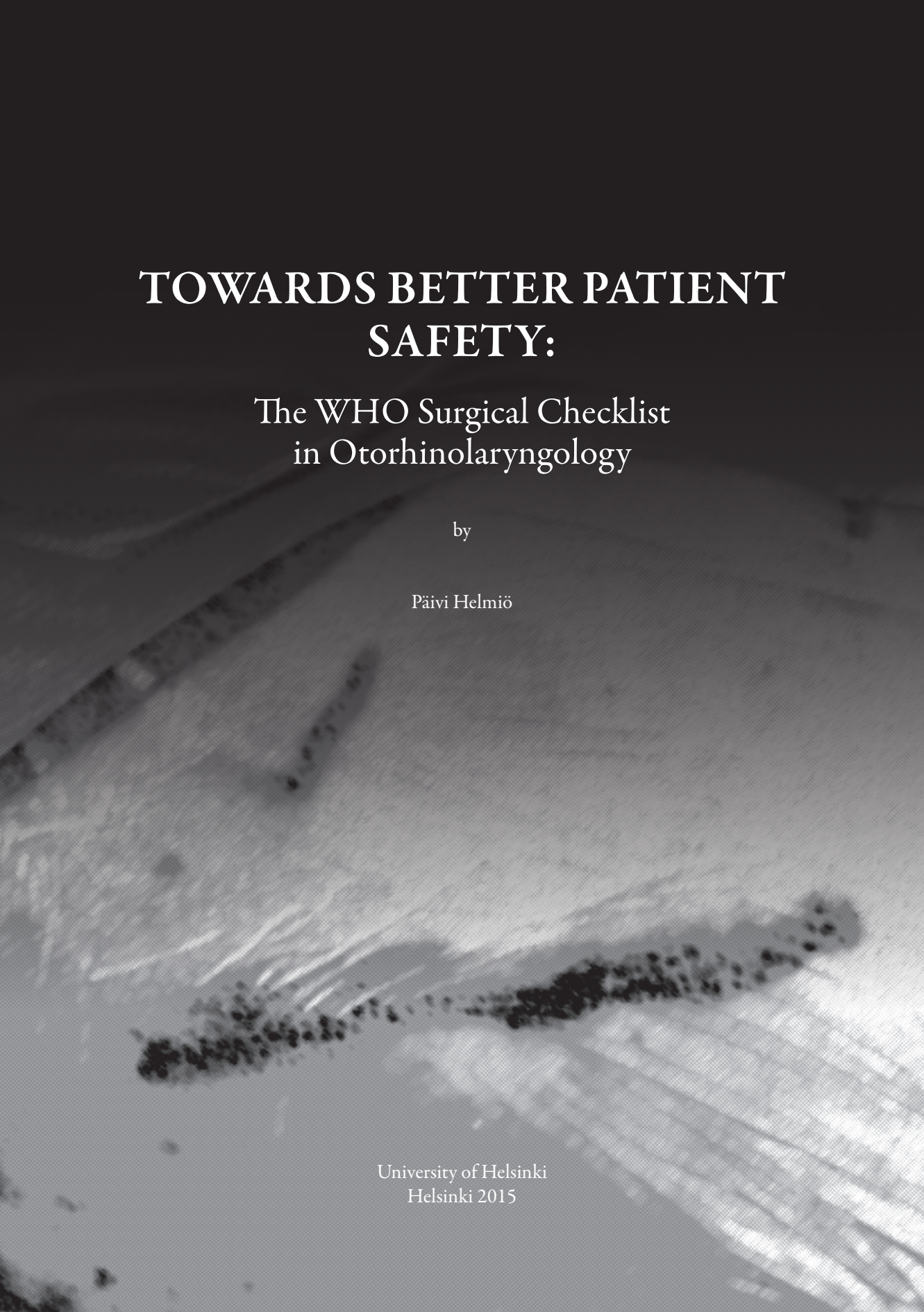
TOWARDS BETTER PATIENT SAFETY:

The WHO Surgical Checklist in Otorhinolaryngology

by

Päivi Helmiö



University of Helsinki
Helsinki 2015

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ACADEMID DISSERTATION

To be presented, with the permission of the Medical Faculty of the University of Helsinki,
for public examination in the lecture hall 3 of the Biomedicum,
on May 8th, 2015 at 13 o'clock.

University of Helsinki
Helsinki 2015

From the Department of Otorhinolaryngology, Faculty of Medicine, University of Helsinki, Helsinki, Finland

Supervised by

Docent Karin Blomgren MD, PhD
Department of Otorhinolaryngology, Helsinki University Central Hospital
University of Helsinki
Helsinki, Finland

Docent Leena-Maija Aaltonen MD, PhD
Department of Otorhinolaryngology, Helsinki University Central Hospital
University of Helsinki
Helsinki, Finland

Reviewed by

Docent Erna Kentala MD, PhD
Department of Ophthalmology, Helsinki University Central Hospital
University of Helsinki
Helsinki, Finland

Docent Leila Niemi-Murola MD, PhD
Department of Anaesthesiology, Helsinki University Central Hospital
University of Helsinki
Helsinki, Finland

Opponent

Professor Juhani Nuutinen MD, PhD
Department of Otorhinolaryngology, Kuopio University Hospital
University of Eastern Finland
Kuopio, Finland

ISBN 978-951-51-1109-8 (paperback)
ISBN 978-951-51-1110-4 (PDF)
http://ethesis.helsinki.fi

Painosalama Oy, Turku, Finland 2015

We cannot change the human condition, but we can change the conditions under which humans work

(Reason 2000)

ABSTRACT

Päivi Helmiö

TOWARDS BETTER PATIENT SAFETY: The WHO Surgical Checklist in Otorhinolaryngology

From the Department of Otorhinolaryngology, Faculty of Medicine, University of Helsinki, Finland. Helsinki 2015.

More than one-half of adverse events in health care are related to surgery. Surgical patient injuries account for about 80% of patient injuries in otorhinolaryngology (ORL). The World Health Organisation (WHO) has developed a Surgical Safety Checklist to prevent errors in the operating theatre. Its use has been shown to reduce complications and mortality. The aims of the present study were to identify errors that may underlie those patient injuries that occur in operative ORL, to assess the effects of the WHO checklist on working processes in the operating theatre, including compliance, and to evaluate how it would fit into the specialty.

Data of the patient injuries that were sustained during treatment by the ORL specialty between the years 2001 and 2011 were obtained from a search of the Finnish Patient Insurance Centre registry. The causes of the injuries were analysed, and whether the WHO checklist could have prevented the error was evaluated. The checklist was implemented in four Finnish hospitals as a pilot in 2009. A prospective before-versus-after-intervention study was conducted with a questionnaire for OT personnel in these four hospitals to evaluate the checklist. The checklist was subsequently implemented for regular use in the operative unit of the Department of Otorhinolaryngology of Helsinki University Central Hospital. After one-year of use, compliance and user attitudes were analysed by using data obtained from the operations database and a survey of operative ORL personnel.

In the 10-year study period, 188 patient injuries were associated with operative ORL. A total of 142 (75.5%) of these injuries occurred due to errors that were made in the operating theatre, and in 125 cases (66.5%) a manual error in performing the surgery was the primary cause of the injury. Six injuries (3.2%) were caused by wrong site surgery. An error had some degree correspondence with a WHO checklist item for 18 injuries (9.6%) and it was determined that 9 of these injuries (4.8%) could have been prevented had the checklist been correctly used. The implementation of the checklist enhanced the communication between the surgical team members, improved verification of the patient's identity and of the correct operation site. Checklist compliance was 62.3% during first year of use. It was considered easy to use and the Safety Attitude Scores of the personnel were found to be on a high level. All check items on the list were considered important for ORL. However, a more compact checklist for outpatient surgery was requested.

Patient injuries in ORL were strongly related to surgery. The WHO Surgical Safety Checklist seems to be a beneficial tool for preventing errors ORL and is highly relevant for the specialty.

Keywords: operative otorhinolaryngology, patient safety, adverse event, patient injury, wrong site surgery, surgical safety checklist

TIIVISTELMÄ

Päivi Helmiö

KOHTI PAREMPAA POTILASTURVALLISUUTTA: WHO:n kirurginen tarkistuslista korva-, nenä- ja kurkkutautien kirurgiassa

HYKS Korva-, nenä ja kurkkutautien klinikka, Lääketieteellinen tiedekunta, Helsingin Yliopisto, Helsinki 2015.

Maailman terveysjärjestö WHO on kehittänyt leikkaussalikäyttöön kolmivaiheisen tarkistuslistan, jonka tarkoitus on ehkäistä virheitä leikkaussalityössä. Tämän tutkimuksen tavoitteena oli kuvata ja analysoida korva-, nenä- ja kurkkutautien alan kirurgisesta hoidosta aiheutuneita potilasvahinkoja ja niihin johtaneita mekanismeja. Tavoitteena oli myös arvioida WHO:n tarkistuslistan käyttöönoton vaikutuksia leikkaussalityöhön, listan käyttömyöntyvyyttä sekä sisällön soveltuvuutta erikoisalalle.

Tutkimuksessa analysoitiin Potilasvakuutuskeskuksen korvaamat potilasvahingot korva-, nenä- ja kurkkutautien erikoisalalta vuosilta 2001-2011. Samalla arvioitiin, olisiko kirurginen tarkistuslista voinut estää vahingon. WHO:n tarkistuslista otettiin pilottikäyttöön neljässä suomalaisessa sairaalassa vuonna 2009, samalla toteutettiin vertaileva tutkimus listan käyttöönoton vaikutuksista leikkaussalitoimintaan. Tarkistuslista otettiin vakituiseen käyttöön Helsingin Yliopistollisen Keskussairaalan korva-, nenä- ja kurkkutautien leikkausyksikössä vuonna 2010. Ensimmäisen käyttövuoden jälkeen analysoitiin listan käyttöaktiivisuutta sekä toteutettiin kyselytutkimus leikkaussalihenkilökunnalle.

Kymmenen vuoden aikana Suomessa korvattiin 188 korva-, nenä- ja kurkkutautien alan leikkauksiin liittyvää potilasvahinkoa. Vahinkoon johtaneista virheistä 142 (75,6 %) tapahtui leikkaussalissa. Kaikkiaan 125 (66,5 %) vahinkoa aiheutui virheestä leikkauksen teknisessä suorituksessa. Kuusi (3,2 %) vahinkoa johtui väärän puolen tai kohteen leikkauksesta. Yhteensä 18 (9,6 %) tapauksessa virhe liittyi WHO:n tarkistuslistassa käsiteltyihin asioihin ja arviomme mukaan yhdeksän (4,8 %) vahinkoa olisi ollut estettävissä asianmukaisesti käytetyn tarkistuslistan avulla. Tarkistuslistan käyttöönoton todettiin parantavan leikkaustiimin kommunikaatiota, lisäävän potilaan henkilöllisyyden varmistamista sekä tietoa leikkauskohteesta. Ensimmäisenä käyttövuonna listaa käytettiin keskimäärin 62,3 %:ssa leikkauksista. Tarkistuslista koettiin helpoksi käyttää eikä sen koettu hidastavan työskentelyä. Listan sisällön arvioitiin sopivan hyvin korva-, nenä- ja kurkkutautien erikoisalalle, joskin päiväkirurgisiin toimenpiteisiin toivottiin lyhyempää listaa.

WHO:n kirurginen tarkistuslista soveltuu hyvin korva-, nenä- ja kurkkutautien erikoisalalle ja sitä käyttämällä pystytään todennäköisesti estämään alan toimenpiteisiin liittyviä potilasvahinkoja.

Avainsanat: korva-, nenä- ja kurkkutautien kirurgia, potilasturvallisuus, haittatapahtuma, potilasvahinko, väärän kohteen leikkaus, kirurginen tarkistuslista

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, which are referred to in the text by the Roman numerals I-V.

I Helmiö P, Blomgren K, Lehtivuori T, Palonen R, Aaltonen LM. Towards better patient safety in otolaryngology: Characteristics of patient injuries and their relationship with the items of WHO surgical checklist. Clin Otolaryngol. 2015; Epub ahead of print.

II Takala RS, Pauniaho SL, Kotkansalo A, Helmiö P, Blomgren K, Helminen M, Kinnunen M, Takala A, Aaltonen R, Katila AJ, Peltomaa K, Ikonen TS. A pilot study of the implementation of WHO surgical checklist in Finland: improvements in activities and communication. Acta Anaesthesiol Scand. 2011; Vol. 55: 1206-14.

III Helmiö P, Blomgren K, Takala A, Pauniaho SL, Takala RS, Ikonen TS. Towards better patient safety: WHO Surgical Safety Checklist in otorhinolaryngology. Clin Otolaryngol. 2011; Vol. 36: 242-7.

IV Helmiö P, Takala A, Aaltonen LM, Pauniaho SL, Ikonen TS, Blomgren K. First year with WHO Surgical Safety Checklist in 7148 otorhinolaryngological operations: use and user attitudes. Clin Otolaryngol. 2012; Vol. 37: 305-8.

V Helmiö P, Takala A, Aaltonen LM, Blomgren K. WHO Surgical Safety Checklist in otorhinolaryngology-head and neck surgery: specialty-related aspects of check items. Acta Otolaryngol. 2012; Vol. 132: 1334-41.

ABBREVIATIONS

ASA	American Society of Anesthesiologists Physical Status Classification System
CSF	cerebrospinal fluid
ESS	endoscopic sinus surgery
HNS	head and neck surgery
HUCH	Helsinki University Central Hospital
JC	Joint Commission
NEJM	The New England Journal of Medicine
OR	odds ratio
ORL	otorhinolaryngology
OT	operating theatre
PIC	Finnish Patient Insurance Centre
RSS	retained surgical sponges
SAQ	Safety Attitudes Questionnaire
SD	standard deviation
SSC	Surgical Safety Checklist
SSI	surgical site infection
SURPASS	Surgical Patient Safety System
UK	United Kingdom
US	United States
WHO	World Health Organisation
WSS	wrong site surgery

1. INTRODUCTION

Patient safety is one of the most important goals for health care organizations at the present time. Errors in treatment and adverse events experienced by patients undergoing health care and surgery can result in significant morbidity and mortality for the affected patient population. Consequently, adverse events can burden the health care providers and incur disproportionately high costs for health care systems.

A wide range of errors that encompass technical, interactive or administrative causes constitutes a potential source of adverse events in health care (Andrews et al. 1997). More than half of adverse events are related to surgical care and are common among surgical subspecialties, including otorhinolaryngology (ORL) (Leape et al. 1991, Gawande et al. 1999, Shah et al. 2004, de Vries et al. 2008, Lehtivuori et al. 2013). An adverse event in surgery often results from simple human error, with wrong site surgery (WSS) being the most drastic example (Reason 1995).

System safeguards should be established to prevent human error from causing injury (Reason 1995, 2005, Sarker and Vincent 2005). Recognition of this led to the initiation and development of systematic preventive protocols, the most widespread being the World Health Organisation (WHO) Surgical Safety Checklist (SSC) (Haynes et al. 2009, de Vries et al. 2010). An international multicentre study reported that SSC improved patient safety in the operating theatre (OT) with significant reductions in complications and deaths (Haynes et al. 2009).

Despite the general interest in the topic, actual research into errors and patient safety in ORL has been limited so far. Operations in ORL are considered to be associated with low morbidity and mortality (Karamchandani et al. 2010). However, all surgical procedures are subject to errors and complications. In 2006, Shah et al. emphasised that 'every specialty must take responsibility for the study of human error within its own domain' (Shah et al. 2006).

The research described in this thesis was undertaken to identify and analyse the errors that cause the patient injuries in ORL and the role of SSC has in their prevention. We therefore examined the effects of SSC on patient safety related issues and assessed whether SSC would be suitable for the working process in the ORL specialty.

2. REVIEW OF THE LITERATURE

2.1 Adverse events in surgery

The volume of surgical procedures is constantly growing. It is estimated that 234.2 million operations are performed worldwide every year (Weiser et al. 2008, Weiser et al. 2011). Surgical techniques, anaesthesia interventions and systems of care have all improved over the years. Patients have also benefited from the use of less invasive techniques and the increasing availability of complex operations (Pronovost and Freischlag 2010).

About one half to two-thirds of the adverse events in health care are related to surgery (Leape et al. 1991, Gawande et al. 1999, Thomas et al. 2000, de Vries et al. 2008). Moreover, approximately half million deaths globally are estimated to occur as a result of avoidable surgical error every year (Weiser et al. 2008).

2.1.1 Terms and definitions

The literature on the patient safety research has expanded during recent years. Nevertheless, universal definitions of the terminology of inappropriate care and harmful outcomes experienced by the patients do not exist (Murff et al. 2003). Various terms such as complications, adverse events, medical or patient injuries, substandard care, iatrogenic injuries, mishaps, negligence or malpractice are used (Andrews et al. 1997). This makes the data search and reliable comparisons between studies challenging.

An 'Adverse event' in health care is generally defined as an unintended injury or complication that results in prolonged hospital stay, disability at the time of discharge or death, caused by healthcare management rather than the underlying disease itself (Thomas et al. 2000, Bosma et al. 2011). The consequences of the adverse events for the patient vary from a harmless inconvenience to permanent disability or even death (Brennan et al. 1991). A wide range of errors that have technical, interactive or administrative causes constitutes a potential source of adverse events (Andrews et al. 1997). An adverse event may be caused by an error or incident. However, most errors or incidents do not cause adverse events. The term 'near miss' is used to describe an error or incident that does not result in harm to the patient.

WSS is used to describe wrong side/site, wrong procedure or wrong patient operations (Clarke et al. 2007). The term 'never event' is also used for WSS situations, in addition to complications related to retained surgical sponges or instruments. The term 'medical malpractice' is used in medical litigations and is defined as: 'A doctor's failure to exercise the degree of care and skill that a physician or surgeon of the same specialty would use under similar circumstances' (Hong et al. 2013c).

2.1.2 Study sources and methods

Traditionally, surgical specialties have taken the responsibility for the research of operation techniques and treatment protocols within their own domain. Results and complications have been analysed on a clinical basis that is related to the diseases and the surgical methods used. The systemic causes of errors have remained poorly understood. The patient's pathway through surgical process has to be analysed on a systemic basis for patient safety purposes, by utilizing the knowledge of the system science (Roberson et al. 2004, Reason 2005, Sarker and Vincent 2005). The objective is to identify the root causes of errors and analyse them.

Patient records provide information about the patient and the care received by the patient. However, the quality of the chart reviews is dependent on the quality of documentation (de Vries et al. 2008). Errors, particularly those that do not result in harm, have not been systematically recorded on the patient charts. Therefore, additional incident-reporting systems have been developed (The Joint Commission Sentinel Event Database http://www.jointcommission.org/sentinel_event.aspx, Marang-van de Mheen et al. 2005, Marang-van de Mheen et al. 2006, Ruuhilehto et al. 2011). The reporting of errors and near misses varies between institutions. Panesar and

colleagues evaluated a national incident reporting system in United Kingdom (UK) by analysing the rate of 'actual harm' versus 'near misses' to be 9% vs. 91% (Panesar et al. 2011).

