Compliance with a Time-out Procedure to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-005075
Article Type:	Research
Date Submitted by the Author:	17-Feb-2014
Complete List of Authors:	Van Schoten, Steffie; NIVEL, Kop, Veerle; NIVEL, De Blok, Carolien; NIVEL, Spreeuwenberg, Peter; NIVEL, Groenewegen, Peter; Department of Sociology, Department of Human Geography, Utrecht University, Wagner, Cordula; Vrije Universiteit Medical Center (VUmc), Department of Public and Occupational Health & EMGO Institute for Health and Care Research
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Health policy
Keywords:	SURGERY, SOCIAL MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Compliance with a Time-out Procedure to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program

Steffie M. van Schoten MSc [1*], Veerle Kop[1], Carolien de Blok PhD[1], Peter Spreeuwenberg[1], Prof. Peter P. Groenewegen PhD [1,2], Prof. Cordula Wagner PhD[1,3]

[1] NIVEL – Netherlands Institute for Health Services Research, Utrecht, Netherlands

[2] Department of Sociology, Department of Human Geography, Utrecht University, Utrecht, Netherlands

[3] Department of Public and Occupational Health & EMGO Institute for Health and Care Research, Vrije Universiteit Medical Center (VUmc), Amsterdam, Netherlands

* Corresponding author

NIVEL – Netherlands Institute for Health Services Research.

PO Box 1568, 3500 BN Utrecht

E-Mail address: s.vanschoten@nivel.nl

Tel: +31 30 2729 730

Fax: +31 30 2729 729

Keywords. *patient safety, compliance, time-out procedure, wrong surgery, checklist*

Word count. 3410

Compliance with a Time-out Procedure to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program

Abstract *(word count: 244)*

Objective. To prevent wrong surgery, the WHO "Safe Surgery Checklist" was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Design. Evaluation study involving observations.

Setting. Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals.

Participants. A random selection was made from all adult patients scheduled for elective surgery on the day of the observation, preferably involving different surgeons and different procedures.

Results. Mean compliance with the TOP was 71.3%. Large differences between hospitals were observed. No linear trend was found in compliance during the study period. Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.

Conclusions. Large differences in compliance with the TOP were observed between participating hospitals which can be attributed at least in part to the type of hospital, surgical specialty, and patient characteristics. Hospitals do not comply consistently with national

guidelines to prevent wrong surgery and further implementation as well as further research into non-compliance is needed.

Keywords. *patient safety, compliance, time-out procedure, wrong surgery, checklist*

Article Summary

Article focus

- To prevent wrong surgery, the WHO "Safe Surgery Checklist" was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team.
- The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Key message

- Mean compliance with the TOP was 71.3%, large differences between hospitals were observed.
- Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.
- Hospitals do not comply consistently with national guidelines to prevent wrong surgery and further implementation as well as further research into non-compliance is needed.

Strengths and limitations of this study

- Structured observations of compliance with TOP at OR and factors that are associated with compliance.
- The presence of the observer might have influenced the behavior of the OR staff, a potential selection bias in the surgical procedures on the observation days, no outcome data are available.

Introduction

Ideally, hospitals should be safe environments for their patients. However, making errors is inherent in all humans.[1] The report "To Err is Human" showed that errors cause 44,000 to 98,000 deaths and over one million injuries each year in American hospitals.[1] As a result, patient safety became a major topic on the healthcare agenda.[2-4] Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.[5] An adverse event is unintentional harm caused by healthcare management rather than by the patient's underlying disease that results in a prolonged hospital stay, temporary or permanent disability, or death.[6] In 2004, adverse events occurred in approximately 5.7% of hospital admissions in the Netherlands: approximately 2.3% of the adverse events were potentially preventable.[6] More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.[6] It is therefore important to ensure and improve patient safety during surgery.

Patient safety in surgery has several aspects. One of these aspects is wrong surgery, which can be classified into three groups: surgery at the wrong site, surgery on the wrong patient, and carrying out the wrong procedure.[7] Wrong site surgery occurs whenever a planned surgical procedure is performed at or on the wrong place, part, side or site. Wrong patient surgery refers to a procedure performed on the wrong patient. Wrong procedure surgery refers to a different procedure being performed than the one planned for the patient. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event database ranked wrong site surgery as the second most frequently reported adverse event between 1995 and 2005.[8] In the United States, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5 per 10,000 operations.[3 8-13]

To prevent wrong surgery, the JCAHO guideline "Universal protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" was adopted in 2003 by the Joint

Commission in the United States.[14] Consequently, the World Health Organization (WHO) introduced a checklist in 2008 for worldwide use, called the "Safe Surgery Checklist". In 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated with a significant decrease in postoperative complication (30%) and mortality rates (50%).[15] Based on these results, the WHO estimated that implementing the checklist could save 500,000 lives every year worldwide.[15] Other studies provided evidence supporting the use of surgical checklists as well.[16-19] In the Netherlands, the SURgical PAtient Safety System (SURPASS) was developed with the same intention. It is based on safety checks used in the aviation industry to reduce human error.[20] Research on the external validation of the SURPASS shows a reduction in unintentional harm.[21-23]

Each of the checklists mentioned above comprises a time-out procedure (TOP). Errors can be avoided by including a preoperative discussion just before the start of the surgical procedure. This takes place during a time-out involving a review of the names and roles of all team members, characteristics of the patient, the operation plan, familiarity with the procedure, the presence of the correct materials/equipment, and potential issues for the patient.[24,25] It is likely that these TOPs reduce uncertainties in the OR among the surgical team and reduce the risk of wrong surgery. The TOP is the final step before the start of the surgical procedure and is therefore crucial in preventing wrong surgery. A TOP is carried out just before anesthesia,[26] and consists of three checks (the patient, the procedure and the side/site), all of equal importance in preventing wrong surgery.

