD infection rate 9.2% in early 2006 before implementation of the ELVIS protocol, 1.2% in 2007 ($p < .0001$), < 1% in 2008–2010 ($p < 0.0001$),	-	(4.5 years)

						and zero through the second quarter of 2011 ($p < .0001$)		
Harrop JS et al., 2010	NS; Ventriculo-stomy; Prospective, Observational	A standardised catheter insertion protocol with or without antibiotic-impregnated catheters; only protocol 281 devices, catheter A 195 devices, non-antibiotic-impregnated catheter 157 devices, catheter B 1001 devices	Preprotocol cases, 327 devices	Neurosurgical patients undergoing ventriculostomy between 2003 and 2008	To reduce ventriculostomy-related infections	Preprotocol infection rate 6.7%; with standardised protocol 8.2%; with catheter A 1.0%; with non-antibiotic-impregnated catheter 7.6%; with catheter B 0.9%	-	NA

[1] Hospital-acquired infections study (II)
[2] Reoperation study (III)
[3] Pilot study (I)

Personnel-related outcomes (Table 8)

Five questionnaire studies were included in the personnel-related outcome review. Two of the studies examining personnel-related outcomes also examined patient-related outcomes (Fargen et al. 2013, Lepanluoma et al. 2014). All of the studies (Fargen et al. 2013, Magill et al. 2017, McLaughlin et al. 2014, Wong et al. 2016), exept for one (Lepanluoma et al. 2014), were carried out in the United States. Altogether, the studies included 565 cases or team members, and the number of participants were quite similar between the studies.

All studies found that using a checklist improved communication and the perceptions of safety in the OR, yet McLaughlin et al. did not find that the 'time-out' would reinforce teamwork (McLaughlin et al. 2014).

Table 8. Surgical Safety Checklists in Neurosurgery: Original studies with personnel-related outcomes.

Author, year (Country)	Study design; target population	Intervention; number of study objects	Control intervention or control group; number of study objects	Inclusion and exclusion criteria	Aim of the study	Professional status	Outcomes
Magill S et al., 2017 (USA)	Questionnaire; NS	Postoperative debriefing; 149 responses	Safety attitudes before debriefing initiative; 112 responses	NA	Implement an initiative to routinely perform postoperative debriefs and evaluate the impact of debrief on OR safety culture	Neurosurgery residents and attendings, anaesthesia residents and attendings, OR nurses, and additional specialists such as neuro-physiologists and technicians involved in neurosurgery cases	Perceptions of OR safety improved and disparity between nurses and surgeons reduced; perceptions of patient safety improved; potential adverse events were prevented
Wong JM et al., 2016 (USA)	Questionnaire; NS	WHO SSC with CSF shunt surgery quality checks; 17 cases	Cases before checklist implementa-tion; 16 cases	New insertion and revision shunt procedures in both adult and paediatric patients were included; cases with additional concurrent procedure(s), removal of shunt hardware or	Creating neurosurgery-specific practice checks as a supplement to the WHO SSC; examining changes in adherence to key process measures as a result of checklist	Neurosurgeons, neuronurses, neuroanaesthe-siologists	Adherence to shunt-specific key processes increased; checklist was easy to use; feeling of preparedness

				externalisation only, and cases for which the OR staff deemed such observation to be disruptive were excluded	implementation; surveying members of the surgical team regarding perceived efficacy and ease of use of the augmented checklist		
Lepänluoma M et al., 2014 (Finland)[1]	Questionnaire; NS	WHO SSC; 76 operations	Operations before checklist implementation; 89 operations	Neurosurgical operations during 6 weeks before and after checklist implementation; voluntarily participation in emergency operations	Assess the impact of the implementation of the checklist on safety-related issues	Surgeons, anaesthesiologists, circulating nurses	Critical events discussed more often; did not improve perception of successful communication; systematic failure in antibiotic timing
McLaughlin N et al., 2014 (USA)	Questionnaire; NS	UCLA Health System surgical safety checklist, time-out process protocol; 93 surgical team members	NA	NA	Assess team members' attitudes regarding improved safety as a result of the pre-incision time-out process	Neurosurgery attendings and neurosurgery residents, anaesthesia attendings, anaesthesia residents, circulating registered nurses, scrub technicians, neuromonitoring technicians	Feeling of improving patient safety and promoting team spirit; time-out not reinforcing teamwork though increasing patient safety through information sharing

Fargen KM et al., 2013 (USA)	Questionnaire; neurointerven-tional procedures	Neurointerventional endovascular safety checklist; 60 procedures with 132 postprocedural surveys and final survey of 21 individuals	Procedures before checklist implementation; 71 procedures with 121 postprocedural surveys	Diagnostic or treatment neurointerventional procedures	Improve communication and reduce adverse events during neurointerventional procedures	Radiation technologists, nurses, neurointerventional physicians	Improved communication

[1] The pilot study (I)

Previous reviews (Table 9)