Hospital and national administrative data provide general incidence information of perioperative mortality and morbidity. Day-of-surgery mortality ratio and postoperative in-hospital mortality ratio are standardised metrics for surgical surveillance (Khuri et al. 1995, Weiser et al. 2009). However, mechanisms that underlie hospital mortality variation are complex (Weiser et al. 2011). Ghaferi and colleagues showed that the complication rate and mortality did not correlate at the hospital level. Hospitals with either very high mortality or very low mortality had similar rates of overall complications, nonetheless 'failure to rescue' patient after major complication varied from 12.5% to 21.4% (Ghaferi et al. 2009). The ability to rescue a patient from a complication relies on the timely recognition of a complication and the effective management of it.

The general estimation of the total volume of adverse events in health care is difficult and controversial (Andrews et al. 1997, Poses 1997). Brennan and colleagues found that adverse event occurred for 3.7% of all hospitalisations in 1991 (Brennan et al. 1991). In 2008, de Vries reported that the median incidence of in-hospital adverse events was 9.2% (de Vries et al. 2008). However, the true incidence data of all adverse events are difficult to ascertain (Makary 2010).

Malpractice claim data and insurance records constitute a detailed source of information on injuries and their contributing or causal factors (Rogers et al. 2006, Studdert et al. 2006, Greenberg et al. 2007, Regenbogen et al. 2007, de Vries et al. 2011). Linking medical malpractice claims' data with clinical data of medical records can provide detailed information on error sequences that led to the adverse event (Studdert et al. 2000). Statements by health care personnel can provide additional information that elucidates the causal mechanism of an injury and also help resolve contemporary problems in working conditions and practices of health care units.

The measurement of the patient safety related qualitative variables, such as safety culture, communication and teamwork is challenging. Structural observations can give particular objective information on these complex issues (Lingard et al. 2004, Aveling et al. 2013). Surveys and interviews that examine responders' subjective experiences of communication, in addition to attitudes and awareness of safety related issues (Russ et al. 2014). Survey instruments have been developed to study the teamwork climate. The Safety Attitudes Questionnaire (SAQ) is a validated measure of patient safety culture and improved SAQ levels have been associated with better patient outcomes (Sexton et al. 2006a, Sexton et al. 2006c, Watts et al. 2010, Zimmermann et al. 2013).

2.1.3 Risks in surgery

Complications in surgical care are strongly related to the patient and to disease specific factors. The American Society of Anaesthesiologists Physical Status Classification System (ASA) score assesses the patient related preoperative risk for morbidity and mortality (American Society of Anesthesiologists Physical Status Classification System https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system, Cohen et al. 2009). Patients who are undergoing surgery are prone to surgical and anaesthesia-related complications. A German study reported about 30% of deaths and serious complications during surgery for ASA score I and II low risk patients, were attributable to anaesthesia (Schiff et al. 2014).

Complication rates have a wide global variation and surgical morbidity and mortality are dependent on quality of the health care system and economic status of the country in question. The risk of any complication after non-cardiac surgery in hospitals of eight countries of different development status that participated in the WHO Patient Safety Programme in 2007 was reported in two studies (Haynes et al. 2009, Weiser et al. 2009). Those studies found the risk to vary between 6.1% and 21.4% at baseline. In-hospital death rate following surgical procedures varied from 0.8% to 3.6%. In the United States (US), the postoperative in-hospital death ratio has decreased from 1.68% to 1.32% between years 1996 and 2006 (Semel et al. 2012). A recent study from

Ontario, Canada reported that the adjusted risk of death within 30 days after surgery was 0.71% (Urbach et al. 2014b).

Unfortunately, 'never event' complications related to wrong patient, wrong procedure and wrong side/site take place in all types of surgeries, though this is unacceptable (Clarke et al. 2007). Although the problem appears to be rare, these devastating events can occur anywhere regardless of the economic status of the country. A total of 25 wrong-site operations were identified in 2 826 367 operations insured by a large malpractice insurer in the US between 1985 and 2004, which gives an incidence of WSS to be 1 in 112 994 operations (Kwaan et al. 2006). Seven per cent of the analysed surgical malpractice claims in the US were for WSS (Regenbogen et al. 2007). The frequency of WSS varies by specialty and type of surgery (Seiden and Barach 2006). More than one-third (35.5%) of the wrong site procedures caused significant harm to the patient (Stahel et al. 2010).

2.1.4 Errors underlying adverse events

Surgical adverse events are common within most surgical specialties (Leape et al. 1991, Gawande et al. 1999, Shah et al. 2004, de Vries et al. 2008, Lehtivuori et al. 2013). Surgical care comprises a combination of decision-making, team performance, communication and technical skill (Sarker and Vincent 2005). Similarly, the errors that contribute to surgical adverse events can be administrative, judgement or knowledge dependent, technical or interactive (Andrews et al. 1997, Rogers et al. 2006, Regenbogen et al. 2007). Errors in surgical care can occur inside or outside of the OT, during, before or after surgery (Gawande et al. 2003e, Greenberg et al. 2007, Griffen et al. 2007).

The different types of errors are shown in Table 1. Manual errors in performing surgery can be*, inter alia*, incidental injuries to anatomical structures, problems to control haemorrhage or misplacement of a graft or prosthesis (Regenbogen et al. 2007). However, these well-recognised complications constitute only one-third to a half of the surgery related errors (Gawande et al. 1999, Wilson et al. 1999, Regenbogen et al. 2007).

Communication and information transfer between the professionals themselves and between the professionals and the patient constitutes a remarkable source of risk of error (Makary et al. 2006, Greenberg et al. 2007, ElBardissi et al. 2009, Mazzocco et al. 2009). An observational study noted that a third of the communication failures in the OT caused negative effects in the processes, such as increased inefficiency and team tension

Table 1. *Subtypes of manual versus judgement/knowledge errors (according Regenbogen et al., 2007).*

	N	%
Manual errors	**127**	**90.1**
Incidental injury to viscera or other anatomy	48	34.3
Breakdown of repair or failure to relieve condition	23	16.4
Haemorrhage	22	15.7
Peripheral nerve injury	20	14.3
Misplacement or improper choice of prosthesis	10	7.1
Retained surgical equipment, due to error of technique	4	2.9
Judgement/knowledge errors	**49**	**35.0**
Delay or error in intraoperative diagnosis and/or treatment	23	16.4
Incorrect procedure or technique chosen	13	9.3
Wrong site operation	10	7.1
Failure to change operative plan in light of contraindication or intraoperative findings	3	2.1
All claims	140	100

Number (N) and proportion (%) of errors cited in 140 malpractice claims with surgical patient injury due to a technical error. Both, manual and judgement errors were involved in 36 claims (Regenbogen et al. 2007).

and in 0.8% of the cases the communication failures resulted in a procedural error (Lingard et al. 2004). Communication breakdown has been shown to be one of the key factors that contribute to surgical adverse events (Gawande et al. 2003a, Sutcliffe et al. 2004, Neily et al. 2009). Similarly, poor communication is one of the leading factors that contribute to WSS (Gawande et al. 2003e, Neily et al. 2009, Cohen et al. 2010).

A variety of adverse events in surgical care result from a simple human error (Reason 2005). A detailed review of wrong-side craniotomies concluded that human error was the most predominant factor to contributing to WSS (Cohen et al. 2010). For instance, inaccurate assumptions can cause WSS: a member of staff other than the surgeon prepared the patient for the operation and the surgeons falsely assumed that the correct side had been prepared when it had not. However, human error related WSS-cases have been more prevalent during emergency situations and during late hours (Cohen et al. 2010).

Human error is almost always the root cause for retained surgical sponges (RSS) and foreign bodies. Similarly, factors that increase the risk of retention of a foreign body were emergency surgery, unplanned change in the operation and high body-mass index of the patient (Gawande et al. 2003a).

The results from a study of US surgical malpractice claims showed that errors occur in common operations with experienced surgeons (Regenbogen et al. 2007). Routine procedures may lull surgery staff into a false sense of security. Errors are part of human behaviour, and even the best-trained professionals are prone to them (Reason 1995, Roberson et al. 2004).

2.2 Adverse events in ORL

Despite the growing interest on the topic, research on the topics of errors and patient safety in ORL has been limited. A majority of the reports originates from the US, and are based on the data obtained from malpractice insurance and court registries. In addition, Shah and colleagues conducted a survey to American ORL specialists concerning errors in 2004 (Shah et al. 2004, Lander et al. 2006).

The ORL-specialty accounts for a small portion of the total adverse events in health care. Information from the professional liability insurance companies, that cover 60% of the practitioners in the US, revealed that 3793 (2.3%) of the claims and $ 213.64 million (1.7%) of the indemnities were for adverse events in the ORL. Moreover, ORL was ranked 17th out of 28 specialties in the numbers of malpractice lawsuits incurred. As many as 85.8% of the ORL specialists to whom claims had been levelled against were fully trained consultants, 60% were over 45-year-old, 97.5% were male and 76 % had experienced previous malpractice litigations. Rhinology accounted for 51% of the malpractice cases and for 70.3% of the indemnities paid on the entire ORL specialty. (Dawson and Kraus 2007).

The characteristics of the patients treated in ORL are distinct from other surgical specialties. All age groups from new-borns to aged people are represented, and the diseases are seldom associated with remarkable co-morbidities. Paediatric ORL has special characteristics and is also prone to a variety of adverse events and surgical complications (Shah and Lander 2009, Shah et al. 2009). As many as 23 (12%) patients of ORL malpractice cases in the US civil court between 2001 and 2011 were children (Hong et al. 2013c).

However, of the reported errors in ORL 37.0% resulted in major morbidity and 2.4% in death (Shah et al. 2004). A recent study on the Finnish patient insurance registry found that 28.2% of the accepted claims resulted in permanent disability and 2.7% in death of a patient (Lehtivuori et al. 2013). Wrongful death was the charge in 25.8% of the ORL malpractice litigations in the US civil-court between 2001 and 2011 (Hong et al. 2013c). An interesting feature is that 21.2% of the cases in the US civil-court trials were for the treatment of malignant disease in ORL (Hong et al. 2013c). A delay in the diagnosis was the most common reason for claims related to head and neck cancer (Lydiatt 2002b, 2002a, 2004, Hong et al. 2013c).

2.2.1 Risks and adverse events in ORL surgery

Adverse events in ORL are strongly related to surgery, which is similar to that found for the other operative specialities (Shah et al. 2004, Hong et al. 2013c, Shah et al. 2014). Therefore, surgical injuries are well presented in claim record data in the ORL specialty (Lehtivuori et al. 2013). Information from the liability insurance companies in the US showed that 63.3% claims in ORL were for mistakes made during surgical care (Dawson and Kraus 2007). In a review of the malpractice litigation cases in US civil trials over the 2001 to 2011 period reported a rate of 76.3 % (151 cases) (Hong et al. 2013c). In a study of claim records for malpractices in otology in the UK, 64.9% of complications were related to surgery (Mathew et al. 2011). The rate was 89.1% for ORL patient injuries in Finland (Lehtivuori et al. 2013). Table 2.

2.2.1.1 Anatomical considerations

The head and neck region has many of vulnerable anatomical structures that place high demands on surgical techniques and skills. Iatrogenic injury to adjacent structures is a significant cause for operation related injuries. The most commonly damaged structures are the cranial nerves, the orbit, the inner ear and the meninges (Lydiatt 2003a, 2003b, 2003c, Hong et al. 2013a, Svider et al. 2013a, Svider et al. 2013d). Forty per cent of the head and neck malpractice cases were centred on damage to a cranial nerve (Hong et al. 2013c). In 38% of salivary surgery malpractice cases, the facial nerve was injured (Hong et al. 2013a). Furthermore, errors in surgical technique in ORL resulted in major morbidity for 56% of the patients (Shah et al. 2004).

Several head and neck structures are bilateral. A recent review by Liou et al. (2014) concluded that WSS accounts for 4-6% of errors in ORL. WSS has occurred in 6.1% of reported errors in ORL and 21% of ORL specialists have been involved in a WSS during their career (Shah et al. 2004, Shah et al. 2011). In a mail survey to ORL specialists in North America, 9.3% of respondents were aware of a case of wrong-side endoscopic sinus surgery (ESS) (Shah et al. 2010). Moreover, WSS had occurred in 9.5% of the clinical negligence claims in operative otology (Mathew et al. 2011). In the majority of the WSS cases in ORL, a site marking was lacking (Shah et al. 2010).

Airway management of ORL patients is frequently a challenge in anaesthetics. It is also a considerable risk source with potential catastrophic consequences. Mortality after tonsillectomy is mostly related to airway complications (Morris et al. 2008). Airway-related claims accounted for 8.6% (N = 27) of malpractices after head and neck surgery (HNS) (Simonsen et al. 2012). Airway problem as an adverse event can also be due to previous intubation that has resulted in laryngotracheal stenosis (Svider et al. 2013c).

Table 2. *Studies on malpractices and patient injuries in otorhinolaryngology.*

Study Country and characteristics	Database	Claims N	Surgical claims %	Claims accepted %	Death N	Indemnity Mean
Hong 2013 US, Civil-court trials	Westlaw database	198	76.3	42	51	1 100 000 $
Dawson 2007 US, Malpractice litigation	PIAA	3 793	63.3	29.8	N.a.	194 924 $
Mathew 2011 UK, Medical negligence claims, otology (26% of ORL)	NHSLA	137	64.9	84	1	62 700 £
Lehtivuori 2013 Finland, Patient injury claims	PIC	422	89.1	26.1	3	3 320 €

Number (N) and proportion (%); N.a.=Not available; PIAA=Physician Insurers Association of America; NHSLA=National Health Service Litigation Authority; PIC=Finnish Patient Insurance Centre (Dawson and Kraus 2007, Mathew et al. 2011, Hong et al. 2013c, Lehtivuori et al. 2013).

2.2.1.2 Procedure specific risks

Typical ORL-procedures are performed in high volumes, last a short time and do not cause immobility. A high proportion of operations occur as outpatient or ambulatory surgeries and are carried out under local anaesthesia. Generally, ORL-operations are considered to have low morbidity and mortality (Karamchandani and McGarry 2010).

Tonsillectomy and adenoidectomy are both common, high-volume operations. These operations are mostly performed on children and young adults. In Finland, about 6 000 tonsillectomies are performed annually. Tonsillectomy was the operation, that had the most patient injury claims, as it accounted for 10.2% of 98 accepted surgical ORL patient injury cases in Finland (Lehtivuori et al. 2013). These routine procedures are a potential cause of devastating complications. The consequence of the procedure was death or major injury in 52% of tonsillectomy court cases in the US (Morris et al. 2008). Fourteen cases of the ORL malpractice lawsuits concerned children whom had undergone tonsillectomy or adenoidectomy, 11 operations resulted in the death of the child in the US between 2001-2011 (Hong et al. 2013c).

The volume of ESS has increased substantially. A retrospective review of a nationwide US database between 2003 and 2007, reported the overall major complication rate of ESS to be 1.0% (Ramakrishnan et al. 2012). A retrospective review of ESS patients, cerebrospinal fluid (CSF) leak complication rate was 0.2% and orbital injury 0.1%, respectively (Ramakrishnan et al. 2012). The consequences of ESS complications in 41 in civil litigation malpractice cases in Boston US, were CSF leak (24%), brain damage (15%), diplopia (17%) and death (5%) (Lynn-Macrae et al. 2004). Moreover, 50% of the iatrogenic orbital complications are caused by ESS (Svider et al. 2013a).

The rhinological procedures constitute the largest subgroup (34.5%) of malpractice claims concerning operative ORL in the US (Dawson and Kraus 2007). The rate of was 18% of US malpractice lawsuits including errors in surgical technique, such as lesions of the orbit, skull base and adjacent nerves, in addition to problems with removable packing left *in situ* (Hong et al. 2013c).

An observational study by Montague and colleagues detected multiple errors in performing the most common otological procedures of myringotomy and ventilation tube insertion (Montague et al. 2004). A more recent study reported that 26% of the clinical negligence claims in ORL made in the UK between 1995 and 2010, concerned otology, and 64.9% of these were due to surgery (Mathew et al. 2011). Malpractice data from the US, indicate that 18 out of 200 (9%) claims concerned ear surgery: the consequence was hearing loss in 10 cases and facial nerve paresis in seven cases (Hong et al. 2013c).

2.3 Prevention of errors in surgery

One of the most important goals for health care systems is to prevent injuries to patients whilst undergoing treatment. The WHO has concluded that in developed countries half of the surgical adverse events that result in death or disability are considered preventable (WHO Patient Safety Safe Surgery http://www.who.int/patientsafety/safesurgery/en). This has been shown in a wide range on studies emanating from different surgical specialities, including ORL (Leape et al. 1991, Gawande et al. 1999, Gawande et al. 2003e, Shah et al. 2004, Seiden and Barach 2006, Cohen et al. 2010, Shah et al. 2010). The WSS events should be completely preventable by reducing the risk for serious mistakes procedurally (Gawande et al. 1999, Seiden and Barach 2006, Croteau 2007, Cohen et al. 2010).

Health care professionals working in an OT are highly educated and trained. Nevertheless, even the best-trained individual is capable of making an error. It was stated in a study by Roberson and colleagues that 'Any system that relies on a single individual for critical decisions will have an irreducible minimum of errors' (Roberson et al. 2004). The 'Swiss cheese model' seen in Figure 1, depicts an error proceeding unhindered to an adverse event when preventive mechanisms are insufficient (Reason 2000).

Using an alternative analogy that is referred to as the 'parmesan cheese model', every time a substandard practice is executed a piece is shaved off from a patient's potential. This 'parmesan cheese model' is a representation of the clinician's responsibility of minimising deficiencies in practice (Moloney 2014).

2.3.1 OT safety culture

Surgical working processes are organised in such a way to minimize or circumvent a variety of commonly known risks by using standardized approaches in the OT. Monitoring cardiac and respiratory outcomes during the anaesthesia is a standard in monitoring and controlling a patient's condition. Sterile work and instruments are essential to avoid surgical site infections (SSI). Prophylactic antibiotics are administered to reduce SSI, as well (Classen et al. 1992, Jaeger et al. 2006). Sponge counts are routinely performed to prevent RSS (Gawande et al. 2003a, Regenbogen et al. 2009, Shah and Lander 2009). The patient's identification bracelets and surgical site markings are used to prevent WSS. However, there is a large variation of these protocols among operative units and specialities, especially in developing countries (Kwok et al. 2013).