The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the OR, whether compliance has changed over time, and to determine factors that are associated with the TOP compliance. Insights into compliance with the TOP and the factors associated with compliance are important because they have the potential to improve the TOP and reduce adverse events in surgical processes throughout the world. This study was

carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital Patient Safety Program (hereinafter "Safety Program") that was carried out during the final year of the program. (Box 1.).

Box1. The Dutch Hospital Patient Safety Program

The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.[26] The Safety Program consisted of ten patient safety themes and clinical guidelines were developed for each theme. Hospitals were given five years to implement these guidelines. One of the themes was prevention of wrong surgery. There are several risk factors for wrong surgery, e.g. insufficient compliance, inadequate identification and verification and bad preoperative planning.[27 28] The Safety Program therefore instructed the participating Dutch hospitals to implement several steps to decrease wrong surgery, based on the SURPASS checklist. One of the steps is identification and verification by means of a TOP consisting of checks on the correct patient, correct side, and correct intervention.[29]

Based on the goals of the Safety Program, it was expected that the compliance with the TOP increased over time and became more visible during the final year of the program when hospitals approached the public deadline at the end of 2012.

The research questions are:

1. *To what extent do Dutch hospitals comply with the time-out procedure before anesthesia in the operating room?*
2. *How has the compliance with the time-out procedure changed during the final year of the Safety Program?*
3. *What factors are associated with compliance with the time-out procedure?*

Methods

Study design

This study was part of a larger evaluation study of the Safety Program that was carried out between November 2011 and December 2012 in eighteen Dutch hospitals (about 20% of all Dutch hospitals). The study protocol was granted approval by the VU University Medical Center ethical review board in Amsterdam. Hospitals were randomly selected using a

stratified sample based on geographical regions and hospital type. Two academic hospitals, four teaching hospitals and twelve general hospitals were included in this study. All hospitals consented to the study and were informed about further practical issues. A random selection was made on the day of the observation from all adult patients scheduled for elective surgery on the day of the observation. The goal was to have ten observation days per hospital at intervals of four to six weeks, and to observe six to ten surgical procedures per day, preferably involving different surgeons and different procedures. One observer per surgical procedure evaluated whether the TOP was carried out before anesthesia, using a standardized recording form that covered the various aspects of doing the TOP: checking the patient, procedure, and side/site, attention of the team (focus), completeness of the team, interruptions, and several background variables such as the type of surgical procedure, the patient's age, and sex. The OR team was not aware of the exact subject matter of the observation; the observer was instructed to introduce the study in abstract terms, referring to it as a study about the surgical process in general.

TOP compliance

The dependent variable was whether the TOP was done correctly and was dichotomous (yes/no). This variable was used to examine mean TOP compliance and the changes in compliance during the study period. A correct TOP consists of three checks: patient, procedure, and side/site. Since all three checks are equally important for preventing wrong surgery, the TOP was only deemed correct when all three checks were performed. The entire OR team gathers around the patient during a TOP and the surgeon asks the patient his/her name, the type of procedure and the side/site of the procedure.

Four independent variables were included so that any relationship with compliance could be determined. The type of hospital was categorized into academic, teaching, and general.

Hospital size was operationalized as the number of beds in the hospital (a continuous variable). Surgical specialty was added as a categorical variable with general surgery as the reference category. Focus (yes/no) was included to measure the degree to which the OR team was paying full attention to the TOP and was not performing any other activities during the TOP. In addition, the patient characteristics 'age' and 'sex' were included as covariates. Completeness of the team (yes/no) was added as a explorative analysis.

Statistical analyses

Descriptive analyses were performed to obtain a picture of the study population, mean TOP compliance, changes in compliance over time, mean compliance for the different hospital types, mean compliance for the different surgical specialties, and the focus and completeness of the team during the TOP.

A multilevel logistic regression analysis with two levels was used to determine whether TOP compliance changed between the ten measuring moments. Multilevel analysis was chosen to correct for the fact that the surgical procedures are not independent from each other, but clustered within hospitals. Time was modeled by adding ten indicator variables for the time points (removing the intercept from the model); trends were tested using polynomial contrasts (to the 4^{th} order) to study changes over time. Variance and intraclass correlations (ICCs) were calculated to assess the clustering of TOP compliance at the hospital and surgical procedure level. An ICC of 20% was seen as moderate.[30] The changes over time were also analyzed for the different hospital types to determine the relationship between hospital type and the changes in TOP compliance. Separate logistic multilevel analyses were performed for each independent variable to analyze the effects of the independent variables 'hospital size' and 'surgical specialty'; this was necessary because not enough units at the highest level (hospitals) were available to have more than one independent variable in a model.[30] Age and

sex of the patient were added as covariates in all analyses. All descriptive analyses were performed using SPSS version PASW Statistics 18. The multilevel analyses were performed using MlwiN version 2.24 (using PQL, second order, unconstrained level 1 variance, options).