Altogether, 11 studies met the criteria for this review. Of these, seven reviews dealt with studies with both patient- and personnel-related outcomes (Ko et al. 2011, Lyons et al. 2014, Patel et al. 2014, Russ et al. 2013, Tang et al. 2014, Thomassen et al. 2014, Zuckerman et al. 2012), whereas four studies focused on patient-related outcomes (Bergs et al. 2014, Borchard et al. 2012, de Jager et al. 2016, Treadwell et al. 2014). One review, covering studies on almost 7,000 patients, had a solely neurosurgical focus and discussed the use of a general surgical safety checklist and other checklists in neurosurgery (Zuckerman et al. 2012). Another review also examined other original neurosurgical studies, but did not report the number of neurosurgical patients involved in the studies (Russ et al. 2013). Nine of the eleven reviews included a mixed patient population. Four of the eleven reviews examined solely or partially the WHO SSC (Bergs et al. 2014, de Jager et al. 2016, Patel et al. 2014, Treadwell et al. 2014). Six reviews defined an intervention as any checklist, surgical checklist, or protocol (Borchard et al. 2012, Ko et al. 2011, Lyons et al. 2014, Russ et al. 2013, Tang et al. 2014, Thomassen et al. 2014). The reviews included 7–30 articles each. Typical outcome measures included mortality, morbidity, postoperative complications, teamwork and communication, and compliance. Ko et al. and de Jager et al. found the quality of original studies to be low or suboptimal, and many studies having a high risk of bias (de Jager et al. 2016, Ko et al. 2011). According to Zuckerman et al., the evidence on the impact of checklist use with neurosurgical patients is sparse (Zuckerman et al. 2012).

The majority of the reviews found that a checklist is a useful, simple and cost-effective intervention in enhancing communication and patient safety in surgical patients. de Jager et al. were the only ones to criticise the power of the change the checklist creates, at least in developed countries, where the level of care is already considerably high. They also suggested that the changes seen so far may be temporal (de Jager et al. 2016).

Table 9. Surgical Safety Checklists in Neurosurgery: Systematic and other reviews analysing patient-related outcomes, compliance and staff perceptions.

Author, year	Literature search records, time period	Target population	Intervention	Purpose of the review	Inclusion and exclusion criteria	Number of studies included	Number of patients	Main outcomes	Conclusions	Comments
de Jager E et al., 2016	MEDLINE, CINAHL, Scopus, Cochrane and ProQuest, from 2007 to June 2015	Mixed	WHO SSC	Systematic literature review of the effects of the SSC on post-operative out-comes	English language, comparison to a control group, other checklists and bundle action - settings excluded	25 studies (various specialties), two randomised controlled trials, 13 prospective and 10 retrospective trials	5,995 patients in RCTs, over 341,000 patients in other trials of which 2 studies with only NS patients (12 540 patients)	Complications decreased in ten studies and increased in one; mortality decreased in four studies and increased in one; the quality of the studies was largely suboptimal	The checklist effect is greater in developing nations; it is possible that many of the positive changes associated with the use of the checklist were due to temporal changes, confounding factors and publication bias	A meta-analysis was not conducted as combining observational studies of heterogeneous quality may be highly biased
Bergs J et al., 2014	The Cochrane Library, MEDLINE, EMBASE and CINAHL until February 2013	Mixed, patients aged 16 years or older undergoing non-cardiac surgery	WHO checklist or other modification	Systematic review and meta-analysis	English language, only quantifiable results	7 studies (various specialties), 6 studies for meta-analysis	Number of patients not reported; number of patients or studies including NS	With checklist use risk ratio for any complication was 0.59, for mortality 0.77 and for SSI 0.57; a	The evidence suggests a reduction in postoperative complications and mortality, but cannot be regarded as definitive in the absence of higher-quality studies	All papers reported the results of non-randomised studies, resulting in potential bias

							patients not reported	strong correlation between checklist use and decrease in post-operative compli-cations		
Lyons VE et al., 2014	CINAHL, ProQuest, and MEDLINE	Mixed	Surgical checklist	Meta-analysis	English language, only quantifi-able results	19 studies (various specialties)	21,594 patients; number of patients or studies including NS patients not reported	Positive effect on teamwork and communi-cation, morbidity, mortality, and com-pliance with safety measures	Surgical safety checklists improve teamwork and communi-cation, reduce morbidity and mortality, and improve compliance with safety measures	This meta-analysis is limited in its gen-eralisability based on the limited number of studies, subjective measures, publication bias and hetero-geneity
Patel J et al., 2014	MEDLINE, EMBASE and PsycINFO, from 1946 to December 2012	Mixed	WHO checklist	Systematic review: surgical specialty, compli-ance, effects on outcomes, staff perceptions	English language	16 studies (all special-ties 10, paediatric surgery 2, orthopaedi c 2, otorhino-laryngolog y 2)	Number of patients not reported; number of patients or studies including NS patients not reported	No specified patient-related outcomes	Checklists improve patient outcomes subsequent to surgery; continual feedback to maintain compliance; NS surgeries were less commonly observed	High variability in the measured effects on patient outcomes, Hawthorne effect is considered a major limitation

Tang R et al., 2014	Pubmed, Medline, EMBASE, Cochrane and CINAHL, between January 2000 and December 2012	Mixed	Surgical checklist	Review of data from OECD member nations effective-ness and success-ful imple-mentation	English language, OECD countries	9 studies (general surgery, non-cardiac surgery 2, tertiary hospitals 2, cancer centre)	Over 42,000 patients; number of studies including NS patients not reported	The use of surgical checklists is limited in countries with numerous protocols; adequate checklist implemen-tation plays a central role	Effectively implemented checklists have potential to be effective at reducing complication and mortality	Conclu-sions for Australian context: evidence from OECD member countries is non-conclusive
Thomassen Ø et al., 2014	MEDLINE, Cochrane, Web of Science and EMBASE by May 2012	Mixed	Any checklist	To summarise the medical literature aiming to show the effects of safety checklists with various outcomes	Studies where checklist intro-duced a new method, procedure or action were excluded	34 studies (any surgery)	Over 60,000 patients, number of studies including NS patients not reported	Communi-cation improved, adverse events were reduced, adherence to standard operating proce-dures enhanced, morbidity and mortality were reduced	Safety checklists appear to be effective tools for improving patient safety in various clinical settings	None of the included studies reported negative effects on safety, no quantitative studies focusing on workflow
Treadwell JR et al., 2014	MEDLINE, CINAHL, EMBASE and	Mixed	WHO checklist, SUR-PASS	To sum-marise experi-ence with	Articles describing actual use of	33 studies (any surgery),	Over 8,100 patients; one review with NS	Surgical checklists offer a promising	Surgical checklists represent a relatively	Caveats: checklists are often imple-