Results from the study on US surgical claims, showed that errors occur typically in common operations with experienced surgeons in high volume centres (Regenbogen et al. 2007). This conclusion challenges the conventional wisdom that surgical complications are linked to lack of a surgeon's specialisation and experience, or that the treatment sites associated with higher proportions of complications is exclusively associated with low volume hospitals. Similarly, traditional safety considerations, including strict supervision of residents or restricting operations to high volume hospitals, can address only some of the errors (Regenbogen et al. 2007).

2.3.2 Improving teamwork and communication

Teamwork and communication in the OT place high demands on personnel to be both systematic and fluent. Communication breakdown is one of the root causes behind many surgical adverse events (Gawande et al. 2003a, Sutcliffe et al. 2004, Neily et al. 2009). These failures are complex and relate to hierarchy and conflicting roles (Sutcliffe et al. 2004).

The roles of the OT professionals during surgical care are hierarchical and strictly defined.

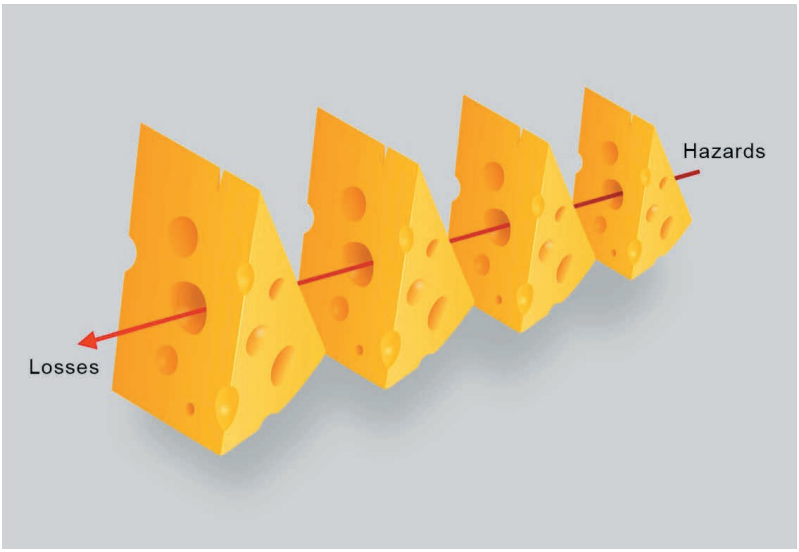


Figure 1. *The 'Swiss cheese model' when preventive mechanisms are insufficient, modified from Reason (2000), BMJ.*

A survey of 1033 OT staff members revealed a reluctance of senior theatre staff to accept input from junior members (Sexton et al. 2000). In contrast, aviation crews undergo structural training in collaboration and team decision-making, with the aim of encouraging junior crew to feel confident enough to raise safety concerns and for senior crew to learn how to accept their own errors being checked (Helmreich et al. 1999, Roberson et al. 2004).

Perceptions about teamwork differ between professions (Sexton et al. 2000). Surgery is too often viewed primarily as a solo activity by the surgeon than as a team activity (Pronovost and Freischlag 2010). Surgeons are well aware of technical demands related to certain procedures. Surgical tuition is focused on instructing the trainee surgeon in decision-making and technical skills, but this training does not currently emphasise working as a member of a team. It is stated that surgery and anaesthesia boards should consider that surgeons are required to have teamwork competency skills (Pronovost and Freischlag 2010).

Enhancing communication in the OT can reduce human errors and thus reduce the number of adverse events (Gawande et al. 2003e, Sutcliffe et al. 2004, Lingard et al. 2005, Lingard et al. 2008, Mazzocco et al. 2009, Nagpal et al. 2010, Neily et al. 2010, Pronovost and Freischlag 2010). The giving of a preoperative briefing has been shown to reduce communication failures (Lingard et al. 2008, Nundy et al. 2008). Similarly, structural information sharing during intraoperative and handoff phases was also found to affect complication rates (Mazzocco et al. 2009). A formalised team-training programme for OT personnel decreased the risk-adjusted surgical mortality (Neily et al. 2010).

A summarized multimodal approach, including structured information sharing, team training programmes and organisational changes to support team function is needed to improve teamwork and communication (Weller and Boyd 2014). Modern safety initiatives that focus upon a systemised communication process in the OT, team training programmes, and organisational team support will improve surgical safety (Weller and Boyd 2014).

2.3.3 Safety checklists

According to Reason 'Human fallibility can be moderated, but it cannot be eliminated' (Reason 1995). In high reliability organizations system defences have been created to trap an error before

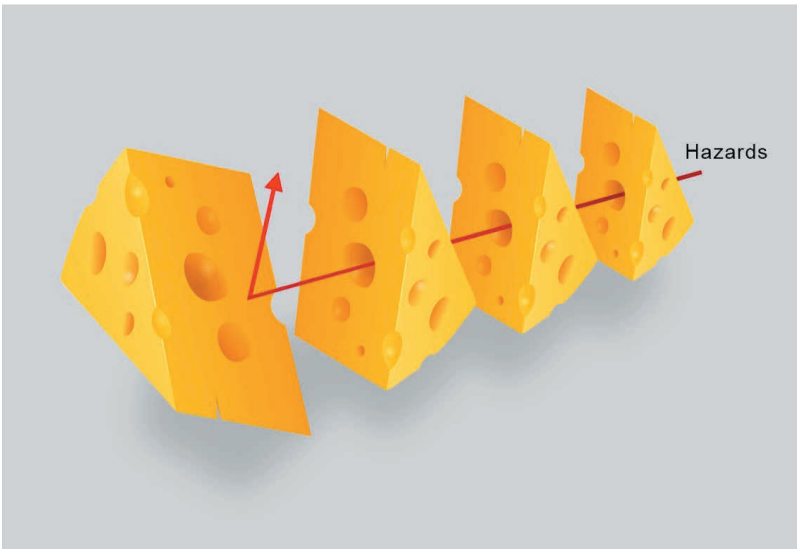


Figure 2. *The 'Swiss cheese model' with the efficient preventive mechanisms.*

it leads to failure (Helmreich et al. 1999, Reason 2000). This is shown in 'Swiss cheese model' in Figure 2. System defences can be in the form of preventive policies and protocols, such as checklists.

Safety checklists have been used to prevent accidents occurring as a result of human error in aviation and other complex human interaction requiring activities, since as far back as the 1930s (Reason 2000, Weiser et al. 2010c). Checklists decrease the chance of human error by standardising the work processes and avoid reliance solely upon memory (de Vries et al. 2009). Furthermore, checklists highlight and increase awareness of safety related issues.

An understanding of human related mechanisms in generating error has also motivated the development of checklists to detect faults in surgery. One of the first checklist prototypes for OT was piloted in 2003 in Canada (Lingard et al. 2005). In addition to surgery, checklists have been designed for a variety of health care practices; i.e. medicine, endoscopies, obstetrics, anaesthesia, trauma and transfer-of-care (Kim et al. 2012, Wittenberg et al. 2013, Black and Morin 2014, Braham et al. 2014, Lee et al. 2014, Matharoo et al. 2014). During recent years, checklists have become a standard part of surgical care; this evolution is described in following chapters.

2.3.3.1 Universal Protocol™

The Joint Commission (Bergs et al.) established by the American College of Surgeons with the other medical associations from the US and Canada to improve health care, announced a Universal Protocol ™ for preventing WSS, wrong procedure, wrong person surgery, on July 1st, 2004 (The Joint Commission History http://www.jointcommission.org/about_us/history.aspx, The Joint Commission Universal Protocol http://www.jointcommission.org/standards_information/up.aspx). The protocol includes a pre-operative verification process, marking the operative site and a Time Out (final verification checklist), which is performed immediately before starting the operation/procedure. This protocol was distributed to and is administered in all accredited hospitals and office based surgical facilities in America. The liability insurers in America have presumed its use.

A Time Out has been shown to be a useful safety and quality improvement tool (Altpeter et al. 2007). However, it has not been entirely successful in eliminating all WSS occurrences (Seiden and Barach 2006). In 2007, Hunter wrote about improvements with added time out components and suggested 'extended time out' to be universally implemented to lessen the likelihood of WSS (Hunter 2007).

2.3.3.2 The SSC

The WHO initiated a global challenge entitled: 'Safe Surgery Saves Lives' to improve the safety of surgical care around the world by defining a core set of safety standards in 2007 (WHO Patient Safety Safe Surgery http://www.who.int/patientsafety/safesurgery/en). Subsequently, the SSC was developed to improve the safety of surgical care in all operative fields (WHO Surgical Safety Checklist http://www.who.int/patientsafety/safesurgery/ss_checklist/en/). The SSC has a three-parts (Figure 3.). First check 'Sign in' is performed before anaesthesia induction, second 'Time out' before skin incision and third 'Sign out' after operation before the patient leaves the OT. The 19 check items were designed to be relevant in all environments where surgery takes place.

The WHO group conducted a prospective study on the effectiveness of the SSC in eight cities around the world that represented a variety of levels of developed of health care infrastructures. The results were published in the New England Journal of Medicine (NEJM) in January 2009. Surgery related mortality was reduced from 1.5% to 0.8% and the rate of surgical complications from 11.0% to 7.0% with the SSC use (Haynes et al. 2009). After these promising results for this simple and accessible intervention, the use of SSC spread quickly around the world. Its use was soon made mandatory in several countries (Vats et al. 2010, Askarian et al. 2011, Paugam-Burtz and Guerrero 2011, Urbach et al. 2014b). The pub-

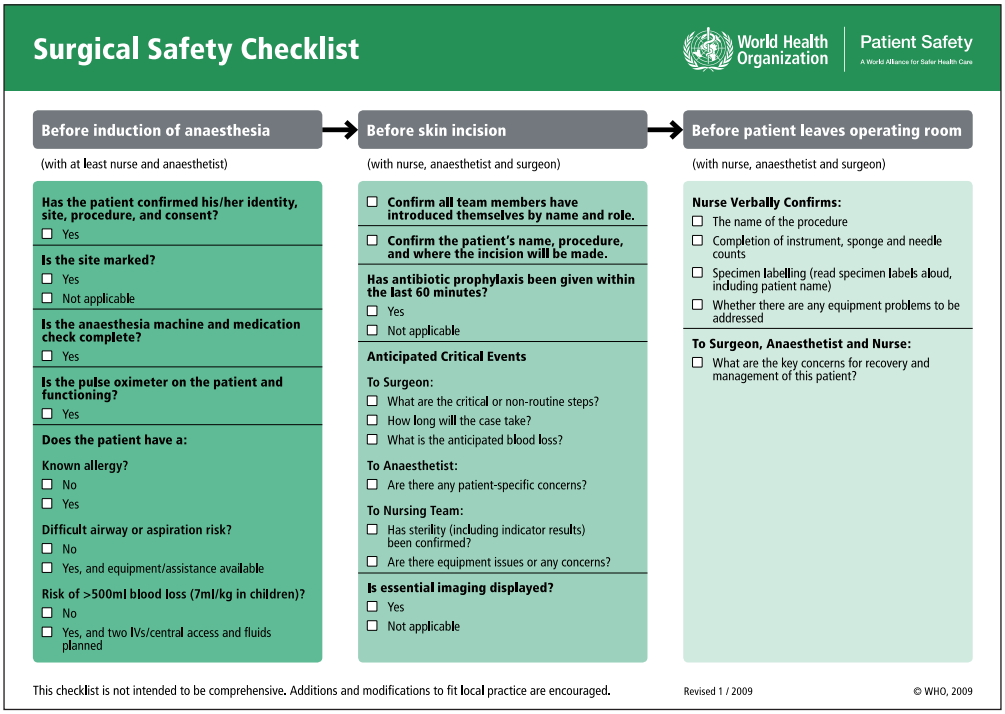


Figure 3. *The WHO Surgical Safety Checklist.*

lished studies about SSC soon started to proliferate. The majority of the published data are, however, only observational and report challenges in implementation and compliance.

We conducted an active follow-up of the literature and PubMed searches and found 10 intervention studies on the effectiveness of SSC on patient outcomes. There is a wide variety in sample sizes and designs within these studies and thus, comparison of results have limitations. Results of the main outcomes of the studies are presented in Table 3. (Haynes et al. 2009, Weiser et al. 2010a, Askarian et al. 2011, Sewell et al. 2011, Bliss et al. 2012, van Klei et al. 2012, Haugen et al. 2013, Kwok et al. 2013, Lubbeke et al. 2013, Haugen et al. 2014, Urbach et al. 2014b). In addition to these studies, several reviews and meta-analyses have attempted to summarise the results obtained so far (Borchard et al. 2012, Fudickar et al. 2012, Walker et al. 2012, Tang et al. 2013, Bergs et al. 2014, McDowell and McComb 2014, Thomassen et al. 2014).

These studies demonstrated a decrease in complication rate and mortality with considerably varying magnitude and significance. A Norwegian study found that SSC was associated with a remarkable reduction in morbidity and length of hospital stay (Haugen et al. 2014). In a subgroup analysis by the WHO group, urgent surgery complications diminished by more than a third (Weiser et al. 2010a). Similarly, SSC was associated with significant effectiveness in studies that emanated from Iran and Moldova (Askarian et al. 2011, Kwok et al. 2013). A study on trauma and orthopaedic patients in the UK showed a team communication improvement, but no significant reduction in early complications (Sewell et al. 2011). In a Swiss study on high-risk patients, a trend toward reduced re-operation rate was associated with SSC, but no influence on postoperative in-patient death emerged (Lubbeke et al. 2013).

The study with the largest sample size was conducted in Canada by Urbach et al. but it found no significant improvement in complica-

Table 3. *Intervention studies on effectiveness of Surgical Safety Checklist on patient outcomes.*

Study Country and characteristics *Setting*	**Intervention**	**Operations pre/post** **N**	**Complications pre/post** **%** Significance testing	**Mortality pre/post** **%** Significance testing
Haynes 2009 8 countries*, non-cardiac *Prospective*	SSC	**3 733/3 955**	**11.0/7.0** P=0.003	**1.5/0.8** P<0.001
Weiser 2010 8 countries*, urgent operations *Prospective*	SSC	**842/908**	**18.4/11.7** P<0.001**	**3.7/1.4** P=0.007**
Askarian 2011 Iran, elective *Prospective*	SSC	**144/150**	**22.9/10.0** P=0.030**	**N.a.**
Sewell 2011 UK, trauma and orthopaedic *Prospective*	SSC	**480/485**	**8.5/7.6** RR 0.89 (0.58-1.37)	**1.9/1.6** RR 0.88 (0.34-2.26)
Bliss 2012 Connecticut, US, high-risk procedures *Prospective cohort with historical controls*	Preprocedure check, team training and SSC	**246/73** (2 079 historical controls)	**23.6/8.2** P<0.001	**N.a**
van Klei 2012 Netherland, non-cardiac *Retrospective cohort*	SSC	**14 362/11 151**	**N.a.**	**3.13/2.85** OR 0.91 (0.78, 1.05)
Kwok 2013 Moldova *Prospective*	Pulse oximetry and SSC	**2 145/2 212**	**21.5/8.8** P<0.001	**4.0/3.1** P=0.151
Lübbeke 2013 Switzerland, high-risk, ASA 3-5 *Prospective*	SSC	**609/1 818**	**N.a.**	**4.3/5.9** RR 1.44 (0.97-2.14)
Haugen 2014 Norway *Prospective, stepped wedge cluster randomised*	SSC	**2 212/2 263**	**19.9/11.5** P<0.001	**1.6/1.0** P=0.151
Urbach 2014 Ontario, Canada *Before and after administrative data analysis*	SSC	**109 341/106 370**	**3.86/3.82** P=0.530**	**0.71/0.65** P=0.070**

Number (N) of studied operations and proportion (%) of complication/mortality; SSC=Surgical Safety Checklist; ASA=American Society of Anesthesiologists Physical Status Classification; P=Probability; N.a.=Not available; RR=Risk ratio; OR=Odds ratio; *Same study centres; ** The P-values have been rounded to an accuracy of three decimal places.

tions (P=0.53) and mortality (P=0.07) (Urbach et al. 2014b). This result inspired a vigorous discussion among patient safety community (Albert 2014, Avidan and Evers 2014, Haynes et al. 2014, Leape 2014, Robblee 2014, Urbach et al. 2014a, Weiser and Krummel 2014). It can be assumed that safety improvement tools should be more comprehensive than the SSC in order to have significant effects on well-developed health care infrastructures. It is noteworthy, that the pre-intervention (baseline) data revealed that the Canadian in-hospital mortality rate was extremely low (0.71%) (Urbach et al. 2014b, Weiser and Krummel 2014). However, even a minor improvement can have clinical significance and on a personal level, every prevented death or disability counts.

2.3.3.3 The SURPASS checklist

De Vries stated that 'the standardization of surgical processes should not be limited in OT' (de Vries et al. 2010). The Surgical Patient Safety System (SURPASS) checklist, developed by the Dutch group, is a multidisciplinary checklist that covers the entire surgical pathway (SURPASS-Checklist http://www.surpass-checklist.nl/dl-Checklist.jsf?pageId=Download&lang=en). This

comprehensive safety system includes six check points from admission to discharge and a total of 124 items to be checked (de Vries et al. 2009). Perioperative check points in SURPASS are slightly more detailed when compared with SSC.

The patient outcomes of 3760 patients in pre- and 3820 in a post-interventional group were examined in a study of regional academic hospitals in the Netherlands between 2007 and 2009. In-hospital mortality decreased from 1.5% to 0.8% and complications from 27.3 to 16.7 per 100 patients (de Vries et al. 2010). The same group assessed error contributing factors described in 294 surgical malpractice claims and noted that 29% of those errors might have been intercepted by the SURPASS checklist (de Vries et al. 2011). These studies confirmed this comprehensive checklist to be an effective safety improvement tool in the health care system of a highly developed country.

2.3.3.4 The effects of checklists on teamwork and communication

A systematic review by Russ and colleagues, concluded that safety checklists improve both perceived and observed teamwork and communication in the OT (Russ et al. 2013). Similarly, safety checklists have been shown to reduce failures in communication (Lingard et al. 2008, Henrickson et al. 2009).

An intervention based on a checklist improves inter-professional communication and reduces the number of communication failures (Lingard et al. 2008). Checking the items serves as a structural team briefing before an operation (Verdaasdonk et al. 2009). The introduction of team members and sharing information about the patient and the following procedure, supported by the checklist, creates an atmosphere where teamwork is emphasized. This perception of teamwork among OT staff may further lower the threshold to speak up in difficult critical situations (Russ et al. 2013).

In paediatric surgical unit, teamwork and communication were improved by the use of 'paediatric surgical safety checklist' (Norton and Rangel 2010). In a study on trauma and orthopaedic patients conducted in the UK, OT staff communication was improved by the use of the SSC as was the patient outcomes (Sewell et al. 2011). Similarly, the WHO group showed that the use of the SSC improved the perception of teamwork and safety climate among OT team members measured by the modified SAQ. The majority of studied OT staff thought that the checklist improved team communication (Haynes et al. 2011). This result originates from the same study that showed remarkable improvement of patient outcomes (Haynes et al. 2009).