Results

Descriptive analyses

1281 surgical procedures were observed at the participating hospitals. After patients younger than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96. The gender distribution was 41.4% male, 53.8% female, and 4.8% unknown. The range in types of surgical procedures was broad; observers had been instructed to observe different procedures and observed surgical procedures of in total 13 different specialties. Mean compliance with the TOP during the total study period was 71.3%. Descriptive analyses showed that TOP compliance did not improve during the study period. There was a large spread between hospitals: one of the hospitals never performed the TOP correctly and two had mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at the ninth measuring moment for all the participating hospitals. The academic hospitals had a mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%. Differences between specialties were shown to exist: trauma, gastroenterology and hepatology, and ENT medicine had the highest compliance rates. Anesthesiology, cardiothoracic surgery, and cosmetic surgery had the lowest compliance rates. In 44% of the observations the team was not focused on the TOP and in 56%, the team was incomplete.

Multilevel regression analyses

In the first multilevel regression analysis, the changes in TOP compliance were tested. The effect was statistically significant for the fourth-order polynomial ($p < 0.01$), meaning that

TOP compliance was not linear but fluctuated over time and no clear trend was observed. Furthermore, there were large differences between the measuring moments and between individual hospitals. See Figure 1. The multilevel analysis shows that 44% (ICC = 44.01) of the total variance in TOP compliance can be attributed to the differences between the individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11 (40%). See Table 1.

When correcting for age and sex of the patient, the ICC dropped to 26% (ICC = 26.58). The relationship between the age of the patient and the TOP was found to be significant ($p < 0.05$). This relationship was tested and found to be linear. Based on the results described above, there was no rationale to correct for time (measurement points) in further analyses. Observations from the different measurement points were pooled in the remaining analyses.

Separate analyses were performed for the independent variables 'hospital size', 'surgical specialty', and 'focus'. No statistically significant relationship was found between hospital size and TOP compliance (data not shown in tables). A positive relationship was found between patients undergoing ENT surgery and the TOP (reference = general surgery; $p < 0.01$). Another positive relationship was found between patients undergoing ophthalmic surgery and the TOP (reference = general surgery; $p < 0.05$). See Table 2. This indicates that TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic surgery compared to patients undergoing general surgery. The relationship between the age of the patient and TOP compliance was found to be significant ($p < 0.05$) in all analyses. This indicates that TOP compliance decreases with the patient age in all analyses. The TOP is performed less often for older patients. An additional analysis was performed based on these results to determine which of the three individual checks of the TOP attributed most to the negative relationship between the age of the patient and TOP compliance. Table 3 shows the

results of the additional analysis. The check procedure contributes most to the negative relationship between age of the patient and TOP compliance, this check is more often skipped when an older patient is involved. The relationship between the focus of the team during the TOP and the correct execution of the TOP is shown in Table 4. There is a positive significant relationship between focus and TOP compliance, which indicates that the TOP is more often correctly executed when the entire team is focused on the TOP and not performing any other activities at the same time.

Discussion

The objective of this study was to investigate the compliance at Dutch hospitals with the national guidelines of a TOP set by the Safety Program and how this changed over the final year of the program. Furthermore, we studied variables that might be associated with compliance. This study found a mean TOP compliance of 71.3%. There was no linear trend in the TOP compliance during the study period. Large differences were found between individual hospitals, which were partly influenced by age of the patient. The type of hospital was associated with the TOP compliance: academic hospitals had lower compliance rates than general and teaching hospitals. Given the low number of academic hospitals in this study (N=2), these findings cannot be generalized to academic hospitals as a whole. ENT medicine and ophthalmological surgery had higher TOP compliance than the reference group (general surgery). No statistically significant relationship between TOP compliance and hospital size was found. The TOP was correctly performed more often when the OR team was focused on it. The negative relationship between age of the patient and the TOP indicates that greater patient age is associated with lower TOP compliance. Of all the observed TOPs, 44% were performed without the focus of the entire team, and the team was not complete in 56% of the TOPs.

A wide range in compliance rates for surgical checklists can be found in previous studies, ranging from 12% to 99% with a mean of 75%.[31-33] The compliance rate (71.3%) found in our study is slightly lower than the mean rate found in other studies.

We found a difference in TOP compliance between the different types of hospitals. The general and teaching hospitals hardly differed from each other, which is interesting because a previous study [34] found teaching hospitals to be better at implementing checklists than general hospitals. According to the organizational learning theory, the availability of knowledge in an organization contributes to the adoption of innovations.[34 35] Teaching hospitals are learning environments, aimed at spreading and developing knowledge; better compliance can therefore be expected in teaching hospitals. However, we found that academic hospitals showed lower TOP compliance.

The literature is inconsistent about the influence of hospital size on the use of checklists. Some argue that larger hospitals are better developed and use standardized processes, which increases the quality of the hospital more often,[36-38] whereas others conclude that smaller hospitals implement checklists better.[39] We found no relationship between TOP compliance and hospital size. The high ICC rates found in this study suggest that the differences between individual hospitals is high, and differences in compliance can not be explained by general hospital characteristics such as hospital size.

The relationship found between surgical specialties and the TOP is different from the results of previous studies. One study showed a difference between surgeons and anesthesiologists[40] and another study showed no difference between surgical specialties at all.[41] The TOP is a standardized procedure, and the way in which it should be carried out does not depend on the surgical specialty performing the procedure or the patient characteristics. We found that other surgical specialties teams performed the TOP more often than general surgery teams. Further research is needed to verify these results.

The negative relationship between TOP compliance and the age of the patient was an unexpected result, since the TOP should be executed in the same way for all patients. We found lower TOP compliance for older patients, in particular that the surgical procedure is verified less often with the patient. Elderly people are a vulnerable group with a higher risk of complications after surgery. Further in-depth research is needed to explain the differences in compliance for different age groups.