	Cochrane from 1 January 2000 to 26 October 2012		checklist, a wrong-site surgery checklist, anaesthe-sia equipment checklist	surgical checklist use and efficacy for improving patient safety	anaesthe-sia equipment checklists were reported elsewhere	23 reports of WHO checklist implement ation; 10 studies with health outcomes	patients, number of NS patients not reported	interventio n for decreasing patient morbidity and mortality due to surgical operations	simple and promising strategy for addressing surgical patient safety worldwide; WHO SSC has been successfully adapted for implementation in a wide variety of settings; successful implementation is key	mented as part of a multifacete d strategy, reporting bias may play a role, all surgical checklists may not be beneficial
Russ S et al., 2013	MEDLINE, EMBASE, PsycINFO by Feb 2012 Google Scholar and Cochrane Database for Systematic Reviews by July 2012	Mixed	Any surgical safety checklist	Systematic review on the impact of surgical safety checklists on teamwork and communi-cation in the OR	English language, human subjects only	3 studies including NS, 18 studies other specialties	Over 4,600 responses from personnel pre- or post-interven-tion; 2 studies included neuro-surgical operations	No specified patient-related outcomes	Safety checklists improve the perceived and observed teamwork and communication in the OR, and reduce errors relating to poor team skills	Reports also possible negative impacts of checklist use on communi-cation and team function when checklist is used suboptimall y or not integrated into the process

Borchard A et al., 2012	MEDLINE including Pre-medline, EMBASE, Cochrane Collaboration Library, published between 1995 and April 2011	Mixed	Checklist or protocol; WHO, SURPASS, Universal Protocol	Systematic review, a random effects meta-analysis of effectiveness data was conducted if 2 or more studies reported a specified outcome	English, French and German languages; studies with patient-related outcomes, compliance or critical factors for implementation	22 studies (any surgery); 20 quantitative studies, 2 qualitative studies	Over 25,000 patients in 11 of 22 studies; one study with 6,345 NS patients	With the use of checklists, the relative risk for mortality is 0.57 [95% confidence interval (CI): 0.42–0.76] and for any complications 0.63 (95% CI: 0.58–0.67); the overall compliance rate ranged from 12% to 100% (mean: 75%) and for the Time Out from 70% to 100% (mean: 91%)	Checklists are effective and economic tools to decrease mortality and morbidity; explaining "why" and "how" the checklist should be used are the most critical factors for successful checklist implementation	Limitations concerning the method of review, heterogeneity of the studies, few high-quality and no randomised studies; insufficient to evidence-based recommendations
Zuckerman SL et al., 2012	MEDLINE and PubMed, reference lists of identified articles	All surgical fields, specific to NS	General SSC and diverse checklists for general, functional and vascular NS	A summary of previously published NS operative checklists	Any area of NS, any kind of checklist	8 NS studies; 22 other surgery	6,417 NS patients in 3 of 8 NS studies, rest not reported	No specified patient-related outcomes	Literature on the use of SSC in NS has been sparse; no checklist available for oncology or paediatric NS; neurosurgical awareness is needed	Reported patient outcomes sparse, discussion about the use of various kinds of checklists among standardised safety and quality measures

Ko HC et al., 2011	Cochrane Library, MEDLINE, CINAHL and EMBASE, published between 1980 and September 2009	ICU, emergency department, surgery and acute care patients	Paper-based safety checklists	Systematic review, whether the use of safety checklists, compared to not using checklists, improves patient safety in acute hospital settings	English language comparative studies; any patient-relevant clinical outcomes	9 cohort studies with historical controls of standard care: 1 study with surgical patients, 8 other studies (ICU, ED, acute care)	9,943 surgical, ICU or acute patients in 6 of 9 studies, number of NS patients unknown	Different checklists measured by different outcomes in a variety of settings suggest some benefits of safety checklists to protocol adherence and patient safety	More studies needed to enable confident conclusions in acute hospital settings	Studies generally of low to moderate quality and of low level of evidence; all but one study containing a high risk of bias

6 Discussion

6.1 Summary of study results

In the pilot study (I), the use of the WHO Surgery Safety Checklist (WHO SSC) improved safety-related performance in the OR, and a contemporary adverse event analysis showed a reduction in wound complications and unplanned readmissions. A closer analysis on HAI register data on postoperative neurosurgical infections (study II) found less early onset SSIs with the WHO SSC use but failed to show a decline in the total incidence of SSIs during the patients' follow-up up to one year. The implementation of the WHO SSC in routine use was associated with a decrease in preventable complication-related neurosurgical reoperations, especially those due to preventable infection-related complications. All infections leading to reoperations, including wound infections, and especially the infections categorised as preventable, decreased significantly after the checklist implementation (study III). The systematic review (study IV) found positive evidence on the use of various surgical checklists by reducing complications in general neurosurgery, paediatric neurosurgery and shunt operations. Checklists were found to enhance the safety culture in the OR by promoting teamwork and communication. Although we found improved safety-related performance and reduced complications associated with WHO SSC use, as an isolated intervention the WHO SSC is not enough to enhance all aspects of neurosurgical patient safety. However, with full WHO SSC compliance and combined with other safety proactive efforts, it could reach its full potential.