Safety checklists have been developed to serve as tools for standardised communication (Lingard et al. 2005). This use of standardised communication improves information transfer process. This can be one mechanism by which patient outcomes are improved by using the checklists (Mazzocco et al. 2009, Nagpal et al. 2010, Russ et al. 2013).

2.3.3.5 Designing a checklist

Designing safety checklists for health care has parallels with, and draws upon safety checklist experiences in the aviation industry, where multiple safety checklists are used to control important steps of tasks (Weiser et al. 2010c). When designing a checklist, processes must be critically reviewed (Verdaasdonk et al. 2009). Checklist development consists of identification of critical tasks, drafting of checklist items and several validation stages including piloting and modifications (Weiser et al. 2010c).

Consistency, directness and clarity are important requirements for checklists (Verdaasdonk et al. 2009). The balance between brevity and comprehensiveness must be carefully evaluated (Weiser et al. 2010c). It is essential to prevent the list from becoming exhaustive (Karamchandani and McGarry 2010, Vats et al. 2010). Excessively long or very difficult checklists may have negative effects on task performance, whereas checklists that are too short may have no effect at all (Verdaasdonk et al. 2009).

Safety checklists are used as supplementary security tools on existing safety protocols. However, there is a wide variation of health care facilities and safety standards. When current standards already cover the monitoring and control of checked objects, the introduction of a safety

checklist's effect is presumably moderate. This may be one explanation for the lack of SSC responses reported for the high-income countries of Canada and Switzerland (Lubbeke et al. 2013, Urbach et al. 2014b). A more comprehensive SURPASS checklist has, however, produced a significant reduction of complications and mortality in an already high-standard care environment (de Vries et al. 2010).

The SSC was designed to be relevant and support clinical practice in all environments where surgery takes place (Weiser et al. 2010c). It is recognised that the SSC should be modified to meet the needs of quite different surgical specialities and environments (Clark and Hamilton 2010, Norton and Rangel 2010). This modification is also encouraged by the WHO: 'different practice settings will adapt it to their own circumstances' (WHO Surgical Safety Checklist http://www.who.int/patientsafety/safesurgery/ss_checklist/en/). It must be considered, however, that modification can also adversely influence the efficacy (Verdaasdonk et al. 2009, Weiser et al. 2010c).

Reports on modifying the SSC for various operations and working environments have recently been published (Norton and Rangel 2010, Perea-Perez et al. 2011, Cavallini et al. 2013, Connor et al. 2013). As an example, the items 'Weight', 'Warmer in place' and 'Appropriate intra venous access' have been added to a safety checklist for paediatric operations (Norton and Rangel 2010). On the other hand, it is reasonable to assume that a safety checklist for ambulatory oral surgery does not need a 'Sign in' check as it consists only of before- and after-surgery sections (Perea-Perez et al. 2011).

2.3.3.6 Implementation of and compliance with checklist

Implementation of safety protocols, such as checklists, should be systematic and well administered (Norton 2007, Norton and Rangel 2010, Vats et al. 2010, Levy et al. 2012). Unsuccessful implementation will result in incomplete compliance and hence will lessen the checklist's effect on the prevention of errors.

The implementation of a checklist is likely to succeed when used as a tool in multifaceted organisational programmes and lead by a multidisciplinary team (Conley et al. 2011, Aveling et al. 2013). Training of the OT staff, active leadership, regular audits and feedback are important for successful implementation and maintenance of checklist use (Verdaasdonk et al. 2009, Norton and Rangel 2010, Vats et al. 2010, Conley et al. 2011).

Motivation of the OT staff to use the SSC is essential for good compliance (Verdaasdonk et al. 2009). Education of the users during implementation, should *inter alia* emphasise the reasons 'why' there is a need for an improvement and 'how' the checklist has to be conducted (Borchard et al. 2012). Users need to understand the benefits and the importance of completing the checklist (Russ et al. 2014). When personnel do not understand the rationale behind using the checklist, the benefits are compromised and the compliance is incomplete (Conley et al. 2011). It is also suggested that with suboptimal use, or when individuals have not been brought into the process, checklists might conversely have a negative impact on the teamwork (Russ et al. 2013).

A safety checklist should be fully and carefully completed. As a part of the implementation process, a standardized policy that confirms checklist use for each procedure is needed (Styer et al. 2011). The checks should be done with due care and replies to the checks must be truthful and exact (Vats et al. 2010). An inadequately performed checklist can provide a false sense of security and will lessen its efficiency in preventing errors (Vats et al. 2010). A Dutch cohort study showed significantly lower mortality in operations with fully completed checklists (van Klei et al. 2012).

A study from the UK demonstrated a significant increase in SSC compliance following educational intervention (Sheena et al. 2012). This result also demonstrates that to maintain the correct use of the checklist on-going feedback is needed (Vats et al. 2010, Conley et al. 2011). Monitoring and reporting compliance has also proven to be effective regulatory support by the hospital leaders (Healy 2012).

The commitment of the surgeons is particularly important for a successful implementa-

tion of the checklist (Lingard et al. 2005, Vats et al. 2010, Fourcade et al. 2012). Vats and colleagues conducted a UK based observation study and reported that the SSC was more likely to be completed thoroughly when the surgeons and anaesthetists were supportive of its use (Vats et al. 2010). Moreover, a longitudinal interview-based study conducted in UK showed that the most common barrier to SSC implementation was resistance from senior surgeons (Russ et al. 2014). However, hierarchical relationships can be the major barrier especially in a low income setting (Aveling et al. 2013).

Several studies have revealed, that the widespread 'mandatory implementation' by the governments and health care organisations have resulted in incomplete SSC compliance of around 60% (Vats et al. 2010, Kearns et al. 2011, Paugam-Burtz and Guerrero 2011, Vogts et al. 2011). A mandated implementation of a safety checklist without active support can also result in high rates of reported compliance without true behaviour change (Fourcade et al. 2011, Pickering et al. 2013, Haynes et al. 2014).

2.4 Prevention of errors in ORL surgery

Roberson and colleagues wrote in 2004 that ORL specialists could benefit from learning the principles of system science (Roberson et al. 2004). Thereafter, it has been emphasised that 'every specialty is unique, and must therefore take responsibility for the study of human error within its own domain' (Shah et al. 2006). Despite that early statement, patient safety research studies for ORL have been few in number even up to the present time.

2.4.1 Site marking

A recent review concluded that WSS accounts for 4-6% of errors in ORL (Liou and Nussenbaum 2014). This value is in accordance with the results of two surveys, which revealed variable and insufficient site-marking protocols within the specialty (Shah et al. 2010, Shah et al. 2011). A survey was sent to ORL specialists in North America and it found that 20% of responders did not mark the

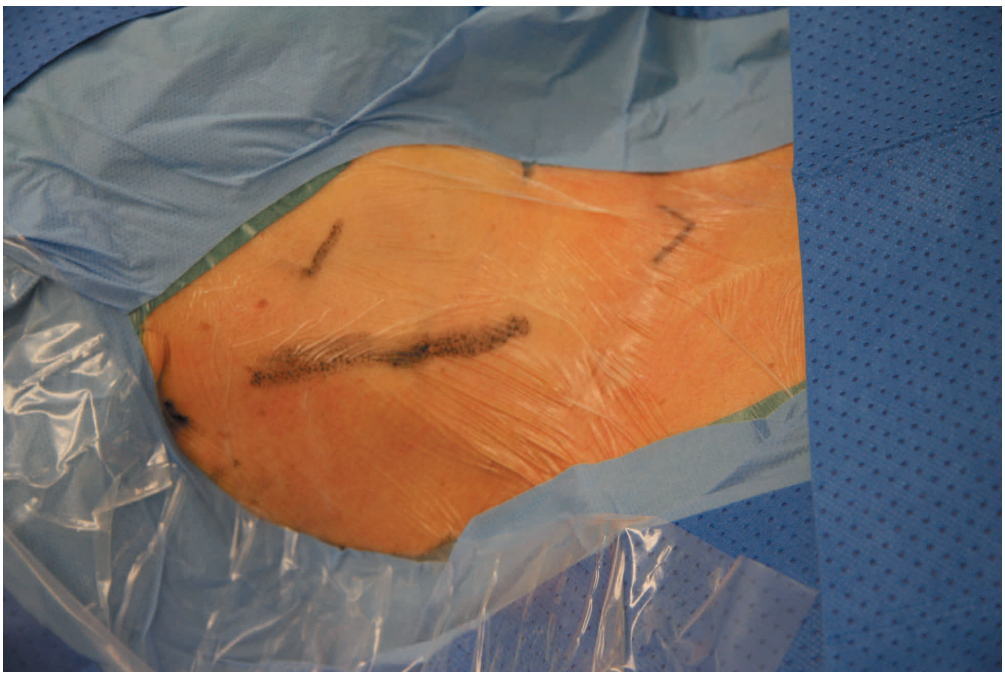


Figure 4. *Marking of the operation site for neck surgery.*

operation site at all and 30% relied on a review of the imaging as a check for the correct side for ESS.

A Universal Protocol ™ Time Out was used in 32.4% of the wrong-site sinus surgery cases (Shah et al. 2010). It is interesting to note that this protocol did not previously request site marking on body cavity surgery including ESS. Implementation of the WHO Checklist has promoted the use of site marking as routine. In addition to the SSC, Knepil and colleagues published their experiences with a simple skin marking system for oral surgical procedures (Knepil et al. 2013). Marking an operation site on the skin is a simple procedure and would be just as useful for superficial operations as for body cavity operations in the ORL region (Figure 4.).

2.4.2 Checklists for ORL-related surgeries

The Sinus Surgery Checklist has been developed to prevent ESS specific errors (Soler and Smith 2012). It has three sections namely: prior to intubation, prior to instrumentation and prior to extubation. It contains safety checks regarding, *inter alia*, the display of the radiograms, epinephrine labelling and documentation of materials left *in situ*. In a prospective observational study the Sinus Surgery Checklist increased the performance of these safety tasks during the course of ESS (Soler et al. 2012).

A proposal for a checklist for ambulatory oral surgery was presented in 2011 (Perea-Perez et al. 2011). It consists of before- and after-surgery sections and it has been proposed for operations under local anaesthesia, by an OT team without an anaesthetist being present. This configuration is used in various ORL operations.

2.4.3 The SSC in ORL

The WHO SSC was rapidly taken into wide use after its introduction in 2009. Its implementation was mandatory in many countries and hospitals, including operative ORL units. Karamchandani and McGarry wrote in Clinical Otolaryngology in 2010 that: 'In ORL, we are unlikely to see immediate large benefits from the SSC due to the predominance of low mortality and low morbidity procedures. Perhaps only head and neck surgery exhibits the levels of risks that would demonstrate effect of significant size.' (Karamchandani and McGarry 2010). This statement is inconsistent with the knowledge of the errors that can occur in the specialty (Chapter 2.2.1). 'Human error occurs in all practice components in otorhinolaryngology, including diagnostic, treatment, surgical, communication, and administrative' (Shah et al. 2004).

Fishpool and colleagues soon responded with the preliminary and encouraging findings from the ORL discipline: 'we identified three potential adverse incidents, of varying magnitude, that were prevented' (Fishpool et al. 2010). After this letter was published, we could find only one publication that studied the SSC in the ORL-specialty. In that study the SSC compliance in ORL was audited and observations were made by ORL trainees in two hospitals in the UK (Sheena et al. 2012). It was reported that the 'Time out' phase was fully completed in only 33% of cases, the mean time for its completion was 60 seconds; completion of two other phases was even worse. Following an educational intervention, overall compliance increased to 90.4%.

However, we were not able to find studies published in the literature that specifically examine the effects of the WHO checklist on ORL-operations or have studied the relevance of the check items for the specialty.

3. AIMS OF THE STUDY

The present study had the following aims:

1. Identify errors and incidents that contribute to patient injuries in ORL then assess the correspondence of these factors with the SSC content and to evaluate whether the injury could have been prevented by the use of a checklist. (I)

2. Study the effects of SSC implementation on the OT working process in a multicentre prospective setting. (II)

3. Evaluate the effects of SSC implementation on patient safety related issues and communication in OT within the ORL-specialty. (III)

4. Investigate compliance and user opinions about SSC after one year of its implementation, in addition to assessing the safety attitudes within an ORL operating department. (IV)

5. Evaluate the specialty-related relevance and utility of the check items in ORL, with special reference to outpatient surgery. (V)

4. MATERIALS AND METHODS

4.1 Patient injuries in ORL

4.1.1 Errors in ORL surgery (I)

The Finnish Patient Insurance Centre (PIC) insures all patients who have been treated by the official health care providers in Finland (Finnish Patient Insurance Centre http://www.pvk.fi/en/). A retrospective review of these national patient insurance charts was conducted (I). All those patient injury claims within the ORL specialty whose cases closed between 1st of November 2001 and 31th of October 2011, were sought in the PIC claim records database. The claims covered the treatments that had been given between the years 1998 and 2011. A total of 233 claims were accepted as compensated patient injuries and included in the study.

Age, gender, diagnosis and major co-morbidities of the patient in addition to information of health care providers and institutions were recorded as background data. All medical records, experts' assessments and compensation decisions of the included claims were reviewed. Two ORL specialists evaluated the operation-related injuries in detail. Incidents and errors contributing to the injury were identified and classified. One or two noteworthy independent errors were defined for each patient. The structure of the classification used was based on the care-flow-process of the patient. It was modified from the classification presented for ORL by Shah et al. (Shah et al. 2004).

4.1.2 Patient injuries and SSC (I)

Incidents and errors were compared with the items of WHO SSC on a case-by-case basis to evaluate whether a properly used checklist might have prevented the claim. Incidents were classified as 'preventable', if they had a direct correspondence to one or more checklist items. An incident was classified as 'possibly preventable' when it was noted as only one step of the error-chain. For instance, in cases when there was no charting of materials left *in situ*, they were not removed and a patient got an infection caused by a retained foreign body.

For statistical processing, descriptive data were summarised using numbers and proportions (%). Statistical analyses were carried out with IBM SPSS software version 22.0 for Mac.

4.2 The effects of SSC on OT work

4.2.1 Pilot implementation of the Finnish SSC (II, III)

The preliminary results of the effectiveness of the WHO SSC were published in January 2009 (Haynes et al. 2009). Shortly after that, a project for the pilot implementation of Finnish modification of the SSC was announced. Six operative departments of four hospitals, Turku University Hospital, Tampere University Hospital, Helsinki University Central Hospital (HUCH) and Vaasa Central Hospital, were participated in the project. These operation units covered several surgical specialities and approaches, for instance, day care surgery.

A group of experienced clinicians who were anaesthetists and specialists in several surgical fields evaluated the SSC, designed the implementation strategy and organized the actual implementation. The SSC was translated into Finnish and minor changes were designed for the pilot version of the list. All the original check items were retained and a few new items were added mainly to the anaesthesia category (Appendix 11.1). Prior to the implementation, the OT staff attended three 45-minute lectures on how and the reasons for using the checklist. The circulating nurses were appointed as checklist coordinators, and guidelines on the use of the checklist were available in the OT and also on the back page of the printed list. An implementation of this pilot version of the Finnish SSC announced for one month, in September 2009.

4.2.2 The SSC multicentre study (II)

We evaluated the effects of the implementation of the SSC on the OT working process, by conducting a prospective 'before and after intervention' study that covered all six operation units that participated in SSC pilot implementation (II).

A structured multiple-choice questionnaire was designed for the study. It consisted of three forms that we respectively addressed to the surgeon, the anaesthetist, and a circulating nurse. The questionnaire asked about the existing safety checks together with the safety related issues and communication in the OT (Appendix 11.2). The reply alternatives were 'yes', 'no', 'do not know' and 'not relevant'. At the end of the questionnaire some space for respondents' free-text comments was provided. In addition, information of the duration of the operation and timing of the administration prophylactic antibiotics were sought.

The questionnaire was completed at the end of every operation, during two separate one-month study periods, before and after the pilot implementation of the SSC. The surgeon, anaesthetist, and circulating nurse answered the questionnaire independently. The 'before-intervention period' (first study period) took place during May 2009. The checklist was implemented for one-month use on September 1, 2009, and at the same time, data collection for this 'after-intervention period' (second study period) began.

The data from all centres were analysed as a whole for a multicentre study (II). Data were presented in numerical form as the proportion of answers (%). Comparisons between before and after checklist groups were categorical and were therefore analysed by the chi-square test. P-values of less than 0.05 were considered statistically significant. Statistical analyses were carried out with SPSS 16.0 for Windows (SPSS Inc. Chicago, IL, USA).

4.2.3 The SSC in ORL (III)

Questionnaires from the operative unit of the Department of Otorhinolaryngology of HUCH were analysed as a subgroup to evaluate effects of SSC implementation on patient safety related issues and communication within the ORL-specialty (III).

All 'not relevant' values were excluded from among the definite variables (side of operation, prophylactic antibiotics and radiological images). The values of the categorical variables were further classified by being dichotomized as either 'yes' or 'non-confirmed' for statistical processing of this smaller subgroup data. The 'non-confirmed' class included 'no', 'do not know' and missing values. Data are presented in numerical form as the proportion of 'yes' answers (%), unless otherwise indicated. Comparisons between before and after intervention groups were analyzed by using the chi-square test. P-values of <0.05 were considered statistically significant. Statistical analyses were carried out with SAS/STAT software, Version 9.1.3 SP3 of the SAS System for Windows (SAS Institute Inc., Cary, NC, USA).

In addition, the operation database was searched for identification of characteristics of the operations performed in the operative ORL unit of HUCH. Patient-identifying data were not collected.

4.3 The use of SSC in the ORL

4.3.1 SSC compliance (IV)

The Finnish version of the WHO SSC was implemented for regular, and mandatory, use in the operative ORL unit of HUCH on 1 September 2010 (Appendix 11.3). Over 7000 operations are performed annually in this unit, over half of which are outpatient procedures. The completion of each checklist component ('Sign in', 'Time out', 'Sign out') was registered in the operation database by a circulating OT nurse for every operation. This registration was also mandated by the hospital administration. We conducted a search of these data on operations performed between 1 September 2010 and 31 August 2011 to study the compliance during the first year after implementation. Completion rates of every three checks were analysed month by month.

4.3.2 Survey for SSC users (IV, V)

We conducted a survey of OT personnel after one year of using the checklist to evaluate user opinions on SSC and safety attitudes within the operative ORL unit of HUCH (IV). In addition, we assessed the relevance of SSC check items for ORL specialty (V).