Completeness and focus are important factors in the TOP and performing it when team members are busy with other activities creates a risk. Our study showed that focus in the team contributes to the TOP being performed correctly. However, there was poor focus on the TOP in almost half of the surgical procedures observed. Based on these results, it seems that hospitals still have a lot to gain by carrying out the TOP properly.

Strengths and limitations

Our study was the first to evaluate TOP compliance over time through observations in the OR and look at the factors associated with compliance. Our dependent variable was a process indicator, because the incidence of wrong surgery is too low to be observed with our study design. Based on the literature, it is fair to assume that higher TOP compliance will decrease the incidence of wrong surgery,[15] although this study gives no information about the actual number of wrong surgeries.

This study has several limitations. Firstly, the presence of the observer might have influenced the behavior of the OR staff and indirectly of our dependent variable TOP. However, the design of our study aimed to prevent this potential observer bias, because the precise goal of the observations was not known to the OR team. Secondly, a potential selection bias can be found in the selection of surgical procedures on the observation days. Surgical procedures were selected based on practical considerations: the day of the week, the

duration of the procedure, and the OR schedule. The relationships found between different specialisms might be partially overestimated, because the same surgical teams were sometimes observed on the same day or on different observation days. However, the overall goal was to observe as may different surgical procedures with different teams as possible, in order to limit potential selection bias. Thirdly, there is no information available about the changes in compliance during the first period of the Safety Program, and hospitals may have made progress during this period.

Conclusions

The mean TOP compliance was 71.3% during the final year of the Safety Program and no improvement in compliance over time was found. Large differences were found between hospitals, and these differences were influenced by age of the patient. Compliance was influenced by several factors: academic hospitals performed the TOP less often than general and teaching hospitals, different surgical specialties showed different compliances with the TOP, the TOP was performed less often for older patients, and TOP compliance was higher when the entire team was focused on the TOP. Furthermore, in almost half the TOPs, the team was not focused on the TOP or the team was incomplete. Despite the fact that almost three quarter of operations are preceded by a TOP, hospitals need to make an effort to improve TOP compliance and the way in which the TOP is carried out in order to prevent wrong surgery from happening in the future.

Figure legend

Figure 1. Trend in the time-out procedure compliance per hospital type, and overall mean (n=1232)

Tables

Table 1. Trend in the time-out procedure per hospital type (n=1232; 18 hospitals)

	Trend	Trend per hospital type						
		General hospital		Teaching hospital		Academic hospital		
Fixed effects	**Mean percentage**	**95% CI**	**Mean percentage**	**95% CI**	**Mean percentage**	**95% CI**	**Mean percentage**	**95% CI**
TOP (constant)								
MM 1	73.52	53.20-87.14	85.18	2.00-94.35	59.00	21.26-88.46	16.48	0.91-80.91
MM 2	71.64	51.26-85.85	76.73	54.48-90.09	75.65	36.60-94.36	45.91	2.90-96.02
MM 3	66.79	45.78-82,73	67.09	42.94-84.66	82.19	44.85-96.32	23.86	1.55-86.19
MM 4	76.77	57.01-89.17	82.01	60.92-93.02	80.40	41.08-96.02	25.73	1.76-87.03
MM 5	77.26	57.99-89.32	87.56	70.27-95.44	72.30	32.65-93.36	5.97	0.29-57.90
MM 6	82.18	64.73-92.05	81.27	60.55-92.46	94.63	65.68-99.39	59.61	5.32-97.48
MM 7	81.20	62.89-91.67	82.23	61.44-93.07	91.13	57.87-98.72	46.67	2.40-96.89
MM 8	79.41	60.46-90.68	82.59	62.33-93.16	85.56	46.93-97.54	45.42	1.80-97.43
MM 9	48.44	28.65-68.74	52.86	29.81-74.75	66.00	26.36-91.33	6.00	0.40-50.29
MM 10	69.68	48.46-84.88	71.32	47.57-87.20	83.56	43.24-97.13	48.84	2.39-97.38
Random effects Variance components:								
ICC	44.056	40.106						
hospital (level 2)	2.591 (0.916) *	2.203 (0.798) *						
surgical procedure (level 1)	0.988 (0.040)	0.984 (0.040)						

MM = Measuring moment, TOP = Time-out procedure, 95% CI = 95% confidence interval, ICC = Intraclass correlation

*p<0.05

Table 2. Relationship between surgical specialties (n=1130; 18 hospitals) and compliance with the time-out procedure.

	Model 0 (time-out procedure + age + sex)	**Model 1 (model 0 + specialties)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties - General surgery	-	*Reference*
Specialties - Gynecology	-	0.050 (0.264)
Specialties – ENT	-	0.905 (0.316) *
Specialties - Ophthalmology	-	0.616 (0.302) *
Specialties – Orthopedic surgery	-	0.163 (0.241)
Specialties – Urology	-	0.084 (0.287)
Specialties – other	-	0.046 (0.279)
Patient age	-0.011 (0.004) *	-0.011 (0.004) *
Patient sex	0.064 (0.153)	0.074 (0.155)
Random effects		
Variance components:		
Intraclass correlation	25.331	25.499
hospital (level 2)	1.116 (0.422) *	1.126 (0.426) *
surgical procedure (level 1)	0.996 (0.042)	1.006 (0.043)

*p<0.05

Table 3. Age effects for the three different checks in the time-out procedure: checking the patient (n=1074), the procedure (n=1074), and the side/site (n=1074)