6.1.1 Wound and infection complications

The pilot study (I), the hospital-acquired infection study (II) and the reoperation study (III) showed reduction in all wound complications, in early onset SSIs in short term, and in infection-related reoperations, respectively. Multiple other factors may also have affected these results during the study period. According to some studies, work overload, nurse understaffing and work stress increase nosocomial infections (Hugonnet et al. 2007, Virtanen et al. 2009). Seasonal variations on the workload in the ward may have an impact on the surgical site infection rates. During the period before the checklist implementation in 2009, there were 9% more patient days on the neurosurgical ward than during the checklist period. Whether this difference was related to the use of the checklist or contributed to the adverse event rates, remains unanswered. Also, the risk of infections and complications has been stated to be higher in operations performed during duty hours (Kelz et al. 2008, Kelz et al. 2009). In the hospital-acquired infection study (II), the number of urgent neurosurgical operations performed during duty hours was higher than usual. There is also more variation in the ward workforce during duty hours, which can expose to higher risk of SSI. Also differences in the types of operations and surgical risks in terms of infection may affect the interpretation of the results.

The hospital-acquired infection study (II) showed a reduction of early onset infections in a short term but failed to show a decline in the total incidence of SSIs during the patients' follow-up up to one year. This might indicate the benefit of checklist checks targeted at the timing of prophylactic antibiotic and confirmation of sterility, which both influence the occurrence of early SSIs. The neurosurgical patient population is heterogenic with already prolonged hospital stay compared to many other surgical subspecialties. The total percentage of postoperative infections of 4.1-4.5% in this study material is in accordance with previous studies (Abu Hamdeh et al. 2014, Cassir et al. 2015, Kolpa et al. 2019, Lietard et al. 2008). The study institution has a fixed protocol for antibiotic prophylaxis in neurosurgery. During the pilot study (I) a systematic error was discovered in the timing of antibiotic prophylaxis leading to a premature antibiotic administration in neurosurgical operations (Lepanluoma et al. 2014, Takala et al. 2011). Interestingly, the infection rate declined already during the implementation of the WHO SSC, even though the timing error was noticed and corrected in late 2009 after the implementation had been completed. During the data collection of the reoperation study (III), information on the timing of antibiotics was unfortunately not registered in the electronic patient records used for other patient information, i.e. the information would have needed to be tracked down from anaesthesia patient records. This could be a focus of further studies. Other checklist-related explanations for the declined infection rate may include better awareness of patient-related risks (e.g. ASA score), readiness to compensate bleeding, and sterile instrument check. During the pilot study (I) period, no significant changes were made in the physical environment, treatment protocols, surgical materials or wound dressings which could have influenced the reduction of infections.

In previous studies, using a checklist has been proven to reduce postoperative complications during rather short observation periods (Fudickar et al. 2012, Haugen et al. 2015, Haynes et al. 2009, van Klei et al. 2012). In the hospital-acquired infection study (II), the occurrence of postoperative neurosurgical SSI's was examined over an almost five-year period, and the incidence of neurosurgical SSI's was rather constant. Changes in wound dressing materials or sutures, ward employment level, or the nursing care intensity did not explain the temporary fluctuation in infections. It has been reported that long working hours, higher work stress and poor collaboration among ward personnel correlates with incidence of hospital-acquired infections (Virtanen et al. 2009).

The higher number of deep SSIs after the checklist implementation in the hospital-acquired infection study (II) might be explained by the different spectrum of operations: although not statistically significant, operations for malignant intracranial tumours were the most numerous procedures preceding a postoperative infection. Operations of intracranial tumours are typically lengthy and more complicated. Long duration of operation, undergoing two or more operations, and operation for malignancy have been proven to increase the risk for postoperative infection (Abu Hamdeh et al. 2014, Golebiowski et al. 2015, Gradl et al. 2014, Korinek 1997, Korol et al. 2013, McCutcheon et al. 2016, Valentini et al. 2018, Valentini et al. 2008). This study suggests that the use of the WHO SSC alone is not able to reduce the risk of deep SSI among these patients. In the study hospital, re-dosing the prophylactic antibiotic is a routine practice if the procedure lasts longer than 3 hours. Adding a routine check of re-dosing could be a future enhancement in the checklist. The timing of the prophylactic antibiotic is routinely documented in patient's anaesthesia records. Unfortunately, the accessibility of the recording system and the availability of the electronic patient data has varied over time. In the hospital-acquired infection study (II), the timing of prophylactic antibiotic was excluded due to afore mentioned reasons and this should be considered as a limitation.

6.1.2 Other outcomes

Overall, the results of this study, considering change in communication and teamwork, and the decline of adverse events along checklist implementation, are in accordance with previous studies (Haynes et al. 2011b, Haynes et al. 2009).

The use of the WHO SSC enhanced safety-related procedures and information transfer between team members (Boyer et al.). Especially information transfer between the anaesthesiologist and the surgeon improved. Understanding and paying attention to risks, and preparing for them, may reduce complications. Team members' better awareness of the procedure may associate with less adverse events in major operations. However, the efficacy and benefit of using the WHO Surgical Safety Checklist has been proven to associate only with full checklist completion (van Klei et al. 2012). In study I, only in 68% of the cases the checklist was performed completely. Among the patients with SSI, the adherence to at least the 'time out' check was 80%.