A structured questionnaire see Appendix 11.4 was designed for the study. The respondent's vocational education, age, gender, and experience of ORL-HNS practice were recorded (IV and V). The OT team members were asked to estimate the frequency of checklist use in the operations in which they participated in order to measure the self-reported SSC compliance (IV). Space for comments about the usability and use of the checklist, concerns about patient safety and the relevance of the check items, with special reference to outpatient surgery was made available at the end of the questionnaire (IV and V).

The multiple-choice portion of the questionnaire consisted of 12 questions that measured safety attitudes within the respective OT. These questions inquired about the SSC effects on teamwork and safety climate and were first published by the WHO group (Haynes et al. 2011). Six of these questions originated from the OT modification of the validated SAQ and six further questions were related to the SSC itself (Sexton et al. 2006a, Haynes et al. 2011). The SAQ was originally derived from the Flight Management Attitudes Questionnaire (Helmreich et al. 1996). In addition, the responders' opinions about the relevance of every check item for ORL was sought (V). All these multiple-choice answers were recorded on a five-point Likert scale that included 'disagree strongly' (1), 'disagree slightly' (2), 'neutral' (3), 'agree slightly' (4) and 'agree strongly' (5).

A survey was conducted in October 2011. The questionnaire was handed to 48 ORL specialists, 11 anaesthetists and 47 operation and anaesthesia nurses working in the OT. The answers were collected anonymously.

Continuous data are presented as numbers (N) and proportions (%) for each answer. Means with standard deviations (SD) and ranges were calculated. Moreover, the values of five point Likert scale variables were further categorised by classifying them dichotomously as 'agree' or 'neutral, disagree or no answer'. Statistical analyses were carried out with PASW Statistics software version 18.0 for Mac (SPSS INC., Chicago, IL, USA).

5. RESULTS

5.1 Patient injuries in ORL

A total of 223 claims for the ORL-specialty were accepted and compensated as patient injuries by the PIC. A patient was typically treated for a common disease by a fully trained ORL specialist in a central or university hospital (Table 4.).

The mean age of the patient was 46.3 years, and ranged from 1 to 85 years. Sixteen (7.2%) patients were children. Nineteen (8.5%) patients were treated for a malignant disease. The majority 188 (80.6%) of patient injuries were associated with operative care and 35 (15.7%) injuries resulted from an error in outpatient care.

5.1.1 Errors in ORL surgery (I)

Errors identified in operation related patient injuries are presented in Table 5. In 72 (32.3%) cases, two noteworthy errors independent of each other could be detected. As an example, in the same operation one error was iatrogenic trauma to the facial nerve and the other was postoperative infection due to retained packing after ear surgery. Error occurred in the OT in 142 (75.5%) cases. Fourteen (7.4%) patients had undergone an urgent operation. Eighty-three (44.1%) of these injuries were related to surgery of the nose and paranasal sinuses.

A manual error in performing operation could be verified in 125 (66.5%) cases. Incidental injury to the adjacent nerve or anatomical structure occurred in 86 (45.7%) operations. It was notable, that in most cases when the injury was noticed during the operation, adequate procedures to repair the injury were immediately carried out. Unfortunately, nerve injuries often resulted in permanent morbidity. Two manual errors in performing surgery caused death. One patient died of mediastinitis after perforation of the oesophagus with a rigid oesophagoscope and the other because of uncontrolled bleeding after intracranial protruding of an instrument.

WSS occurred six times, in 3.2% of operation-related injuries. In all cases, the site marking was lacking. Multiple errors were identified in one case of wrong side ear surgery. Hair was removed from the wrong side due to a misunderstanding arising from language problems and thus, a wrong side was prepared for the operation. Removal of the wrong site skin tumours and lymph nodes resulted in reoperations and an additional scar, and delay in diagnosis for one patient. The wrong vocal cord filling resulted in permanent morbidity. Two child-patients suffered from oral breathing and infection due to retained nasopharyngeal gauzes. Both patients needed re-anaesthesia for the removal of the gauzes.

5.1.2 Patient injuries and SSC (I)

An error had some degree correspondence with a WHO SSC item in 18 injuries (9.6%). Both reviewers evaluated nine (4.8%) of these errors as being

Table 4. *Characteristics of health care providers in ORL related patient injuries in Finland between 2001 and 2011.*

	N	%
Hospital		
University hospital	80	35.9
Central hospital	93	41.7
Local hospital	18	8.1
Primary health care	12	5.4
Private health care provider	20	9.0
Training of physician		
ORL specialist	169	75.8
ORL trainee	23	10.8
Other	31	13.9
Total	223	100

Number (N) and proportion (%).

Table 5. *Errors identified in ORL operation related patient injuries, classified on the care flow basis.*

	Error 1.		Error 2. *	
	N	%	N	%
Preoperative judgement and surgical planning				
Incorrect/unnecessary procedure or technique	8	4.3	7	3.7
Insufficient patient information	0	0	3	1.6
Error in preoperative care	0	0	3	1.6
Operation theatre				
No prophylactic antibiotic	1	0.5	0	0
Problems in anaesthesia	3	1.6	0	0
Wrong site surgery	6	3.2	0	0
Manual error in performing surgery	125	66.5	15	8.0
Retained gauze/instrument	2	1.1	0	0
Equipment related errors	4	2.1	0	0
Insufficient charts or instructions	0	0	8	4.3
Other error in the operating theatre	1	0.5	1	0.5
Postoperative period				
Postoperative ward care	1	0.5	2	1.1
Wrong/insufficient medication	0	0	1	0.5
Infection	12	6.4	8	4.3
Haemorrhage	7	3.7	0	0
Insufficient postoperative treatment/ follow up	4	2.1	6	3.2
Retained foreign body e.g. nasal tampons	9	4.8	4	2.1
Unintended outcome	5	2.7	13	6.9
Operative care, All	188	100	71	37.8

Number (N) and proportion (%) of errors detected in 188 accepted operative ORL related patient injury claims. *In 71 (37.8%) claims two independent errors contributing to the patient injury could be identified.

'preventable' by a correctly completed checklist. In addition, there were nine (4.8%) cases assessed as 'possibly preventable' by using the checklist. One patient suffered severe and unexpected airway problems while she was being intubated for a thyroid operation. This resulted in permanent laryngeal injury. Eight patients with retained foreign material –related problems, had insufficient charting of materials left *in situ*. All injuries with identified correspondence to SSC item are shown in Table 6.

Table 6. *Patient injuries in operative ORL due to an error with correspondence to a WHO surgical checklist item.*

	N	%
Errors with correspondence to the checklist, All	**18**	**9.6**
Preventable error, All	**9**	**4.8**
Wrong ear opened	1	0.5
Wrong skin lesion/scar excised	3	1.6
Wrong lymph node extirpated	1	0.5
Wrong vocal cord injected	1	0.5
Prophylactic antibiotic not administrated	1	0.5
Retained nasopharyngeal gauze after tonsillectomy	2	1.1
Possibly preventable error, All	**9**	**4.8**
Airway misjudgement	1	0.5
Retained removable packing, insufficient documentation of left materials	8	4.3
Surgery-related injuries, Total	188	100

Number (N) and proportion (%) of errors.

Table 7. *Returned questionnaires from six participating units of four centres.*

	Before the checklist implementation		After the checklist implementation	
Operative unit, hospital	**N**	**%**	**N**	**%**
Neurosurgery, Turku University Hospital	89	9.9	73	8.6
Plastic- and general surgery, Turku University Hospital	144	16.0	115	13.6
Paediatric surgery, Tampere University Hospital	49	5.4	36	4.3
Operative gynaecology, Tampere University Hospital	140	15.5	55	6.5
Otorhinolaryngology, Helsinki University Central Hospital	288	32.0	412	48.6
Outpatient surgery unit, Vaasa Central Hospital	191	21.2	156	18.4
Total	901	100	847	100

Number (N) and proportion (%) of operations.

5.2 The effects of SSC on OT work

5.2.1 The SSC multicentre study (II)

Questionnaires from all six participating units of the four study centres were returned after a total of 1748 operations, 901 had been performed before and 847 after the SSC implementation of the checklist (Table 7). The proportion of replies to various questions ranged from 91 to 99%. An anaesthetist was neither present nor answered the questions some for operations that had been performed under local anaesthesia.

The use of the checklist had no association on operation time, the mean duration of the operations was 1h:09min ± 1:05 (mean ± SD) before

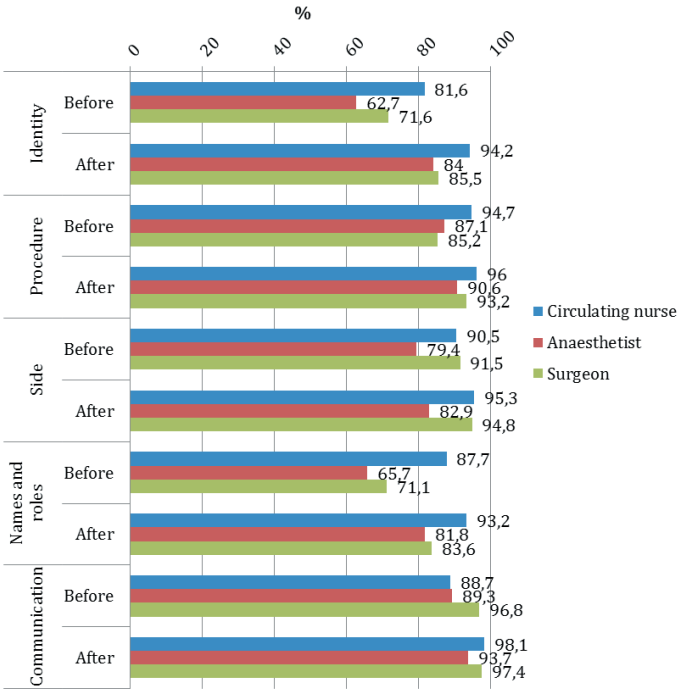


Figure 5. *Proportion (%) of yes replies of returned questionnaires from all study sites, before and after the implementation of the SSC. Items are knowledge of patient's identity, planned procedure, correct surgical side, names and roles of the team members and success of communication in the OT.*

Table 8. *Characteristics of patients and operations performed in the ORL department of HUCH, before and after the implementation of the SSC.*

	Before		After	
	N	%	N	%
Patient				
Children (under age 16)	73	24.0	78	17.6
ASA class I-II	245	80.6	381	86
Operation				
Outpatient procedure	120	39.5	260	58.7
Urgent operation	53	17.4	29	6.5
Local anaesthesia	50	16.4	87	19.6
Operation type				
Ear, tympanostomy	16	5.3	22	5
Ear, other	39	12.8	62	14
Adenoids and tonsils	61	20.1	140	31.6
Laryngology	32	10.5	28	6.3
Nose	34	11.2	57	12.9
Paranasal sinuses	34	11.2	46	10.4
Neck	27	8.9	40	9
Salivary gland	26	8.6	11	2.5
Other	35	11.5	37	8.4
Total	304	100	443	100

Number (N) and proportion (%) of operations recorded to the operation database. ASA=American Society of Anesthesiologists Physical Status Classification System.

and 1:09 ± 1:06 after (P=0.872). When required for prophylaxis an antibiotic was given within 60 minutes before incision in 37.8% of the operations before and in 40.5% after the implementation of the SSC. This difference was not significant but there were considerable differences among the six individual operating units.

The identity of the patient was confirmed more frequently and the knowledge of the type and side of the operation increased after the implementation of the checklist (P<0.001). Similarly, knowledge of the names and roles of team members improved significantly (P<0.01) and successful communication between the team members was reported more frequently. Results by professions are presented in Figure 5. Furthermore, critical events were discussed more frequently between the surgeon and the anaesthetist and postoperative prescriptions were also better recorded.

5.2.2 The SSC in the ORL (III)

A total of 747 operations were performed in the ORL department of HUCH during the study periods, 304 before and 443 after the pilot implementation of Finnish SSC. The questionnaires for 700 (93.7%) operations were returned, 288 (94.7%) before and 412 (93.0%) after the implementation. Characteristics of the patients and the types of operations are presented in Table 8.

Mean duration of the operations was 58 minutes before and 55 minutes after the checklist implementation of the SSC. A minority of the patients (13.9% before and 9.5% after the checklist) received prophylactic antibiotic, with no significant improvement in timing of the administration (P =0.44).

The surgeon, anaesthetist, and circulating nurse answered the questionnaire independently at the end of every operation. The checklist improved knowledge of the patient's identity by all OT-team members in the ORL OT (P<0.001) (Table 9.). The ORL specialist and anaesthetists 'yes' replies to the question about knowledge of the procedure type increased (P=0.002 and P=0.009). Team members were aware of the side of the operation more frequently, but the difference was not significant. Two respondents' comments did express concerns about the correct side of the op-

Results

Table 9. *OT teams knowledge of patient-identities, planned procedure, and correct surgical side in the ORL department of HUCH before and after the implementation of SSC.*

	ORL specialist		Anaesthetist		Circulating nurse	
	Before	After	Before	After	Before	After
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Identity of patient	206 (71.5)	345 (83.7)	178 (61.8)	343 (83.3)	253 (87.9)	396 (96.1)
Procedure	231 (80.2)	366 (88.8)	223 (77.4)	351 (85.2)	276 (95.8)	383 (93.0)
Side (when defined)	175 (84.1)	257 (87.7)	145 (66.8)	184 (74.5)	210 (90.9)	295 (93.7)

Number (N) and proportion (%) of 'yes' replies by profession before and after checklist implementation.

eration. Wrong side was written in the plan in one operation, but the skin was marked correctly. In another operation, the wrong side was written in the plan, and this was revealed in the check.

The anaesthetist's knowledge of the patient's medical history, medication, and allergies increased after the implementation of SSC (P<0.001). A check revealed critical information in one operation about the patient's medical condition that led to cancellation of that operation. The proportion of pre-checks of anaesthesia equipment increased from 70.5 to 84.0% of the operations. The use of the SSC had no effect on the preparation for a difficult intubation. One anaesthetist wrote: 'In otorhinolaryngology we are always prepared for a difficult airway.' Blood loss of over 500 ml (>7 ml/kg in children) was estimated in only 2.1% of the operations before and 1.5% after the implementation of the SSC.

The SSC improved ORL specialists and anaesthetist's knowledge of the other OT-team members names and roles (P<0.001) and they discussed possible critical events in the operation more frequently (P<0.001). Similarly, the recording of postoperative prescriptions improved with use of the SSC. The answer to the question about communication between OT team members was associated with the respondent's profession. No change in communication during operations was found according to the ORL specialists. Moreover, they opined that communication was successful in a majority of the operations. However, the anaesthetists and circulating nurses reported significant improvement in communication after the use of the SSC (P=0.006 and P<0.001). These results are presented in Table 10.

5.3 The use of SSC in the ORL

5.3.1 SSC Compliance (IV)

A survey of OT personnel in the ORL department of HUCH was conducted one year after the implementation of the SSC. The response rate was high (95.3%), a total of 101 of the original 106 questionnaires handed out were returned. Characteristics of the respondents are presented in Table 11.

A total of 7148 operations were performed in the operative ORL unit of HUCH during the one-year study period. The 'Sign in' check of the SSC was completed in 4456 (62.3%), the 'Time out' check in 4368 (61.1%) and the 'Sign out' check in 3831 operations (53.6%). After the first months some decrease in the use activity occurred (Figure 6.).

Table 10. *OT team members answers of issues related to teamwork in the ORL department of HUCH.*

	ORL specialist		Anaesthetist		Circulating nurse	
	Before	After	Before	After	Before	After
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Knowledge of OT-team's names and roles	175 (60.8)	335 (81.3)	217 (75.4)	360 (87.4)	266 (92.4)	388 (94.17)
Risks discussed	70 (24.31)	151 (36.7)	71 (24.7)	161 (39.1)	N.q.	N.q.
Postoperative instructions recorded	235 (81.6)	375 (86.7)	212 (73.6)	351 (85.2)	N.q.	N.q.
Successful communication	268 (93.1)	395 (95.9)	228 (79.2)	358 (86.9)	187 (64.9)	374 (90.8)

Number (N) and proportion (%) of 'yes' replies by profession, before and after SSC implementation. OT=operating theatre; N.q.=not questioned.

Table 11. *Respondent characteristics.*

	N	%
Age, years		
<30	15	14.9
30-39	27	26.7
40-49	26	25.7
50-59	27	26.7
60-69	5	5.0
Gender		
Men	31	30.7
Women	69	68.3
Education		
ORL specialist	32	31.7
ORL trainee	14	13.9
Anaesthetist	8	7.9
Anaesthetist trainee	3	3.0
Nurse	44	43.6
Experience, years		
<1/2	13	12.9
1/2-1	5	5.0
1-5	27	26.7
>5	55	54.5
Work in outpatient unit		
Yes	23	22.8
No	77	76.2
All	**101**	**100**

Number (N) and proportion (%) of respondents. Gender and age were missing in one questionnaire.

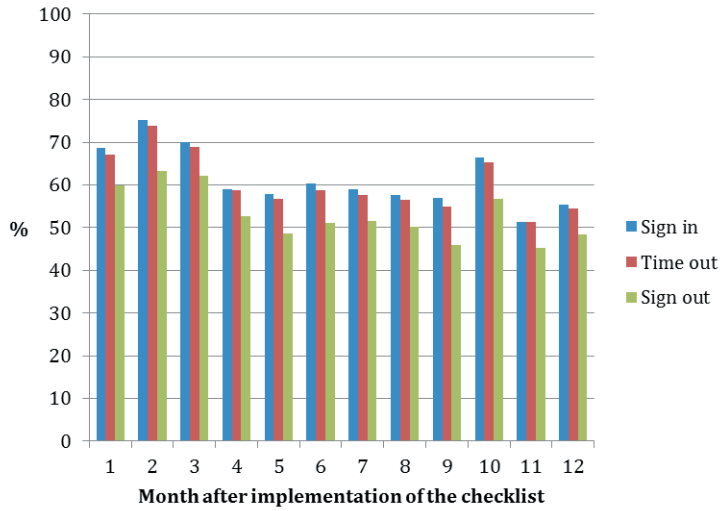


Figure 6. *Compliance with checklist use during the first year in the ORL department of HUCH. The proportions of operations for which the check was completed are shown.*

Results

Table 12. *Self-estimated checklist compliance by professions.*

N	Profession	Mean (%)	SD (min-max)
32	ORL specialist	65.0	28.5 (5-99)
14	ORL trainee	62.9	20.2 (30-90)
8	Anaesthetist	72.5	18.6 (50-95)
3	Anaesthetist trainee	70.0	20.0 (50-90)
44	Nurse	71.6	20.6 (10-99)
101	All	68.1	23.1 (5-99)

Number (N) of responses; Means of estimated proportions (%) of operations for which the checklist was used; SD= standard deviation; Min=minimum; Max=maximum

The personnel's mean estimation of checklist compliance was 68.1% with a SD of 23.1%. This value varied between the professions and the level of professional education. A few ORL specialists reported very low use rates, with the lowest being 5% (Table 12.).