	Model 0 (check patient + age + sex)	**Model 1 (check procedure + age + sex)**	**Model 2 (check side/site + age + sex)**
Fixed effects	Estimate (SE)	Estimate (SE)	Estimate (SE)
Check patient (constant)	3.499 (0.334)	-	-
Check procedure (constant)	-	2.276 (0.282)	-
Check side/site (constant)	-	-	2.739 (0.204)
Patient's age	0.008 (0.008)	-0.021 (0.006)*	0.012 (0.007)*
Patient's sex	-0.185 (0.288)	0.124 (0.198)	0.160 (0.246)
Random effects			
Variance components:			
Intraclass correlation	27.172	24.990	10.854
hospital (level 2)	1.228 (0.623) *	1.096 (0.464) *	0.401 (0.236) *
surgical procedure (level 1)	0.834 (0.036)	0.922 (0.040)	0.950 (0.041)

*p<0.05

Table 4. Relationship between focus (n=1074; 18 hospitals) during the time-out procedure and compliance with the time-out procedure.

	Model 0 (time-out procedure + age + sex)	**Model 1 (model 0 + focus)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time-out procedure (constant)	1.540 (0.163)	1.471 (0.156)
Focus	-	0.567 (0.171)*
Patient's age	-0.006 (0.005)	-0.005 (0.005)
Patient's sex	-0.012 (0.162)	-0.016 (0.163)
Random effects		
Variance components:		
Intraclass correlation	8.971	7.991
hospital (level 2)	0.324 (0.154) *	0.286 (0.140) *
surgical procedure (level 1)	0.968 (0.042)	0.966 (0.042)

*p<0.05

Acknowledgements

We wish to thank the participating hospitals, their contact persons and employees who participated in our study.

Competing interests

The authors declare that they have no competing interests.

Contributions

SS and VK did the statistical analyses, interpreted the results of the analyses and drafted the manuscript. SS took part in the data collection. CB was involved in the design of the study, organized the data collection and critically revised the manuscript. PS did the statistical analyses and reviewed the parts of the manuscript that involved the statistical analyses. PG was involved in the design of the study, advised on the statistical analyses and critically revised the manuscript. CW was involved in the design of the study and critically revised the manuscript. All authors meet the criteria for authorship, were involved in revising and approving the final manuscript and accept responsibility for the data presented.

Funding

This research was funded by the Ministry of Education, Culture and Science in the Netherlands.

Data sharing statement

No additional data are available.

Reference List

1 Kohn LT, Corrigan J, Donaldson MS. To err is human: building a safer health system. 6 ed. Joseph Henry Press; 2000.

2 See LC, Chang YH, Chuang KL, *et al*. Animation program used to encourage patients or family members to take an active role for eliminating wrong-site, wrong-person, wrong-procedure surgeries: Preliminary evaluation. *Int J Surg* 2011; 9(3):241-247.

3 Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? *Arch Surg* 2006; 141(9):931.

4 Zhan C, Kelley E, Yang HP, *et al*. Assessing patient safety in the United States: challenges and opportunities. *Med Care* 2005; 43(3):I-42.

5 WHO. Patient Safety. 2013.
Ref Type: Online Source

6 Zegers M, De Bruijne MC, Wagner C, *et al*. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care* 2009; 18(4):297-302.

7 Gibbs VC. Thinking in three's: Changing surgical patient safety practices in the complex modern operating room. *World J Gastroenterol* 2012; 18(46):6712.

8 DeVine J, Chutkan N, Norvell DC, *et al*. Avoiding wrong site surgery: a systematic review. *Spine* 2010; 35(9S):S28.

9 Ammerman JM, Ammerman MD, Dambrosia J, *et al*. A prospective evaluation of the role for intraoperative x-ray in lumbar discectomy. Predictors of incorrect level exposure. *Surg Neurol* 2006; 66(5):470-473.

10 Kwaan MR, Studdert DM, Zinner MJ, *et al*. Incidence, patterns, and prevention of wrong-site surgery. *Arch Surg* 2006; 141(4):353.

11 Jhawar BS, Mitsis D, Duggal N. Wrong-sided and wrong-level neurosurgery: a national survey. 2007.

12 Mody MG, Nourbakhsh A, Stahl DL, *et al*. The prevalence of wrong level surgery among spine surgeons. *Spine* 2008; 33(2):194.

13 Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007; 246(3):395.

14 Angle JF, Nemcek AA, Jr., Cohen AM, *et al*. Quality improvement guidelines for preventing wrong site, wrong procedure, and wrong person errors: application of the joint commission "universal protocol for preventing wrong site, wrong procedure, wrong person surgery" to the practice of interventional radiology. *J Vasc Interv Radiol* 2009; 20(7 Suppl):S256-S262.

15 World Health Organization. New scientific evidence supports WHO findings: a surgical safety checklist could save hundreds of thousands of lives. 2011. 2011.
Ref Type: Generic

16 Haynes AB, Weiser TG, Berry WR, *et al*. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Eng J Med* 2009; 360(5):491-499.

17 Mazzocco K, Petitti DB, Fong KT, *et al*. Surgical team behaviors and patient outcomes. *AM J Surg* 2009; 197(5):678-685.

18 Gawande AA, Zinner MJ, Studdert DM, *et al*. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery* 2003; 133(6):614.

19 Lübbeke A, Hovaguimian F, Wickboldt N, *et al*. Effectiveness of the surgical safety checklist in a high standard care environment. *Med Care* 2013; 51(5):425-429.