In the reoperation study (III), the compliance to perform at least the 'time out' phase of the checklist during the primary operation preceding a complication-related reoperation was on rather same level as in all neurosurgical operations of the study (67% vs. 78%). Yet, the lack of adherence to use the checklist in individual operations did not seem to increase the occurrence of preventable adverse events. This result may be biased due to the delay of five months between the implementation and the electronic recording of the use of the checklist as the real use of the checklist may have been higher than depicted by the marks in the operating room electronic charts. The checklist use was optional in emergency operations during the first 5 months, which may have reduced the checklist use compliance to some extent but did not affect the recorded rate of checklist use.

6.1.3 Strengths and limitations

Studies I, II and III were retrospective comparison studies with simple before and after setting. They all were among the first studies on the effects of WHO SSC use on solely neurosurgical patients. The results of all three studies were concordant showing a reduction in postoperative infection complications with the WHO SSC use. The total number of patients during the study periods, up to over 5,400 patients in study III, was significant, even if the numbers of patients with a studied endpoint were rather small. The length of follow up time up to 1 year in certain complications in study III and of the study periods of up to 5 years in studies II and III were considerable than in many other studies (Belykh et al. 2019, Fargen et al. 2013, Haugen et al. 2015, O'Leary et al. 2016, Ryan et al. 2014).

In the pilot study (I), the number of patients was small which may induce type II error (false negative). The study population was selected through a survey on the implementation of the checklist, and the setting was not randomised. However, even randomisation would have involved a risk of bias, as the personnel would have become familiarised with the checklist after the first operation. Furthermore, it is impossible to blind the use of the checklist. Though blinding the analysis of patient records concerning the checklist might have increased objectivity. In this study, a researcher (M. Lepänluoma) not involved in neurosurgical treatment performed the patient record analysis. It would also have been possible to collect data from a separate control group, but this would have meant a different surgical subspecialty with different risk factors. Also, the implementation of the checklist elsewhere in the same hospital at the same time would have diluted the contrast of the control group as they would have been indirectly exposed to the same information and knowledge of the checklist as the study group. The types of operations were not equally distributed between the groups, which may have had some impact on the complication profiles. Only predetermined adverse events were considered, and, for instance, upper respiratory tract infections or urinary tract infections were not considered in the study.

Although the HAIs were actively reported throughout the study period of the hospital-acquired infection study (II), there might have been higher awareness of HAIs in the latter half of the observation period. A patient safety programme was started in Turku University Central Hospital in 2009. The awareness of SSIs and the need of microbiological diagnosis as well as recording of the results to HAI register might have improved over time; the number of infections treated without microbiological diagnosis was smaller after 2009. The coverage of the HAI register was incomplete, and hence affects the results. Also, the incidence of the infections by tertiles varied significantly, which affects the interpretation of the results. The percentage of intracranial tumour patients was higher after the checklist implementation, and these patients usually have a higher infection risk per se. Also, the patients were slightly older towards the end of the study period. Both tendencies might affect negatively the benefits of the checklist.

The number of studied complication episodes was rather small, yet the total number of neurosurgical operations during the reoperation study (III) period was substantial. The small number of cases in many diagnosis groups might limit the power of the study to demonstrate a statistically significant difference. However, when proportioned to the volume and the standard of neurosurgical care, even the small enhancements are clinically significant. The reliability of the hospital discharge register as the source of the primary data may be questioned, but the information to the analysis came directly from the electronic medical records instead of having been separately recorded in the discharge register. The study concentrated on complications leading to reoperation. It is very unlikely that a reoperation performed in the OR would not have been recorded in the electronic operations and procedures registry and/or patient records. To avoid a bias due to missing or wrong codes, a wide range of complication codes and other complication-related diagnosis and procedure codes was used. It is theoretically possible that the defined search terms may have missed occasional cases, but the occurrence of this kind of error would, however, affect both study groups.

The rate of the checklist use during the study period is not directly comparable with long-term results of the checklist use rate due to technical reasons. Regardless of the gap in electronic recording the checklist use, the study data was collected with an intention-to-treat principle from the beginning of May 2009, and operations without a record of checklist use are reported as ‘no use’ cases, although the checklist most likely has been used to unknown extent in these operations.

In the systematic review, a single data search did not find studies and reviews comprehensively, and the search needed to be developed and refined. Some articles included in the review were found only with manual data search. Checklist use in study settings is difficult to randomise, and therefore gaining reliable evidence is compromised. The methodologic quality of many studies was suboptimal which complicates the interpretation of the results and diminishes the reliability.

6.2 Future perspectives

The WHO Surgical Safety Checklist is generally considered to be one of the evidence-based procedures to prevent postoperative surgical infections, although a recent systematic review has suggested that in the early studies, its value might have been overestimated especially in the developed countries (de Jager et al. 2016). The use of the WHO SSC and studies around it should continue in order to make more analysis on its effects on postoperative infections in the long run. To make the checklist more user-friendly, it should be locally adapted and modified according to the surgical subspecialty and its needs. In some neurosurgical operations, the checklist could include special points specific to the procedure or subspecialty of neurosurgery in question, like details concerning the use of microscope and microsurgical instruments. Also, the increasingly bigger role of robotics and AI in the OR should be considered in the future contents of checklists.