Some disregard for using the SSC was revealed in the open responses: 'answers to items are dismissive', 'staff is not concentrating on the checks'. The checks were done incompletely, and some sections were omitted. One senior ORL specialist wrote: 'Time-out has never been done in my operations'. In addition, there was confusion about who should lead each check and when to do the checks: 'I have never received information on how to use the checklist'.

5.3.2 User attitudes (IV)

A total of 12 questions that measured safety attitudes within the OT, were included in the questionnaire. The scores obtained for six OT work related safety attitude questions are presented in Table 13. Some differences between the professions emerged. The mean score for the question about teamwork was 4.04 for all respondents, with higher scores from physicians than from nurses. Nevertheless, in seven responses under the headline 'Concerns about patient safety', communication between OT team members was criticised.

Similarly, answers to six checklist-related safety attitudes questions were mostly positive. As much as 76.0% of the respondents agreed that the checklist improved OT safety and 68.0% agreed that it helped to prevent errors. As much as 93.0% of OT staff would have wanted the checklist to be used, if they were to have an operation. The checklist related attitudes are presented in Figure 7.

Accordingly, a positive attitude towards the SSC was expressed in by 35 responders in the

Table 13. *Operating theatre (OT) related safety attitude scores by profession.*

	ORL specialist	ORL trainee	Anaesthetist	Anaesthetist trainee	Nurse	All
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
1. I would feel safe being treated here as a patient.	3.97 (0.60)	4.43 (0.51)	4.14 (0.69)	4.00 (1.00)	3.73 (0.82)	**3.94 (0.74)**
2. Briefing OT personnel before a surgical procedure is important for patient safety.	4.53 (0.51)	4.64 (0.50)	4.00 (1.53)	5.00 (0)	4.70 (0.51)	**4.60 (0.64)**
3. I am encouraged by my colleagues to report any safety concerns I may have.	3.50 (1.11)	3.79 (0.58)	4.00 (0.82)	4.00 (0)	4.16 (0.83)	**3.88 (0.92)**
4. In the OTs here, it is difficult to speak up if I perceive a problem with patient care. *	1.94 (0.91)	2.64 (1.34)	2.00 (1.16)	2.00 (1.00)	2.75 (1.37)	**2.40 (1.25)**
5. The physicians and nurses here work together as a well co-ordinated team.	4.13 (0.66)	4.14 (0.54)	4.14 (0.69)	4.33 (0.58)	3.91 (0.83)	**4.04 (0.72)**
6. Personnel frequently disregard rules or guidelines that are established for the OT. *	2.19 (0.93)	2.36 (1.08)	2.57 (0.79)	3.67 (0.58)	2.32 (1.12)	**2.34 (1.04)**

Responses were scored on a five-point Likert scale, anchored by 'strongly disagree' (1) and 'strongly agree' (5). Values are means of the responses with standard deviations (SD). *The fourth and sixth statements are negative and reverse-scored.

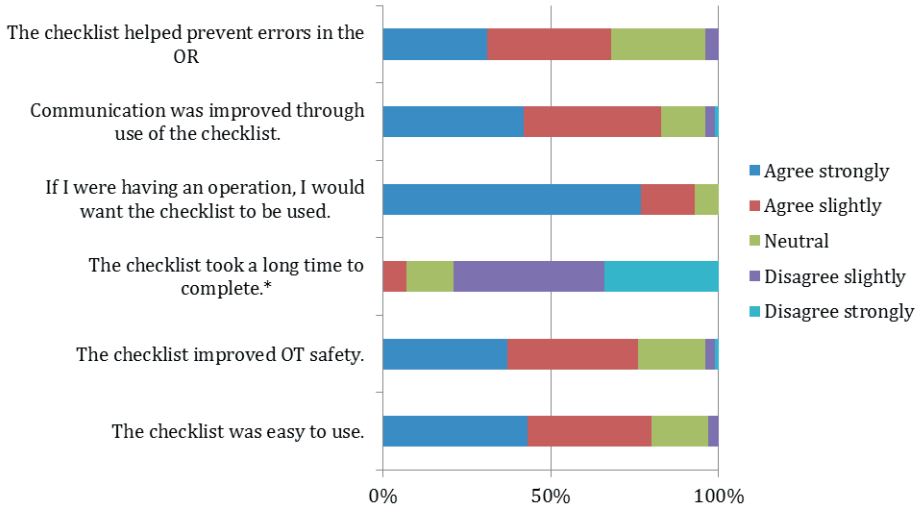


Figure 7. *The checklist related safety attitudes. Proportions of responses, total N= 101. *The fourth statement is negative.*

other comments section of the questionnaire. Examples of these comments include: 'the checklist is beneficial', 'it has prevented errors here', 'it should always be used' and 'nowadays no operation should be done without the checklist'. However, 15 nurses wrote that some senior ORL specialists neglected the SSC and its completion was difficult with them. They found this to be frustrating: 'a few persons' negative attitudes towards the checklist will hinder its use'.

5.3.3 Specialty-related aspects of SSC check items (V)

A majority of the respondents considered that all items on the SSC were important for ORL operations. The distribution of the opinions about the SSC items is presented in Figure 8. The calculated mean scores of estimated importance of the check items varied from 4.08 to 4.89 on the five-point Liker scale. The item 'Allergy' had the highest score with the least variation (SD 0.32). 'Team members introduced' had the lowest score and the most variation (SD 1.09). In free-text comments seven persons considered this item unnecessary when the same team works together the whole day.

There were a few proposals for additional items. Three responders suggested inclusion of the items 'When had the patient last eaten?' and 'Special instrumentation needed?' for the 'Sign In' check. Sixteen respondents wrote that no items should be removed. 'The checklist should always be the same, repetition and familiarity make it easy to use.' Nine comments suggested that the item 'Prophylactic antibiotics' should be moved from 'Time out' to the 'Sign In' check. A nurse commented: 'if it is noted before incision is made, the administration will delay the operation'. In contrast, an anaesthetist wrote critically without further specifications that the checklist is not well-suited for children.

We asked the respondents to comment on whether they found some items unnecessary for outpatient surgery. Nine persons suggested a more compact checklist, especially for operations performed under local anaesthesia. Ten respondents suggested the item 'Blood loss over 500 ml' to be removed and commented: 'a patient with that amount of blood loss does not fill the criteria for outpatient surgery'.

Results

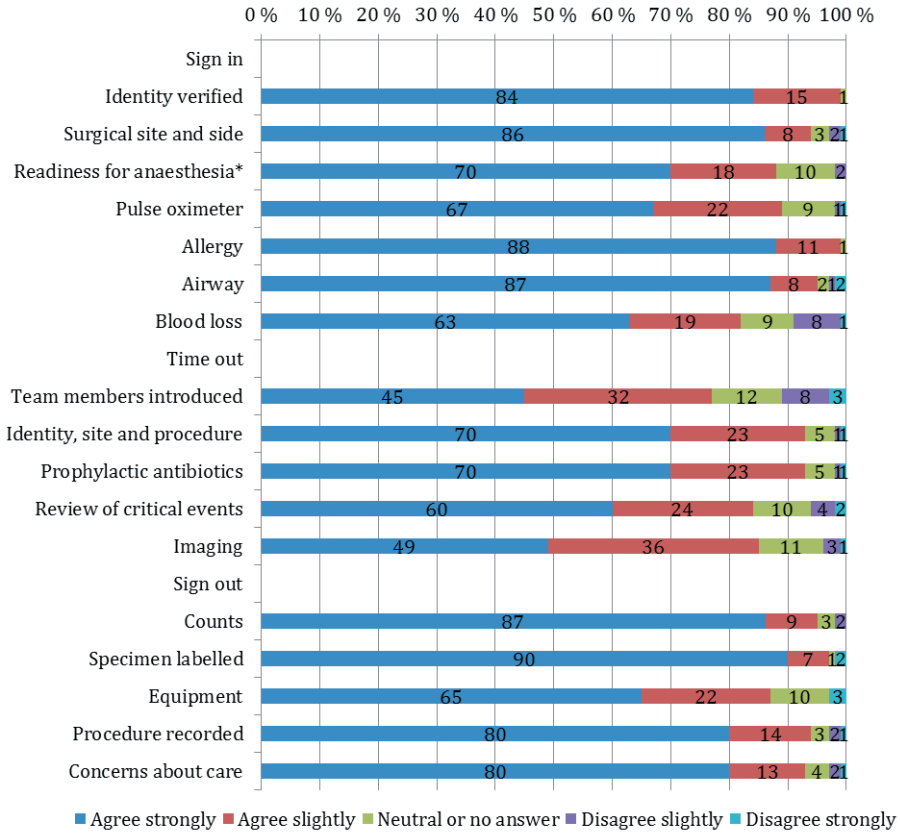


Figure 8. *Operating room staff's opinions about the importance of items in the SSC for ORL procedures. The proportion (%) of responses, total N=101. *In the Finnish version of the SSC.*

6. DISCUSSION

The principal purpose for conducting the research for these studies was to bring surgical patient safety issues about the ORL-specialty into daylight and to evaluate prevention measures, with special reference to SSC.

6.1 Patient injuries in ORL

Despite the general interest in the topic, research of errors and patient safety in ORL has been limited. The present study focused on identifying the errors that contribute to patient injuries (I). Our results confirmed the previous data, which showed that patient injuries in ORL were strongly related to operative care (Shah et al. 2004, Lehtivuori et al. 2013).

Operations in ORL are considered to have low morbidity and mortality risks (Karamchandani et al. 2010). Approximately 31 000 operations are performed in the ORL specialty in Finland annually (Lehtivuori et al. 2013). A total of 188 ORL-operation related patient injury claims were accepted by the PIC during a 10-year period (I). Thus, it can be estimated that 0.06% of operations performed for ORL resulted in injury over that 10-year period.

The PIC insures all patients treated by the official health care providers and deals with the compensation payments relating to all patient injuries in Finland. Thus, the PIC register used in this study is nationwide and is therefore highly representative (I). The proportion of patient injury claims for ORL that were accepted for compensation by the PIC was 26.1%, whereas in the US, the respective rate for malpractice claims was reported to be 29.8% (Dawson and Kraus 2007, Lehtivuori et al. 2013). Although all patients are insured by PIC, it is likely that not all patients who have sustained injuries during treatment will have put in a compensation claim (I). Thus, the true volume of injuries is probably greater than that indicated by the number of claims handled by the PIC.

It is also known that the accepted patient injury claims represents only a minority of all errors and adverse events that occur in health care. Unfortunately, information of all errors and especially near misses can not be collected from claim records nor from any other data source. We agree with previous comment that the true incidence of injuries data are difficult to obtain (Makary 2010).

Typical injuries were well-known complications of common procedures carried out by the fully trained ORL specialists in high-volume centres (I). These findings are consistent with the claim record study that includes all surgical disciplines (Regenbogen et al. 2007). Manual error in performing surgery was the cause for two-thirds of operation related injuries and most of these were injuries to adjacent structures (I). The head and neck region consists of vulnerable anatomical structures that place very high demands to surgical technique and skills. However, the manual errors behind the patient injuries are multifactorial, surgeon dependent and thus a difficult subject for preventive initiatives (Regenbogen et al. 2007).

The procedures of nose and paranasal sinuses were the largest subgroup (34.5%) of claims for ORL procedures in the US (Dawson and Kraus 2007). In our study, the corresponding rate was 37.2% (I). These included manual errors, such as lesions on the orbit, skull base and adjacent nerves, in addition to removable packing being left *in situ*. Remarkably the insufficient documentation of materials left *in situ* were found in eight (4.3%) cases of ESS. A Sinus Surgery Checklist has been presented to prevent these ESS specific errors (Soler et al. 2012, Soler and Smith 2012).

6.1.2 Patient injuries and SSC

One in ten operative error in ORL corresponded with the WHO SSC items according to the present claim record data and thus 4.8% of injuries might have been prevented had a correctly completed SSC been used (I). Furthermore, it can be argued that a correctly completed checklist could have intercepted nearly one patient injury caused by ORL surgery per a year in Finland.

However, it is not possible to make definite conclusions about checklists' effectiveness in reducing complications in a retrospective analysis. We are dependent of the information recorded in charts of claim record data. In a few cases, the exact consequences of the injuries remained unclear due to incomplete documentation (I). However, results from two previously published studies that used the same type of study design have shown good agreement with the results from prospective studies that demonstrated improved patient outcomes (de Vries et al. 2011, Panesar et al. 2011).

Wrong site surgery and retained swabs should not occur in modern surgery. Unfortunately, these preventable 'never events' still happen. In total six (2.7%) of the studied patient injuries were caused by WSS (I). A recent review concluded that WSS accounts for 4-6% of errors in ORL (Liou and Nussenbaum 2014). Moreover, this suggests that the items of the SSC are indeed relevant to operative ORL. The consequences of these complications can be devastating to both the patient and the surgeon and will weaken peoples' trust in medical care in general. In the present study, two (1.1%) children had forgotten gauzes left in their nasopharynx after tonsillectomy. Luckily, these potentially hazardous complications did not result in more serious consequences that of reanaesthesia (I).

The claims data in study I covered the treatments given between 1998-2011. The checklist was piloted for one-month use in six operative units four hospitals in 2009 and the mandatory implementation of the SSC for all Finnish hospitals began after 2010. Seventeen claims were for injuries sustained in years 2010 and 2011. Only one case had a direct correspondence with an item on the checklist occurred during this period and this was for a retained nasopharyngeal gauze. It is interesting to note that the checklist was not used in that particular case. The last WSS case in this series occurred in 2008. The practice of site-marking have been mostly lacking among Finnish ORL specialist until recent years. The nationwide implementation of SSC might have increased the awareness of the WSS hazard, and thus has given impetus to site-marking policies.

However, it has been previously demonstrated that in highly-developed health care infrastructures more comprehensive safety improvement tools than SSC can and should be used (de Vries et al. 2009). The present study demonstrated, that 4.8% of injuries might have been prevented with SSC use (I). In a malpractice claims study that used the same type of study design, 29% of error contributing factors might have been intercepted by the use of the comprehensive SURPASS checklist and 40% of deaths and 29% of incidents leading to permanent damage could have been prevented (de Vries et al. 2011).

6.2 The effects of SSC on OT work

The impressive results from the WHO group study were published in the NEJM in January 2009 (Haynes et al. 2009). A pilot implementation of the Finnish version of the SSC in six operative units in four Finnish hospitals was announced almost immediately after that. The present studies were among the first to be performed after the WHO group published its results and our studies were also the first published data on the effect of the SSC in the ORL specialty (II, III).

This study showed that SSC improved recognised aspects associated with safe surgery in the OT, by improving the verification of the patient's identity, disseminating knowledge of the patient's medical condition and ensuring the correct side of the operation (II). The findings of the studies were consistent for ORL operations (III). It has been previously shown that systemising the process in the OT can reduce the risk of WSS (de Vries et al. 2010). Although the use of the checklist improved the verification of patient identity, it was still recognised to be inadequate in itself (II, III). It is essential to confirm the identity of the patient, even repeatedly. The bypassing of preventive systems such as preoperative checks and time-outs elevates the probability of WSS occurring (Cohen et al. 2010).

In the present study, experience of successful communication between team members improved after the implementation of the SSC (II, III). Similar improvements have also been previously demonstrated in paediatric, trauma and orthopaedic series using SSC (Norton and Rangel 2010, Sewell et al. 2010). Critical events were discussed more commonly between anaesthetists and surgeons or ORL specialists (II, III). The use of the checklist also improved the recording of the postoperative prescriptions and instructions. It can be concluded, therefore, that the SSC improved sharing of patient-related medical information among OT staff.

Our findings support the previous results, that preoperative briefings reduce the numbers of communication failures (Lingard et al. 2008, Nundy et al. 2008). It is widely recognised that enhancing communication in the OT can reduce human errors and thereby reduce the numbers of adverse events (Gawande et al. 2003e, Sutcliffe et al. 2004, Lingard et al. 2005, Lingard et al. 2008, Mazzocco et al. 2009, Nagpal et al. 2010, Neily et al. 2010, Pronovost and Freischlag 2010). Thus, it can be assumed that improved communication resulting from SSC use will also have positive effects on patient safety in ORL operations.

An argument against using safety checklists in surgery is that it is considered by some to be time consuming. Sheena and colleagues have observed that the mean time for completion of SSC Time out check in ORL OT was found to be only 69 seconds (Sheena et al. 2012). The use of the SSC did not prolong operations in the present studies (II, III). Thus, refusal to use the checklist cannot therefore be defended by a lack of time. Indeed the converse appears to be the case as a preoperative briefing has been shown to reduce OT delays (Nundy et al. 2008).

The safety intervention itself will increase the awareness of safety issues amongst OR staff. Although, this is a hoped-for result, the study groups cannot therefore be considered as completely random samples (II, III). Formal statistical testing might not be relevant in this kind of open study design. However, Leape wrote in the editorialist replies in the NEJM 2014, that a before-versus-after study is the relevant design for safety interventions that require major culture change (Leape 2014). Furthermore randomised study design is unachievable.

The response rate in studies II and III was high and the sample was representative of all the professional groups that work in the OT. The implementation of the checklist and concomitant responding to the questionnaire required changes in routines. Despite that, the OT personnel were supportive. Completing the questionnaire at the end of the operation may be a limitation as answers to questions about the specific items might have been more precise immediately after the checks.

Study of the use of the SSC in the ORL specialty was conducted in a large tertiary care university hospital that covers all subgroups of surgery in ORL-HNS (III-V). One-fifth of the patients were children, and the majority of patients were otherwise in good medical condition. The operations and patients fully represented the characteristics of typical ORL patients (III). The present study confirms, that SSC fits into the surgical working process in ORL well.

6.3 The use of SSC in the ORL

6.3.1 SSC Compliance

Although, safety checklists such as the SSC have become beneficial tools in error prevention, their value should be placed in the right perspective. The SSC or any other tool will not prevent errors if it is not properly used or not used at all. Compliance and user attitudes are known to have a remarkable effect on the performance and benefits of checklists (Borchard et al. 2012).

This study revealed an incomplete compliance with the checklist use in an ORL unit (IV). Despite positive attitudes towards the checklist, the 'Sign in' and 'Time out' checks were completed in about 60% of the operations, and the 'Sign out' checks in only 53.6% of operations during a one year study period (IV). The use of the SSC was also overestimated by OT staff. It is previously noted, that the mandatory implementation of a

checklist can result in high rates of reported compliance but without evident behaviour change (Pickering et al. 2013, Haynes et al. 2014). Our study supports this conclusion.

Unsuccessful implementation of a safety checklist can result in low compliance rates. Education of the users during the implementation, must emphasise the reasons 'why' there is a need for an improvement (Borchard et al. 2012). Unfortunately, the actual implementation strategy was not studied in our series, which limits the analysis and the conclusions that can be made about the compliance. In any case, a compliance rate of around 60% indicates that the implementation strategy and the utilisation of the SSC have not been sufficient in the studied organisation (IV).