20 Hales BM, Pronovost PJ. The checklist: a tool for error management and performance improvement. *J Crit Care* 2006; 21(3):231-235.

21 De Vries EN, Prins HA, Crolla RM, *et al*. Effect of a comprehensive surgical safety system on patient outcomes. *N Eng J Med* 2010; 363(20):1928-1937.

22 De Vries EN, Eikens-Jansen MP, Hamersma AM, *et al*. Prevention of surgical malpractice claims by use of a surgical safety checklist. *Ann Surg* 2011; 253(3):624.

23 De Vries EN, Prins HA, Bennink MC, *et al*. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. *BMJ Qual Saf* 2012; 21(6):503-508.

24 DeFontes J, Surbida S. Preoperative safety briefing project. *Perm J* 2004; 8(2):21-27.

25 Nederlandse Vereniging voor Anesthesiologie, Nederlandse Vereniging voor Heelkunde. Richtlijn: Het peroperatieve traject. 2011.
Ref Type: Report

26 VMS Safety Program. Prevention of wrong surgery. 2009.

27 Joint commission. Lessons learned: Wrong site surgery. 28-8-1998.
Ref Type: Report

28 MediRisk. OK-project: Schadecategoriën en vangnetcriteria voor de operatieafdeling. 2007.
Ref Type: Report

29 De Blok C, Koster E, Schilp J, *et al*. Implementatie VMS Veiligheidsprogramma. Evaluatieonderzoek in Nederlandse Ziekenhuizen. (In Dutch). 2013. Utrecht/Amsterdam: NIVEL en EMGO+ Instituut.
Ref Type: Report

30 Twisk JW. Applied multilevel analysis: a practical guide. Cambridge University Press; 2006.

31 Spence J, Goodwin B, Enns C, *et al*. Student-observed surgical safety practices across an urban regional health authority. *BMJ Qual Saf* 2011; 20(7):580-586.

32 Altpeter T, Luckhardt K, Lewis JN, *et al*. Expanded surgical time out: a key to real-time data collection and quality improvement. *J Am Coll Surg* 2007; 204(4):527-532.

33 Borchard A, Schwappach DL, Barbir A, *et al*. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012; 256(6):925-933.

34 Dijkstra R, Wensing M, Thomas R, *et al*. The relationship between organisational characteristics and the effects of clinical guidelines on medical performance in hospitals, a meta-analysis. *BMC Health Serv Res* 2006; 6(1):53.

35 Nevis EC, DiBella AJ, Gould JM. Understanding organizations as learning systems. *Sloan Manage Rev* 1997; 36(2).

36 Zuiderent-Jerak T, Kool T, Rademakers J. De relatie tussen volume en kwaliteit van zorg: tijd voor een brede benadering. 2012.

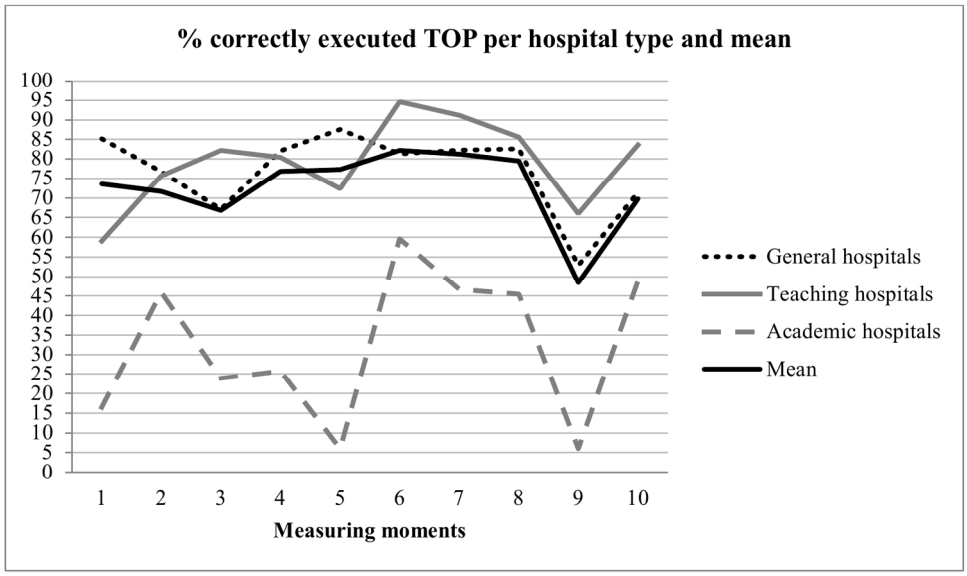
37 Mutter RL, Wong HS, Goldfarb MG. The effects of hospital competition on inpatient quality of care. *Inquiry* 2008; 45(3):263-279.

38 Sari N. Do competition and managed care improve quality? *Health Econ* 2002; 11(7):571-584.

39 Soria-Aledo V, Da Silva ZA, Saturno PJ, *et al*. Difficulties in implementing a surgical check list in operating theatres. *Cir Esp* 2012; 90(3):180.

40 De Vries EN, Hollmann MW, Smorenburg SM, *et al*. Development and validation of the SURgical PAtient Safety System (SURPASS) checklist. *Qual Saf Health Care* 2009; 18(2):121-126.

41 Blanco M, Clarke JR, Martindell D. Wrong site surgery near misses and actual occurrences. *AORN J* 2009; 90(2):215-222.