The quality level of surgical care is already high in developed countries, yet there is always room for improvement. Adding a simple procedure, like the checklist, does not make a great difference in the overall amount of surgical complication or the level of care, whereas in developing countries the difference and improvement may be more notable as the starting level is lower. The obstacle there is, that to demonstrate a statistically significant change in patient outcomes in high-quality level health care requires a vast number of patients to have enough power in the study. In some study designs that may turn out to be practically impossible. In more developed countries, the checklist should hence be seen more as a tool to enhance the quality of patient care through multiple ways rather than a compulsory tick-box exercise or a replacement of teamwork or communication.

To successfully execute a change in a work environment requires good planning, a proper implementation and readiness to encounter confrontation and resistance. Otherwise the change will not be truly integrated into work practices and there will be only a temporal change in patient outcomes. A new way of working should be sold through positive visions and long-term improvements to the personnel executing the change in their daily routine. If just dictated from above, changes can face considerable resistance, and the eventual meaning of the change may be overshadowed by a common principle of resisting management. The WHO SSC was made known to the public along with a large-scale study on its benefits and improvements on patient outcomes (Haynes et al. 2009). Encouraged by that, the checklist was implemented quite quickly in many places. This haste may have caused poor implementation and thereby resistance resulting in the lack of positive long-term results (Leape 2014). Rationalising changes in work environments in developed countries is often troublesome, but the economic benefits of using a checklist is not often discussed. It has been stated that the checklist is cheap to use, it does not incur many additional costs nor does it take much time to use. But the thing that should be brought up are the savings that it creates in the long run when less money is spent on treating fewer patients with complications (Semel et al. 2010). As more beneficial study results on checklist use have come out, and bearing in mind the financial aspects, the WHO SSC should be revived as updated and with local adaptations. The surgeons should be encouraged to engage in the use and development of the checklist and to take more role in leadership in the OR – more successful checklists are developed when engaging the end-users (Thomassen et al. 2011). This would probably raise their awareness of the importance of their role in the surgical patient safety. However, patient safety should be a shared goal of the multi-professional team treating surgical patients.

The checklist was created to be universal and suitable for any OR around the globe. As noted earlier, the level of surgical care and its requirements are very different around the world, and therefore the checklist should be developed to better meet the needs of an OR of high-level surgical care. More studies are needed to assess the current problems and complications of surgical patients and to develop checklist points that would reduce them. The checklist could also be broadened to pre- or postoperative phases, or a totally separate checklist for e.g. the preoperative phase of a specific surgical patient group, could be created as in the Dutch SURPASS checklist (de Vries et al. 2009). Norwegians have adapted a local version of the SURPASS checklist with the already established WHO SSC, and preliminary results in neurosurgical patients have been promising (Storesund et al. 2019). In addition to the surgical safety checklist, WHO recently published additional guidelines on the prevention of surgical site infections (Allegranzi et al. 2016a, Allegranzi et al. 2016b, World Health Organization 2016) . Some of those could be combined with the original surgical safety checklist. Enhanced or new checklists could more comprehensively improve surgical patient safety also outside the OR. These efforts could optimise the patients' care process (Haugen et al. 2019b) and bring money savings throughout the pathway.

As all patient data is nowadays in electronic form in Finland, the digitalisation of the checklist and merging it with the OR information system should also be considered (Amsterdam Medical Center 2011). More synchronous use of the checklist with other patient information could enhance checklist use and patient safety. With the help of AI, more data can be processed simultaneously, and all significant details in a patient's medical history could more easily be considered. This combined with interpersonal communication and clinical work could improve surgical patient safety. Being so, a revised neurosurgical checklist with considerations to digitalisation and AI would be of fundamental importance in the near future.

7 Conclusions

The implementation of the WHO Surgical Safety Checklist enhanced safety-related performance among OR personnel. At the same time, a reduced number of wound complications and fewer unplanned readmissions were noticed. The HAI register-based analysis found a reduction in early surgical site infections along with WHO SSC use but failed to find evidence that it would decrease the overall incidence of SSIs after neurosurgery. The implementation of the checklist seemed to prevent early superficial SSIs in neurosurgical patients. The occurrence of preventable adverse events as the cause of complication-related reoperations among neurosurgical patients was significantly reduced after the implementation of the WHO SSC. The proportion of both all and preventable wound-infection diagnoses, and the proportion of all and preventable infections leading to a reoperation, decreased significantly after checklist implementation. A separate literature review on checklists in neurosurgery found checklist use to reduce complications, and to enhance OR safety culture. The overall results of this thesis were in accordance with previous studies and reviews on the topic.

Based on these findings, it may be suggested that a checklist as a single perioperative intervention has only limited effect on the prevention of SSIs among complex neurosurgical patients. There is a need of continuous attention to the reduction of infection risks throughout the hospital stay after neurosurgical procedures. Also, digitalisation and the utilisation of AI in the improvement of surgical patient safety should be considered.

Further studies and efforts are required to find ways to control and reduce SSIs in neurosurgery. With further development, the benefits of the surgical safety checklist could be delivered to its full extent.

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Appendices

Appendix 1. The original WHO Surgical Safety Checklist (WHO Patient Safety).

Surgical Safety Checklist

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

Before induction of anaesthesia

(with at least nurse and anaesthetist)

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

- ☐ Yes

Is the site marked?

- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?

- ☐ Yes

Is the pulse oximeter on the patient and functioning?

- ☐ Yes

Does the patient have a:

Known allergy?

- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?

- ☐ No
- ☐ Yes, and equipment/assistance available

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

- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

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

Has antibiotic prophylaxis been given within the last 60 minutes?

- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:

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

To Anaesthetist:

- ☐ Are there any patient-specific concerns?

To Nursing Team:

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

Is essential imaging displayed?

- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:

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

To Surgeon, Anaesthetist and Nurse:

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

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

Revised 1 / 2009

Appendix 2. The Finnish translation of WHO Surgical Safety Checklist used during pilot study.

Leikkaustiimin tarkistuslista 1/2010 – LIHAVOITU TEKSTI LUETAAN ÄÄNEEN

Alkutarkistus
Ennen anestesian aloitusta

☐ Potilaalta (/omaiselta) on varmistettu **henkilöllisyys, toimenpide ja suostumus***
- *vastaanottanut hoitaja vahvistaa*

☐ **Leikkausalue / -puoli merkitty**
☐ Ei tarvetta
- *vastaanottanut hoitaja vahvistaa*

☐ **Anestesiavalmius** vahvistettu
- *anestesiologi vahvistaa:*
  - ASA-luokka
  - Pituus ja paino
  - Perussairaudet ja peruslääkkeet / ei ole
  - Implantit ja proteesit / ei ole
  - Leikkausta edeltävä lääkitys / ei tarvetta
  - Veren hyytymiseen vaikuttava lääkitys / ei tarvetta
  - Laboratoriovastaukset / ei tarvetta
  - Anestesiavälineistö tarkistettu / ei tarvetta

☐ **Pulssioksimetri** asennettu ja toimii
- *anestesiahoitaja lukee ääneen happisaturaation*

☐ **Allergiat**
- *anestesiologi sanoo ääneen tiedossa olevat potilaan allergiat*

☐ **Vaikea hengitystie / aspiraatio**riski
☐ Ei ole
☐ On ja tarvittavat välineet saatavilla
- *anestesiologi vahvistaa*

☐ **Oletettu verenvuoto** yli 500 ml
☐ Ei ole
☐ Yli 500 ml (lapsilla 7ml/kg), huomioitu
- *anestesiologi vahvistaa*

Tarkistus ennen toimenpiteen aloitusta
"Aikalisä ennen leikkausviiltoa"

☐ **Nimet ja tehtävät** tiedossa
- tiimin jäsenet esittäytyvät toisilleen tai varmistavat ääneen, että kaikki salissa tuntevat toisensa

☐ **Potilas, leikkauskohde ja toimenpide**
- leikkaava lääkäri vahvistaa

☐ **Antibioottiprofylaksia**
☐ Annettu 60 min sisällä
☐ Ei tarvita
- anestesiahoitaja ilmoittaa antibiootin antoajan
- jos profylaksiasta on kulunut yli 60 min, leikkaava lääkäri päättää uuden annoksen antamisesta ennen viiltoa

Toimenpiteen kulku ja kriittiset tekijät huomioitu ja kerrottu

☐ **Leikkaava lääkäri**:
Leikkauksen kriittiset vaiheet, rutiinista poikkeavat suunnitelmat, leikkauksen oletettu kesto, arvioitu verenvuoto

☐ **Anestesiologi / anestesiahoitaja**:
Erityiset potilaskohtaiset huolenaiheet

☐ **Instrumenttihoitaja ja valvova hoitaja**:
Steriliteetti varmistettu; välineistö, instrumentit ja lääkeaineet saatavilla; diatermialevyn paikka huomioitu

☐ **Radiologiset kuvat**
☐ Esillä
☐ Ei tarvita
- *valvova hoitaja vahvistaa*

Lopputarkistus
Ennen leikkaussalista poistumista

Hoitajat vahvistavat ääneen, että

☐ **instrumentit, taitokset ja neulat** laskettu ja täsmäävät

☐ **näytteisiin merkitty** potilastiedot ja tunnisteet
☐ Ei näytteitä

☐ korjattavat **välineistöongelmat** huomioitu
☐ Ei ongelmia

☐ **Diagnoosi, toimenpiteen nimi ja koodit** kirjattu oikein
- leikkaava lääkäri vahvistaa

☐ **Seurantaohjeet** annettu
- tiimin jäsenet vahvistavat, että ovat käyneet läpi seuranta-aiheessa erityishuomiota vaativat seikat ja välittömät jatkohoitomääräykset

* Suostumus-tarkistuksessa noudatetaan kunkin sairaalan/yksikön sopimaa käytäntöä.

Appendix 3. The structured multiple-choice questionnaire was directed to anaesthesiologists, circulating nurses and surgeons of pilot study (I).

date __ / ___ / _______ OR_______ procedure number / OR _______ 1
Takala RSK et al. Turku University Hospital, Finland

QUESTIONNAIRE FOR THE ANAESTHESIOLOGIST

- ☐ Please, fill in the form right after the operation and return it to the circulating nurse
- ☐ Choose **the best/most accurate option in your opinion**
- ☐ **Leave out all patient details** (eg name, ID)

Before the induction of anaesthesia:	**Yes**	**No**	**I don't know**	**Not relevant**
1. Was identity confirmed from the patient (pt)? ☐ pt unable to answer	☐	☐	☐	☐
2. Were height and weight of the pt recorded?	☐	☐	☐	☐
3. Did all team members know what the planned procedure was?	☐	☐	☐	☐
4. Was everybody aware of the side of the procedure (left / right)?	☐	☐	☐	☐
5. Was everybody aware of possible restrictions in limb or joint movements?	☐	☐	☐	☐
6. Was everybody aware of pt's known allergies?	☐	☐	☐	☐
7. Was everybody aware of pt's relevant medical conditions?	☐	☐	☐	☐
8. Was everybody aware of pt's medication?	☐	☐	☐	☐
9. Had pt received all prescribed preoperative drugs?	☐	☐	☐	☐
10. Was the antithrombotic medication discontinued? ☐ not applicable	☐	☐	☐	☐
11. Were all preoperative lab results available?	☐	☐	☐	☐
12. If blood loss >500 ml (>7ml/kg in children) was anticipated, was cross matched blood available?	☐	☐	☐	☐
13. Were anaesthesia equipment checked?	☐	☐	☐	☐
14. Was difficult airway anticipated and if needed, were the necessary equipment available?	☐	☐	☐	☐
15. Was the monitoring optimal during the procedure?	☐	☐	☐	☐