Motivation of the OT team members is also considered to be essential for a good checklist compliance (Verdaasdonk et al. 2009). Some decrease in compliance was noted a few months after the implementation in the present study (IV). An increase in the use of the SSC took place after the OT nurses had a meeting during which a reminder about SSC use had been issued. This demonstrates that education sessions do have a positive effect on compliance. Users need to understand the benefits of checklist completion (Russ et al. 2014). It is generally accepted, that active leadership, regular audits and feedback are important for successful implementation and maintenance of checklist use (Verdaasdonk et al. 2009, Norton and Rangel 2010, Vats et al. 2010, Conley et al. 2011).

The commitment of surgeons has shown to be particularly important for successful checklist implementation (Lingard et al. 2005). A few ORL specialists reported very low use rates, whereas nurses reported that some senior ORL specialists had negative attitudes towards the SSC (IV). Unfortunately, this finding partially explains the low compliance rates found in the studied ORL department in the present study.

A safety checklist should be completely and carefully completed. A poorly performed checklist can provide a false sense of security and will thus lessen its efficiency in preventing adverse events (Vats et al. 2010). The SSC in the present study was considered easy to use (IV). However, several examples of poor use came to light in other comments section at the end of the questionnaire. Despite the specific guidelines being available in the OT, more information about the correct use of the list was requested. This is consistent with previous studies that demonstrate maintenance of the correct use of the checklist has to be on-going and so education and continual feedback are needed (Vats et al. 2010, Conley et al. 2011).

6.3.2 User attitudes

One year after its implementation, the personnel were mostly satisfied with the use of the checklist in the ORL department (IV). However, the nonchalant use of the SSC by a few senior ORL specialists was revealed. The response rate to the personnel survey was high, and also these results were representative of all OT professionals (IV, V). In addition, the studied OT staff was highly experienced.

The study that was conducted by the WHO group found that clinicians held the SSC in high regard and 93.4% would want it to be used if they themselves were undergoing surgery (Haynes et al. 2011). The rate of that response in the present study was 93.0% (IV). The OT staff's attitudes in Swedish surgical units were found to be highly positive after one year's use; 93% responded that the SSC contributes to increased patient safety (Nilsson et al. 2010). In the present study, the corresponding rate was lower at 76.0%.

The WHO study group showed that improvements in patient outcomes were associated with improved safety attitudes among the respondents (Haynes et al. 2009, Haynes et al. 2011). They also reported mean SAQ teamwork score of 3.68 in a pre-intervention and 3.75 in a post-intervention group. The corresponding teamwork score after one year's use of the SSC in the present study was 4.04 and also, the other OT and checklist-related safety attitude scores were high (IV). This supports the contention that SSC has positive effects on safety attitudes.

Unfortunately, pre-intervention SAQ-scores were not measured in the present study (IV). Instead, we compared our results to those of a small survey we did in the ORL OT after a one-month pilot use of the checklist in 2009 to determine whether safety attitudes had changed after SSC use (unpublished data). In 2009, only 65% of ORL OT staff believed the WHO checklist would improve patient safety and 87% of the respondents would have wanted the checklist to be used if they were having an operation. After the checklist had been routinely used, the number increased to 93.0% (IV).

6.3.3 Specialty-related aspects of SSC check items

After using the SSC for one year, users were mainly satisfied with its content for ORL operations (V). All check items were considered beneficial for the specialty; mean scores of the estimated importance of items varied from 4.08 to 4.89 on a five-point scale. In 'Time out' check, the item: 'Team members introduced' had the widest ranging opinions; about one-fifth of ORL specialists and nurses did not consider it important.

The WHO programme encourages modifications to the SSC to fit better into the context of the specialty, thus it must be noted that modifications of the SSC can influence its efficiency (WHO Surgical Safety Checklist http://www.who.int/patientsafety/safesurgery/ss_checklist/en/, Verdaasdonk et al. 2009, Weiser et al. 2010c). In the present study, some modifications for SSC were proposed and a more compact safety checklist for outpatient surgery was stipulated (V). However, one responder made the following valuable statement: 'The checklist should always be the same, repetition and familiarity make it easy to use'.

Furthermore, nine respondents requested that the checklist to be more compact for minor operations performed under local anaesthesia. A previously presented safety checklist for ambulatory oral surgery consists of before- and after-surgery sections (Perea-Perez et al. 2011). The use of that checklist has been proposed for operations under local anaesthesia by the OT team without an anaesthetist. This setting is also used in various ORL operations. Results from the present study suggest a similar two-phase modification of the SSC to be relevant for outpatient circumstances for ORL operations.

Paediatric operations have unique needs, and the list's suitability for children was reasonably criticised (V). A safety checklist modified for paediatric operations, including the items 'Weight', 'Warmer in place' and 'Appropriate intra venous access', has previously been published (Norton and Rangel 2010). These items are also relevant for paediatric ORL and could be included in a modified safety checklist for ORL.

The objective of safety checklists is to focus users' attention to content of the checked item. The processes and complications typical of a specialty must be critically reviewed to design a customised safety checklist that is optimal for specific needs of that specialty (Verdaasdonk et al. 2009). A checklist for ESS has recently been published to address the errors that are recognised in endoscopic sinus procedures (Soler et al. 2012, Soler and Smith 2012). That checklist is very detailed and is considered to be supplemental to the standard perioperative checklists such as SSC.

6.4 Future aspects

The present study demonstrated that the WHO SSC seems to be a beneficial error prevention tool in ORL surgery (I, III). The use of the SSC improved recognised factors that are associated with safe surgery in ORL and its content was considered useful for the ORL specialty (I, III, V). These results challenge the previously stated opinion that SSC has no role to play in ORL (Karamchandani and McGarry 2010). All methods shown to have an effect should have a role to play in preventing errors and injuries: even a minor improvement has some clinical significance and on a personal level, every prevented patient injury counts.

The small number of patient injuries that are actually incurred in ORL operations constitutes a limitation on the present and future studies. The confirmation of safety interventions effectiveness

Discussion

in reasonable time would necessitate a multi-national before-versus-after intervention study. Whether the SSC has an influence on the actual complication incidence in ORL-HNS remains unknown at the present time.

We agree with Shah and colleagues that the prevention of errors and the development of a specific checklist for ORL needs further consideration and activity by otorhinolaryngological associations (Shah et al. 2010).

7. CONCLUSIONS

The results of the present study lead to the following conclusions:

1. Patient injuries in ORL are strongly related to operative care. Most injuries are well-known complications of common procedures and occur in routine practice by fully trained ORL specialists. The correctly used SSC can prevent some of these injuries from occurring.

2. The SSC improves the sharing of patient-related medical information and enhances communication between the OT team members.

3. The SSC improves teamwork and communication, recognised aspects associated with safe surgery, and it fits well into the ORL specialty.

4. The safety attitude scores are high with the SSC. The OT personnel are generally satisfied with the SSC use in ORL operations. However, a mandatory checklist use without the active management is associated with incomplete compliance.

5. All check items in the WHO SSC are considered important for ORL though a more concise checklist for outpatient surgery is required.

8. ACKNOWLEDGEMENTS

These studies were carried out in the Department of Otorhinolaryngology, HUCH and the University of Helsinki, during the years 2009-2015 and also in the Department of Surgery, Turku University Hospital during the years 2009-2011. I thank the staff of these facilities for their support and participation in these studies.

I express my sincere and deepest gratitude to my supervisors Docent Karin Blomgren and Docent Leena-Maija Aaltonen. In addition to being my excellent, straightforward and like-minded mentors, you have become my friends. It is a pleasure to share my thoughts with you and also conduct research with you both. I also wish to thank you for your adaptable division of labour and the fruitful discussions about these studies. It has been privilege to work with you.

I am deeply grateful to all my collaborators for their contribution to these studies. I would like to express my gratitude to all members of the 'pilot SSC group' and I especially wish to thank Docent Tuija Ikonen for conducting the pilot project and for establishing the first ideas for my research. I am grateful to anaesthetist Riikka Takala, MD, PhD for her excellent collaboration, guidance and 'positive reminding' me during this work. I wish to thank anaesthetist, Docent Annika Takala and the staff of the operative ORL unit of HUCH for their positive attitudes towards these studies and excellent organising of the surveys. I also wish to thank Professor Lasse Lehtonen for good collaboration and support in these studies.

I would like to express my gratitude to the official reviewers of the thesis, Docent Erna Kentala and Docent Leila Niemi-Murola, for their thorough evaluation and valuable constructive criticism. I am also grateful to Alisdair Mclean, PhD for his excellent help in the linguistic revision of the thesis.

I wish to express my sincere and deepest gratitude to Docent Harri Hakovirta, head of the department of Vascular Surgery of Turku University Hospital, for his encouragement and for arranging the flexible timetables when they were needed. I wish to thank you for the opportunity to work under your supervision and also thank for your tireless work for create excellent facilities for the clinical work. Furthermore, I owe many thanks to my vascular surgeon colleagues Olli Hautero, Juho Jalkanen, Kimmo Korhonen, Minna Laukkavirta, Jaakko Viljamaa and Jan-Erik Wickström. It is a joy and privilege to work with you and to share the everyday clinical challenges in an enthusiastic atmosphere. I also wish to thank all my past and present colleagues and the staff in Turku University Hospital.

I would also like to express my deepest gratitude to all the great surgeons who have been enthusiastic mentors for me during my surgical training. Especially, to ORL surgeons Ilpo Kinnunen and Kalle Aitasalo, surgeon Kalle Aalto and vascular surgeon Andres Idla for all guidance and support you have given me as a surgeon. Thanks also go to Professor Antti Mäkitie for his encouragement and guidance during my very first steps of scientific writing.

Thanks to all my friends, together with the great ballet teachers, for providing the vital counterbalance to the work. I owe special thanks to my friend Heidi for her lifelong friendship.

I warmly thank my parents Raimo and Kristiina and my sisters Leena, Johanna and Maija for their love and support. I have also been fortunate to have my grandmother Aili for giving me advice and supporting me all my life. I thank my godfathers Mauri and Aappo and their families for their support and always getting the Kontu-family together.

I express my deepest gratitude to my mother- and father-in-law Tuija and Juri for the loving care of our children whenever needed. You have made our family life run fluently and without your help our work on surgical duty would not be possible. My warmest thanks also go to Raisa and Matti for all the selfless help for our family.

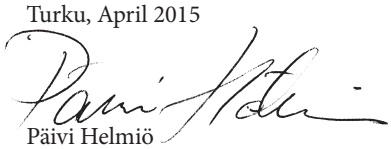
Finally, my most sincere heartfelt gratitude goes to the most important people in my life, my

Acknowledgements

husband Mika and our children Oiva and Eero. You are the purpose of my life. I love you above everything else.

This work was financially supported by the Turku University Hospital Research Funds (EVO), the HUCH Research Funds, the Finnish Medical Foundation, the Finnish Medical Association and the Otorhinolaryngology Research Fund. I wish to express my gratefulness for their support.

Turku, April 2015



Päivi Helmiö

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11. APPENDICES

11.1 Pilot version of the Finnish SSC, translated from English

Surgical checklist – test version

Before induction of anesthesia	*Before incision / beginning of procedure*	*After the procedure, before patient leaves OR*
SIGN IN	**TIME OUT**	**SIGN OUT**
☐ **Identity, procedure and consent** confirmed *- anesthesiologist confirms the identity and social security number of the patient, procedure and the consent*	☐ **Names and roles** known *- all team members introduce themselves (name and role) or confirms aloud that every one knows each others*	☐ **Diagnosis, name of the operation and codes recorded** *- circulating nurse confirms from the surgeon, that diagnosis, name of the operation and codes are correct*
☐ **Is operation site and / or side marked** ☐ No need *- circulating nurse confirms the operation site and whether it is marked or not*	☐ **Patient, site and procedure** *- surgeon confirms aloud the identity of the patient, site of the operation and the procedure*	☐ **Completion of instrument count** *- nurses confirm that the number of instruments, sponges and needles are count*
☐ **Patient ready for anesthesia** *- anesthesiologist confirms:* - ASA-class *(class ___)* - Medical history *(known / not known)* - Preoperative medication *(known / not known)* - Is the patient on antithrombotic medication *(known / not known)* - Laboratory results *(known / not known)* - Anesthesia equipments checked *(yes / no)*	☐ **Antibiotic prophylaxis** ☐ Administered within 60 minutes ☐ No need *- anesthesia nurse states aloud the time when the administration was finished or states that there was no need*	☐ **Specimens are labeled** *- circulating nurse confirms that the specimen are labeled and include the patient identity and that they are ready to be sent to the department of pathology*
☐ **Is the pulse oximeter on the patient and functioning?** *- anesthesia nurse confirms the saturation value on the monitor*	☐ **Anticipated critical events** *- surgeon, anesthesiologist and nurse confirm that the critical events have been discussed within the team* ☐ **Surgeon**: Critical events, non-routine steps, how long will the operation last, anticipated blood loss ☐ **Anesthesiologist / anesthesia nurse**: Patient-specific concerns ☐ **Instrument nurse**: Sterility confirmed. Equipments, instruments and drugs (if needed) available	☐ **Equipment problems** recorded *- circulating nurse confirms that possible equipment problems are recorded*
☐ **Known allergy** *- anesthesiologist confirms known allergies or informs that there is none*		☐ **Postoperative prescriptions and instructions** given *- surgeon, anesthesiologist and nurses confirm that they have discussed the postoperative concerns for recovery and instructions for the management.*
☐ **Difficult airway / risk of aspiratio** ☐ No ☐ Yes and equipments are available *- anesthesiologist confirms*	☐ **Essential imaging displayed** ☐ Yes ☐ No need *- circulating nurse confirms that essential imaging is displayed, if they are needed*	
☐ **Risk of >** 500 ml blood loss (7ml/kg in children) ☐ No ☐ Yes *- anesthesiologist confirms i.v. access and available cross matched blood*		

11.2 Questionnaire for studies II and III

pvm___ / ___ / _____ sali_____ toimenpiteen järjestysnumero /sali_____ 1

LEIKKAUSSALITYÖN SUJUVUUS - PASSARIN KAAVAKE

- Täytä kaavake toimenpiteen aikana tai välittömästi sen jälkeen **valitsemalla mielestäsi paras vaihtoehto jokaiseen kysymykseen**
- Kaavakkeeseen ei kirjata tunnistetietoja henkilökunnasta tai potilaasta
- Kerää ja niputa oma kaavakkeesi, anestesialääkärin kaavake sekä kirurgin kaavake kansioon heti toimenpiteen jälkeen

Profylaktisen antibiootin aloitus – ja lopetusaika: klo ____:____ - _____:_____

Anestesia alkoi klo ____:____ Toimenpide alkoi klo:____:____ (viillon ajankohta)

Toimenpide päättyi klo:____:____ Elektiivinen ☐ Päivystys ☐ Hätä ☐

Ennen anestesian aloitusta:	**Kyllä**	**Ei**	**En tiedä**	**Ei tarvetta**
1. Oliko potilaan henkilöllisyys varmistettu potilaalta? ☐ potilas kykenemätön vastaamaan	☐	☐	☐	☐
2. Oliko potilaan perushygieniasta huolehdittu ennen leikkaussaliin tuloa?	☐	☐	☐	☐
3. Oliko potilaalla antiemboliasukat saliin tullessa?	☐	☐	☐	☐
4. Oliko suunniteltu toimenpide kaikkien tiedossa?	☐	☐	☐	☐
5. Oliko suunniteltu puoli (sin/dex) kaikkien tiedossa?	☐	☐	☐	☐
6. Oliko potilaan asento varmistettu?	☐	☐	☐	☐
Ennen toimenpiteen aloitusta:				
7. Tiesivätkö kaikki salissa olevat toistensa nimet ja tehtävät?	☐	☐	☐	☐
8. Oliko toimenpiteessä käytettävän välineistön steriliteetti varmistettu?	☐	☐	☐	☐
9. Oliko toimenpiteessä tarvittava välineistö saatavilla ja käyttökunnossa?	☐	☐	☐	☐

KÄÄNNÄ →

pvm___ / ___ / _____ sali_____ toimenpiteen järjestysnumero /sali_____ 2

Toimenpiteen jälkeen, ennen potilaan poistumista leikkaussalista:

	Kyllä	**Ei**	**En tiedä**	**Ei tarvetta**
10. Olivatko neulat, taitokset ja instrumentit laskettu ja laskut täsmäsivät?	☐	☐	☐	☐
11. Olivatko PAD/muissa näytteissä potilaan tiedot?	☐	☐	☐	☐
12. Toimiko leikkaussalitiimin kommunikaatio leikkauksen aikana moitteettomasti, myös mahdollisissa ongelmatilanteissa?	☐	☐	☐	☐
13. Toimiko toimenpiteessä käytetty välineistö moitteettomasti?	☐	☐	☐	☐
14. Arviointiinko ja kirjattiinko leikkauksen aikainen vuoto?	☐	☐	☐	☐

Muita huomioita:

_____

_____ _

_____ _____

KIITOS VASTAUKSISTASI !

pvm___ / ___ / _____ sali_____ toimenpiteen järjestysnumero/sali _____ 1

LEIKKAUSSALITYÖN SUJUVUUS - KIRURGIN KAAVAKE

- **Valitse mielestäsi paras vaihtoehto** kaikkiin kysymyksiin
- Täytä välittömästi toimenpiteen jälkeen ja palauta lomake passarille
- Kaavakkeeseen ei kirjata tunnistetietoja henkilökunnasta tai potilaasta

Ennen toimenpiteen aloitusta:	**Kyllä**	**Ei**	**En tiedä**	**Ei tarvetta**
1. Oliko potilaan henkilöllisyys varmistettu?	☐	☐	☐	☐
2. Tiesivätkö kaikki salissa olevat toistensa nimet ja tehtävät?	☐	☐	☐	☐
3. Oliko suunniteltu toimenpide kaikkien tiedossa?	☐	☐	☐	☐
4. Oliko mahdollinen puoli (sin/dex) kaikkien tiedossa?	☐	☐	☐	☐
5. Olivatko ennakoitavissa olevat leikkauksenaikaiset ongelmatilanteet tai riskitekijät käyty läpi anestesialääkärin ja leikkaavan lääkärin kesken?	☐	☐	☐	☐
6. Olivatko tarvittavat laboratoriokoevastaukset valmiit?	☐	☐	☐	☐
7. Olivatko potilaan kuvantamistutkimusten tulokset sekä kuvat valmiina ja saatavilla?	☐	☐	☐	☐
8. Jos toimenpiteessä oli odotettavissa vuotoa (yli 500ml), oliko verivaraus tehty?	☐	☐	☐	☐
9. Oliko antibioottiprofylaksia annettu 60 minuutin sisällä ennen viiltoa?	☐	☐	☐	☐
Toimenpiteen jälkeen, ennen potilaan siirtämistä leikkaussalista:				
10. Aiheuttiko potilaan leikkausasento ongelmia?	☐	☐	☐	☐
11. Toimiko toimenpiteessä käytetty välineistö moitteettomasti?	☐	☐	☐	☐
12. Toimiko leikkaussalitiimin kommunikaatio leikkauksen aikana moitteettomasti, myös mahdollisissa ongelmatilanteissa?	☐	☐	☐	☐
13. Olivatko postoperatiiviset määräykset sekä potilaan toipumisen kannalta oleelliset tiedot kirjattu?	☐	☐	☐	☐
14. Oliko potilaan tromboosiprofylaksia huomioitu?	☐	☐	☐	☐

KÄÄNNÄ

pvm___ / ___ / _____ sali_____ toimenpiteen järjestysnumero/sali _____ 2

Muita huomioita:

_____

_____

_____ _____

KIITOS VASTAUKSISTASI !