159x93mm (300 x 300 DPI)

BMJ Open

Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program in the Netherlands

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2014-005075.R1
Article Type:	Research
Date Submitted by the Author:	23-May-2014
Complete List of Authors:	Van Schoten, Steffie; NIVEL, Kop, Veerle; NIVEL, De Blok, Carolien; NIVEL, Spreeuwenberg, Peter; NIVEL, Groenewegen, Peter; Department of Sociology, Department of Human Geography, Utrecht University, Wagner, Cordula; Vrije Universiteit Medical Center (VUmc), Department of Public and Occupational Health & EMGO Institute for Health and Care Research
Primary Subject Heading:	Surgery
Secondary Subject Heading:	Health policy
Keywords:	SURGERY, SOCIAL MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program in the Netherlands

Steffie M. van Schoten MSc [1*], Veerle Kop BSc[1], Carolien de Blok PhD[12], Peter Spreeuwenberg[1], Prof. Peter P. Groenewegen PhD [1,3], Prof. Cordula Wagner PhD[1,4]

[1] NIVEL – Netherlands Institute for Health Services Research, Utrecht, Netherlands

[2] Department Operations, Faculty Economics and Business, University of Groningen, Groningen, Netherlands[3] Department of Sociology, Department of Human Geography, Utrecht University, Utrecht, Netherlands

[4] Department of Public and Occupational Health & EMGO Institute for Health and Care Research, Vrije Universiteit Medical Center (VUmc), Amsterdam, Netherlands

* Corresponding author

NIVEL – Netherlands Institute for Health Services Research.

PO Box 1568, 3500 BN Utrecht, Netherlands

E-Mail address: s.vanschoten@nivel.nl

Tel: +31 30 2729 730

Fax: +31 30 2729 729

Keywords. *patient safety, compliance, time-out procedure, wrong surgery, checklist*

Word count. 3906

Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program in the Netherlands

Abstract *(word count: 244)*

Objective. To prevent wrong surgery, the WHO "Safe Surgery Checklist" was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Design. Evaluation study involving observations.

Setting. Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals.

Participants. A random selection was made from all adult patients scheduled for elective surgery on the day of the observation, preferably involving different surgeons and different procedures.

Results. Mean compliance with the TOP was 71.3%. Large differences between hospitals were observed. No linear trend was found in compliance during the study period. Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.

Conclusions. Large differences in compliance with the TOP were observed between participating hospitals which can be attributed at least in part to the type of hospital, surgical specialty, and patient characteristics. Hospitals do not comply consistently with national

guidelines to prevent wrong surgery and further implementation as well as further research into non-compliance is needed.

Keywords. *patient safety, compliance, time-out procedure, wrong surgery, checklist*

Article Summary

Article focus

- To prevent wrong surgery, the WHO "Safe Surgery Checklist" was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team.
- The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Key message

- Mean compliance with the TOP was 71.3%, large differences between hospitals were observed.
- Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.
- Hospitals do not comply consistently with national guidelines to prevent wrong surgery and further implementation as well as further research into non-compliance is needed.

Strengths and limitations of this study

- Structured observations of compliance with TOP and factors that are associated with compliance at operating rooms (ORs).
- The presence of the observer might have influenced the behavior of the OR staff, a potential selection bias in the surgical procedures on the observation days, no outcome data are available.

Introduction

Ideally, hospitals should be safe environments for their patients. However, making errors is inherent in all humans.[1] The report "To Err is Human" showed that errors cause 44,000 to 98,000 deaths and over one million injuries each year in American hospitals.[1] As a result, patient safety became a major topic on the healthcare agenda.[2-4] Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.[5] An adverse event is unintentional harm caused by healthcare management rather than by the patient's underlying disease that results in a prolonged hospital stay, temporary or permanent disability, or death.[6] In 2004, adverse events occurred in approximately 5.7% of hospital admissions in the Netherlands: approximately 2.3% of the adverse events were potentially preventable.[6] More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.[6] It is therefore important to ensure and improve patient safety during surgery.

Patient safety in surgery has several aspects. One of these aspects is wrong surgery, which can be classified into three groups: surgery at the wrong site, surgery on the wrong patient, and carrying out the wrong procedure.[7] Wrong site surgery occurs whenever a planned surgical procedure is performed at or on the wrong place, part, side or site. Wrong patient surgery refers to a procedure performed on the wrong patient. Wrong procedure surgery refers to a different procedure being performed than the one planned for the patient. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event database ranked wrong site surgery as the second most frequently reported adverse event between 1995 and 2005.[8] In the United States, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5 per 10,000 operations.[3 8-13]

To prevent wrong surgery, the JCAHO guideline "Universal protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" was adopted in 2003 by the Joint

Commission in the United States.[14] Consequently, the World Health Organization (WHO) introduced a checklist in 2008 for worldwide use, called the "Safe Surgery Checklist". In 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated with a significant decrease in postoperative complication (30%) and mortality rates (50%).[15] Based on these results, the WHO estimated that implementing the checklist could save 500,000 lives every year worldwide.[15] Other studies provided evidence supporting the use of surgical checklists as well.[16-19] In the Netherlands, the SURgical PAtient Safety System (SURPASS) was developed with the same intention. It is based on safety checks used in the aviation industry to reduce human error.[20] Research on the external validation of the SURPASS shows a reduction in unintentional harm.[21-23]

Each of the checklists mentioned above comprises a time-out procedure (TOP). Errors can be avoided by including a preoperative discussion just before the start of the surgical procedure. This takes place during a time-out involving a review of the names and roles of all team members, characteristics of the patient, the operation plan, familiarity with the procedure, the presence of the correct materials/equipment, and potential issues for the patient.[24,25] Although evidence is scarce, it is likely that these TOPs reduce uncertainties in the OR among the surgical team and reduce the risk of wrong surgery. The TOP is the final step before the start of the surgical procedure and is therefore crucial in preventing wrong surgery. A TOP is carried out just before anesthesia,[26] and consists of three checks (the patient, the procedure and the side/site), all of equal importance in preventing wrong surgery.