TURN PAGE ➞

date __ / ___ / _______ OR_______ procedure number / OR _______ 2
Takala RSK et al. Turku University Hospital, Finland

	Yes	No	I don't know	Not relevant
Before incision/starting the procedure:				
16. Was everybody aware of the name and role of each team member?	☐	☐	☐	☐
17. Were critical events discussed between anaesthesiologist and surgeon	☐	☐	☐	☐
18. Was the positioning of the pt acceptable?	☐	☐	☐	☐
After the procedure, before pt leaves the OR (theatre):				
19. Was communication successful between the team members?	☐	☐	☐	☐
20. Were postoperative prescriptions and instructions given?	☐	☐	☐	☐

Other observations and comments:____

____

____

THANK YOU FOR YOUR ANSWERS!

date __ /___/_______ OR_______ procedure number / OR _______ 3
Takala RSK et al. Turku University Hospital, Finland

QUESTIONNAIRE FOR THE CIRCULATING NURSE

- ☐ Please, fill in the form right after the operation and return it to the circulating nurse
- ☐ Choose **the best/most accurate option in your opinion**
- ☐ **Leave out all patient details** (eg name, ID)

Date ___ /___/_______ OR_______ procedure number /OR________

Prophylactic antibiotic: starting – and finishing time: ____:____ - ______:_____

Anaesthesia starting time ____:____ Operation starting time:____:____(time of incision)

Operation finishing time:____:____ Elective ☐ Urgent ☐ Emergency ☐

Please, select the best option for each question:

Before the induction of anaesthesia:	**Yes**	**No**	**Not known**	**Not relevant**
1. Was identity confirmed from the patient (pt)?	☐	☐	☐	☐
☐ pt unable to answer				
2. Had the hygiene of the pt been taken care of?	☐	☐	☐	☐
3. Did the pt wear compression stockings?	☐	☐	☐	☐
4. Did all team members know what the planned procedure was ?	☐	☐	☐	☐
5. Was the positioning of the pt acceptable?	☐	☐	☐	☐
Before incision/starting the procedure:				
6. Was everybody aware of the name and role of each team member?	☐	☐	☐	☐
7. Was everybody aware of the side of the procedure (left / right)?	☐	☐	☐	☐
8. Was the sterility of instruments confirmed?	☐	☐	☐	☐
9. Were all essential equipments and instruments available and undamaged?	☐	☐	☐	☐

TURN PAGE →

date __ / ___ / _______ OR_______ procedure number / OR _______ 4
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After the procedure, before pt leaves the OR (theatre):

	Yes	No	Not known	Not relevant
10. Were needles, sponges and instruments counted?	☐	☐	☐	☐
11. Were all specimens labeled (pt ID)?	☐	☐	☐	☐
12. Was communication successful between the team members?	☐	☐	☐	☐
13. Were there any equipment problems?	☐	☐	☐	☐
14. Was the blood loss estimated and recorded?	☐	☐	☐	☐

15. Other observations and comments:

____

____

____

THANK YOU FOR YOUR ANSWERS!

date __ / ___ / _______ OR_______ procedure number / OR _______ 5
Takala RSK et al. Turku University Hospital, Finland

QUESTIONNAIRE FOR THE SURGEON

- Fill in the form right after the operation and return it to the circulating nurse
- Choose **the best/most accurate option in your opinion**

date___ / ___ / _______ OR_______ procedure number / OR _______

Please, select the best option for each question:

Before incision/starting the procedure:

	Yes	No	Not known	Not relevant
1. Had patient's identity been confirmed?	☐	☐	☐	☐
2. Was everybody aware of the name and role of each team member?	☐	☐	☐	☐
3. Did all team members know what the planned procedure was?	☐	☐	☐	☐
4. Was everybody aware of the side of the procedure (left / right)?	☐	☐	☐	☐
5. Were critical events discussed between anaesthesiologist and surgeon?	☐	☐	☐	☐
6. Were all preoperative lab results available?	☐	☐	☐	☐
7. Were essential imaging available?	☐	☐	☐	☐
8. If blood loss >500 ml (>7ml/kg in children) was anticipated, was cross matched blood available?	☐	☐	☐	☐
9. Was the antibiotic prophylaxis given within 60 minutes?	☐	☐	☐	☐

After the procedure, before pt leaves the OR (theatre):

	Yes	No	Not known	Not relevant
10. Did the position of the patient cause any difficulties to the surgeon?	☐	☐	☐	☐
11. Was communication successful between the team members?	☐	☐	☐	☐

TURN PAGE →

date __ / ___ / _______ OR_______ procedure number / OR _______ 6
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	Yes	No	Not known	Not relevant
12. Were postoperative prescriptions and instructions given?	☐	☐	☐	☐
13. Was thrombosis prophylaxis discussed?	☐	☐	☐	☐
14. Were there any equipment problems?	☐	☐	☐	☐

14. Other observations and comments:

____

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THANK YOU FOR YOUR ANSWERS!

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