KÄÄNNÄ

pvm___ / ___ / _____ sali_____ toimenpiteen järjestysnumero/sali _____ 1

LEIKKAUSSALITYÖN SUJUVUUS - ANESTESIALÄÄKÄRIN KAAVAKE

- Täytä kaavake **valitsemalla mielestäsi paras vaihtoehto** välittömästi toimenpiteen jälkeen ja palauta se passarille
- Kaavakkeeseen ei kirjata tunnistetietoja henkilökunnasta tai potilaasta

Ennen anestesian aloitusta:	**Kyllä**	**Ei**	**En tiedä**	**Ei tarvetta**
1. Oliko potilaan henkilöllisyys varmistettu potilaalta? ☐ potilas kykenemätön vastaamaan	☐	☐	☐	☐
2. Oliko potilaan paino ja pituus kirjattu?	☐	☐	☐	☐
3. Oliko suunniteltu toimenpide kaikkien tiedossa?	☐	☐	☐	☐
4. Oliko puoli (sin/dex) kaikkien tiedossa?	☐	☐	☐	☐
5. Ovatko mahdolliset potilaan asentorajoitukset kaikkien tiedossa?	☐	☐	☐	☐
6. Olivatko potilaan allergiat kaikkien tiedossa?	☐	☐	☐	☐
7. Olivatko potilaan perussairaudet tiedossa?	☐	☐	☐	☐
8. Olivatko potilaan käyttämät lääkkeet tiedossa?	☐	☐	☐	☐
9. Oliko potilas saanut määräysten mukaiset preoperatiiviset lääkkeet?	☐	☐	☐	☐
10. Olivatko veren hyytymistekijään vaikuttavat lääkkeet tauolla? ☐ ko. lääkkeitä ei käytössä	☐	☐	☐	☐
11. Olivatko tarvittavat laboratoriokoevastaukset valmiit?	☐	☐	☐	☐
12. Jos toimenpiteessä oli odotettavissa vuotoa yli 500ml / lapset 7ml/kg, oliko verivaraus tehty?	☐	☐	☐	☐
13. Oliko anestesiavälineistö tarkistettu?	☐	☐	☐	☐
14. Oliko mahdolliseen vaikeaan intubaatioon varauduttu?	☐	☐	☐	☐
15. Oliko potilaan monitorointi kyseisen leikkauksen kannalta optimaalinen?	☐	☐	☐	☐

KÄÄNNÄ →

pvm___ / ___ / _____ sali_____ toimenpiteen järjestysnumero/sali _____ 2

	Kyllä	Ei	En tiedä	Ei tarvetta
Ennen toimenpiteen aloitusta:				
16. Tiesivätkö kaikki salissa olevat toistensa nimet ja tehtävät?	☐	☐	☐	☐
17. Olivatko ennakoitavissa olevat leikkauksenaikaiset ongelmatilanteet tai riskitekijät käyty läpi anestesialääkärin ja leikkaavan lääkärin kesken?	☐	☐	☐	☐
18. Oliko potilaan asento varmistettu? (Esim. silmät suljettu, hermovenytykset, painaumat)	☐	☐	☐	☐
Toimenpiteen jälkeen, ennen potilaan siirtämistä leikkaussalista:				
19. Toimiko leikkaussalitiimin kommunikaatio leikkauksen aikana moitteettomasti, myös mahdollisissa ongelmatilanteissa?	☐	☐	☐	☐
20. Olivatko postoperatiiviset määräykset sekä potilaan toipumisen kannalta oleelliset tiedot kirjattu?	☐	☐	☐	☐

Muita huomioita:_____ ___

_____

_____ ___

KIITOS VASTAUKSISTASI !

Leikkaustiimin tarkistuslista – KOHDAT LUETAAN ÄÄNEEN

Ennen anestesian aloitusta >>>>>>>>>>>>>	*Ennen viiltoa >>>>>>>>>>>>>>>>>>*	*Ennen leikkaussalista poistumista >>>>>*
Alkutarkistus	**Aikalisä**	**Lopputarkistus**
Henkilö ja toimenpide varmistettu *- anestesiologi varmistaa ääneen, että potilaan nimi ja henkilötunnus on tarkastettu, toimenpide vahvistettu ja potilaalta/omaiselta saatu suostumus toimenpiteeseen*	**Nimet ja tehtävät** tiedossa *- jokainen varmistaa ääneen että kaikki leikkaussalissa tuntevat toisensa tai ovat esittäytyneet toisilleen (nimi ja tehtävä)*	**Instrumentit** laskettu ja täsmäävät *-leikkaushoitajat vahvistavat ääneen, että instrumenttien, taitosten ja neulojen lukumäärä on laskettu ja täsmää*
Leikkausalue / -puoli varmistettu Ei tarvetta *- valvova hoitaja ilmoittaa leikkausalueen ja onko merkitty*	**Potilas, leikkauskohde ja toimenpide** *- leikkaava lääkäri vahvistaa suullisesti potilaan, leikkauskohteen ja toimenpiteen*	**Diagnoosi, toimenpiteen nimi** ja **koodit** kirjattu *- valvova hoitaja vahvistaa leikkaavalta lääkäriltä että diagnoosi, toimenpiteen nimi ja koodi on kirjattu oikein*
Anestesiavalmius vahvistettu *- anestesiologi vahvistaa "tarkistettu", mikäli seuraavat asiat on huomioitu / suoritettu:* - ASA -luokka - Perussairaudet ja perusläälkkeet - Leikkausta edeltävä lääkitys - Tromboosi- ja antibioottiprofylaksia - Vuotovaaraa aiheuttavat lääkkeet - Proteesit ja implantit - Laboratoriovastaukset huomioitu - Anestesiavälineistö tarkistettu	**Kriittiset tekijät** huomioitu ja kerrottu *- leikkaava lääkäri, anestesiologi ja hoitajat vahvistavat, että leikkauksen kriittiset asiat on huomioitu ja käyty läpi muun leikkaustiimin kanssa* - Leikkaava lääkäri: Leikkauksen kriittiset vaiheet, rutiinista poikkeavat suunnitelmat, leikkauksen oletettu kesto, arvioitu verenvuoto - Anestesiologi /anestesiahoitaja: Erityiset potilaskohtaiset huolenaiheet - Leikkaushoitajat: Steriliteetti varmistettu. Välineistö, instrumentit ja lääkeaineet saatavilla. Diatermialevyn paikka huomioitu.	**Näytteet** merkitty *- valvova hoitaja varmistaa, miten näytteet on merkitty, että niissä on potilaan tiedot ja ne ovat valmiina lähetettäväksi*
Pulssioksimetri asennettu ja toimii *- anestesiahoitaja vahvistaa lukemalla happisaturaation*	**Antibioottiprofylaksia** Annettu 60 min sisällä Ei tarvita *- anestesiahoitaja mainitsee kellonajan, milloin ab-profylaksia on annettu, tai että sitä ei tarvita*	**Välineistöongelmat** kirjattu *- valvova hoitaja vahvistaa, että on kirjattu mahdolliset välineistöä koskevat ongelmat, jotka on korjattava*
Allergiat tiedossa *- anestesiologi sanoo potilaan allergiat tai että niitä ei ole*	**Radiologiset kuvat** Esillä Ei tarvita *- valvova hoitaja vahvistaa, että tarvittavat radiologiset kuvat ovat esillä, mikäli niitä tarvitaan*	**Jatkohoito-ohjeet** annettu *- leikkaava lääkäri, anestesiatiimi ja leikkaushoitajat vahvistavat, että ovat käyneet läpi potilaan toipumiseen liittyvät riskit ja jatkohoitomääräykset*
Vaikea hengitystie / aspiraation vaara Ei ole On ja välineet saatavilla *- anestesiologi vahvistaa että vaikea ilmatie tai aspiraatio-vaara on huomioitu ja tarvittavat välineet saatavilla*		**Poikkeamat** kirjattu
Verenvuotoriski yli 500 ml (lapsilla 7ml/kg) Ei ole Yli 500 ml, huomioitu *- anestesiologi vahvistaa suoniyhteyden riittävyyden ja että vuodon korvaus on suunniteltu, mikäli korkea vuotoriski*		

HYKS Operatiivinen tulosyksikkö 4/2010

Tarkistuslistan käyttöperiaatteet:

- Lähtökohtana on käyttää listaa varmistamaan ja vahvistamaan **ääneen**, että siinä mainitut asiat suoritetaan tai huomioidaan. Asiat voidaan tehdä siinä vaiheessa, kun ne tulevat kohdalle osana luonnollista työkulkua. Listan avulla varmistetaan, että mikään niistä ei ole unohtunut.

- Tarkistuslistan käyttö on leikkausryhmän **yhteinen asia**. Käytännön toteutuksesta vastaa pitkälti - ja tarkistuslistan etenemistä ohjaa - **valvova hoitaja**. Hän lukee listalta tarkistettavan kohdan (esim. ”Radiologiset kuvat”) ja kohdasta vastaava henkilö vahvistaa ääneen, mitä asialle on tehty (esim. ”Esillä” tai ”Ei tarvita”).

- Tarkistuslistaa käytetään siinä vaiheessa, kun kaikki siihen liittyvät toimenpiteet on tehty. **Alkutarkistus** tehdään kun anestesiavalmistelut ovat valmiit, ja **aikalisän** tarkistus kun ollaan valmiita toimenpiteen aloittamiseen. **Lopputarkistus** tehdään salivaiheen päätteeksi (kun instrumentit ovat lasketut ja anestesiatiimi on leikkaavan lääkärin kanssa käynyt läpi potilaan jatkohoito-ohjeet).

- Tarkistuslistan vastaukset pyritään pitämään vakiomuotoisina ja lyhyinä sujuvan etenemisen varmistamiseksi. Vakiomuotoinen vastaus on joko yleinen vahvistus (esim. ”Kyllä”) tai listassa annettu vastausvaihtoehto (esim. ”Ei tarvetta” tai ”Yli 500 ml, huomioitu”), kun listalla on esitetty selkeät vaihtoehdot.

- Joissain tarkistuslistan kohdissa vakiomuotoinen vastaus kuvaa suoraan asian tilaa. Esimerkiksi Aikalisän kohtaan ”Potilas, leikkauskohde ja toimenpide” vahvistetaan suullisesti potilaan nimi, leikkauskohde ja toimenpide: ”Matti Meikäläinen, oikean polven tähystys”.

- Tarkistuslistan kohtaan annetaan vahvistus vasta, kun kyseinen asia on varmasti huomioitu. Mikäli joku tiimin jäsenistä on epävarma jostain tarkistuslistan kohdasta, ilmoittaa hän asiasta, ja listaa jatketaan vasta kun varmuus asiasta on saatu.

- Mikäli tarkistuslistalla olevaa kohtaa ei ole tehty tai varmistettu ennen tarkistuslistan lukemista (esimerkiksi leikkauspuoli varmistamatta), kyseinen kohta tehdään ennen seuraavaan vaiheeseen siirtymistä (nukutus tai puudutus). Jos varmistusta ei voi tehdä, kirjataan erikseen, mikä kohta jäi varmistamatta ja miksi.

- Valvova hoitaja etenee listaa järjestyksessä ja siirtyy seuraavaan kohtaan vasta, kun on saanut varmistuksen tai vahvistuksen.

- Kun kunkin vaiheen viimeinen kohta listalla on tehty, ilmoittaa valvova hoitaja, että lista on käyty läpi (esim. ”Aikalisä-tarkistuslista tehty”). Tarkistuksesta kuitataan Operaan ”Kolmen kohdan tarkistuslista”.

- Hyvään leikkaussalikäytäntöön kuuluu selkeästi ääneen kuitata annetut ohjeet ja pyydetyt toimenpiteet tehdyiksi. Esim. pyyntö: "Saa antaa hepariinin." ja kuittaus: "Hepariini annettu.".

Lisätietoja: www.who.int/patientsafety, www.who.int/safesurgery tai www.safesurg.org

HYKS Operatiivinen tulosyksikkö 4/2010

11.4 Questionnaire for studies IV and V

TARKISTUSLISTA- JA POTILASTURVALLISUUSKYSELY LEIKKAUSSALIHENKILÖKUNNALLE 10/2011

Tarkoituksenamme on kartoittaa ja kehittää potilasturvallisuuteen liittyvä tekijöitä leikkaussalityössä.

WHO:n kirurginen tarkistuslista on ollut käytössä yksikössämme vuoden ajan. Olemme kiinnostuneita mielipiteestäsi tarkistuslistasta, sekä tarkistuslistakohtien järkevyydestä ja soveltuvuudesta erikoisalamme potilaille.
Vastauksia ei käsitellä yksittäisinä ja vastaajia ei tunnisteta

Vastaajan tiedot
Ympyröi vaihtoehto:

Sukupuoli

Mies	Nainen
1	**2**

Ikä

< 30	30-39	40-49	50-59	60-69
1	**2**	**3**	**4**	**5**

Koulutus/tehtävä

Korvalääkäri, erikoislääkäri	Korvalääkäri, erikoistuva	Anestesialääkäri, erikoislääkäri	Anestesialääkäri, erikoistuva
1	**2**	**3**	**4**

Sairaanhoitaja, anestesia	Sairaanhoitaja, instrumentti	Sairaanhoitaja, muu, mikä	Muu, mikä
5	**6**	**7**	**8**

Olen työskennellyt korva-, nenä ja kurkkutautien leikkaussalissa

< ½ vuotta	½-1 vuotta	1-5 vuotta	>5 vuotta
1	**2**	**3**	**4**

*Työskentelen **pääasiallisesti** päiväkirurgisessa yksikössä*

Kyllä	Ei
1	**2**

Olemme käyttäneet tarkistuslistaa noin _____%:ssa leikkauksista, joissa olen ollut mukana.

Appendices

Ympyröi vaihtoehto:

1	2	3	4	5
täysin eri mieltä	jokseenkin eri mieltä	ei samaa eikä eri mieltä	jokseenkin samaa mieltä	samaa mieltä

Tuntisin oloni turvalliseksi, jos olisin täällä potilaana.
1 2 3 4 5

Leikkaussalihenkilökunnan välinen keskustelu (briefing) ennen leikkausta on tärkeää potilasturvallisuuden kannalta.
1 2 3 4 5

Työtoverini kannustavat raportoimaan eteenpäin, jos koen turvallisuuteen liittyviä huolia.
1 2 3 4 5

Tällä leikkausosastolla on vaikea puhua avoimesti, jos havaitsen potilaan hoitoon liittyvän ongelman.
1 2 3 4 5

Tällä leikkausosastolla lääkärit ja hoitajat työskentelevät yhdessä hyvin toimivana ryhmänä.
1 2 3 4 5

Henkilökunta jättää usein huomioimatta leikkaussalissa voimassaolevia sääntöjä tai ohjeita.
1 2 3 4 5

Tarkistuslistaa oli helppo käyttää.
1 2 3 4 5

Tarkistuslista paransi leikkaussaliturvallisuutta.
1 2 3 4 5

Tarkistuslistan läpikäynti kesti kauan.
1 2 3 4 5

Jos olisin menossa leikkaukseen, haluaisin, että tarkistuslistaa käytettäisiin.
1 2 3 4 5

Tarkistuslistan käyttö paransi tiedonkulkua.
1 2 3 4 5

Tarkistuslista auttoi estämään leikkaussalissa tapahtuvia virheitä.
1 2 3 4 5

3

Ympyröi vaihtoehto:

1	2	3	4	5
täysin eri mieltä	jokseenkin eri mieltä	ei samaa eikä eri mieltä	jokseenkin samaa mieltä	samaa mieltä

Tarkistuslistakohta on mielestäni tärkeä korva-, nenä- ja kurkkutautien leikkauksissa

Alkutarkistus

Henkilöllisyys, toimenpide ja suostumus
1 2 3 4 5

Leikkausalue/-puoli merkitty
1 2 3 4 5

Anestesiavalmius vahvistettu
1 2 3 4 5

Pulssioksimetri asennettu ja toimii
1 2 3 4 5

Allergiat tiedossa
1 2 3 4 5

Vaikea hengitystie/ aspiraatioriski
1 2 3 4 5

Oletettu verenvuoto yli 500 ml (lapsilla 7 ml/kg)
1 2 3 4 5

Aikalisä

Nimet ja tehtävät tiedossa
1 2 3 4 5

Potilas, leikkauskohde ja toimenpide
1 2 3 4 5

Kriittiset tekijät huomioitu ja kerrottu
1 2 3 4 5

Antibioottiprofylaksia
1 2 3 4 5

Radiologiset kuvat
1 2 3 4 5

Lopputarkistus

Instrumentit laskettu ja täsmäävät
1 2 3 4 5

Diagnoosi, toimenpiteen nimi ja koodit
1 2 3 4 5

Näytteet merkitty
1 2 3 4 5

Välineistöongelmat kirjattu
1 2 3 4 5

Jatkohoito-ohjeet annettu
1 2 3 4 5

Poikkeamat kirjattu
1 2 3 4 5

Appendices

4

Mielipiteitäni kirurgisen tarkistuslistan soveltuvuudesta ja tarkistuskohdista korva-, nenä- ja kurkkutautien leikkauksissa:

Onko joku/jotkut tarkistuslistan kohdista mielestäsi **tarpeeton** nimenomaan **päiväkirurgisissa** toimenpiteissä?

Ehdotuksia tarkistuslistaan lisättävistä kohdista:

Mielipiteitäni potilasturvallisuuteen liittyvistä asioista leikkausyksikössämme:

Kiitos vastauksistasi ja turvallista työpäivää!

Karin Blomgren
Annika Takala
Nina Starck
Leena-Maija Aaltonen
Päivi Helmiö

ISBN 978-951-51-1109-8 (paperback)
ISBN 978-951-51-1110-4 (PDF)
http://ethesis.helsinki.fi

Painosalama Oy, Turku, Finland 2015