The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the OR, whether compliance has changed over time, and to determine factors that are associated with the TOP compliance. Insights into compliance with the TOP and the factors associated with compliance are important because they have the potential to improve the TOP and reduce adverse events in surgical processes throughout the world. This study was

carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital Patient Safety Program (hereinafter "Safety Program") that was carried out during the final year of the program. (Box 1.).

Box1. The Dutch Hospital Patient Safety Program

The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.[26] The Safety Program consisted of ten patient safety themes and clinical guidelines were developed for each theme. Hospitals were given five years to implement these guidelines. One of the themes was prevention of wrong surgery. There are several risk factors for wrong surgery, e.g. insufficient compliance, inadequate identification and verification and bad preoperative planning.[27 28] The Safety Program therefore instructed the participating Dutch hospitals to implement several steps to decrease wrong surgery, based on the SURPASS checklist. One of the steps is identification and verification by means of a TOP consisting of checks on the correct patient, correct side, and correct intervention.[29]

Based on the goals of the Safety Program, it was expected that the compliance with the TOP would increase over time and would become more visible during the final year of the program when hospitals approached the public deadline at the end of 2012.

The research questions are:

1. *To what extent do Dutch hospitals comply with the time-out procedure before anesthesia in the operating room?*
2. *How has the compliance with the time-out procedure changed during the final year of the Safety Program?*
3. *What factors are associated with compliance with the time-out procedure?*

Methods

Study design

This study was part of a larger evaluation study of the Safety Program that was carried out between November 2011 and December 2012 in eighteen Dutch hospitals (about 20% of all Dutch hospitals). The study protocol was granted approval by the VU University Medical

Center ethical review board in Amsterdam. Hospitals were randomly selected using a stratified sample based on geographical regions and hospital type. Two academic hospitals, four teaching hospitals and twelve general hospitals were included in this study. All hospitals consented to the study and were informed about further practical issues. Twelve observers participated in this study. Inter observer variability was not measured, but limited by training of observers prior to the start of the observations. Moreover, regular feedback meetings were held where observers exchanged experiences and discussed how to deal with certain situations and observations at the OR. A random selection was made on the day of the observation from all adult patients scheduled for elective surgery on the day of the observation. This selection was made by the observers who were instructed to attend as many different surgeries as possible while ensuring they were present in the OR before the start of each surgery, which was essential in order to be able to observe the TOP procedure. The goal was to have ten observation days per hospital at intervals of four to six weeks, and to observe six to ten surgical procedures per day, preferably involving different surgeons and different procedures. One observer per surgical procedure evaluated whether the TOP was carried out before anesthesia, using a standardized recording form that covered the various aspects of doing the TOP: checking the patient, procedure, and side/site, attention of the team (focus), completeness of the team, interruptions, and several background variables such as the type of surgical procedure, the patient's age, and sex. The OR team was not aware of the exact subject matter of the observation; the observer was instructed to introduce the study in abstract terms, referring to it as a study about the surgical process in general.

TOP compliance

The dependent variable was whether the TOP was done correctly and was dichotomous (yes/no). This variable was used to examine mean TOP compliance and the changes in compliance during the study period. A correct TOP consists of three checks: patient,

procedure, and side/site. Since all three checks are equally important for preventing wrong surgery, the TOP was only deemed correct when all three checks were performed. Furthermore, during a TOP the entire OR team gathers around the patient and the surgeon asks the patient his/her name, the type of procedure and the side/site of the procedure.

Four independent variables were included so that any association with compliance could be determined. The type of hospital was categorized into academic, teaching, and general. In the Netherlands, teaching hospitals provide specialized medical care and are committed to training and education. The level of care can be characterized as complex and lies between that of general hospitals and academic centers. Hospital size was operationalized as the number of beds in the hospital (a continuous variable). Surgical specialty was added as a categorical variable with general surgery as the reference category. Focus (yes/no) was included to measure the degree to which the OR team was paying full attention to the TOP and was not performing any other activities during the TOP. In addition, the patient characteristics 'age' and 'sex' were included as covariates. Completeness of the team (yes/no) was added as a explorative analysis. The complete team in this study was seen as the group of persons that performed the surgery on the patient. To be able to perform a TOP correctly, the complete team was present during the TOP. When this was not the case, meaning that one or more persons joint the team after the TOP had been completed, team completeness was scores as 'no'.

Statistical analyses

Descriptive analyses were performed to obtain a picture of the study population, mean TOP compliance, changes in compliance over time, mean compliance for the different hospital types, mean compliance for the different surgical specialties, and the focus and completeness of the team during the TOP.

A multilevel logistic regression analysis with two levels was used to determine whether TOP compliance changed between the ten measuring moments. Multilevel analysis was chosen to correct for the fact that the surgical procedures are not independent from each other, but clustered within hospitals. Time was modeled by adding ten indicator variables for the measurement moments (removing the intercept from the model); trends were tested using polynomial contrasts (to the 4th order) to study changes over time. Variance and intraclass correlations (ICCs) were calculated to assess the clustering of TOP compliance at the hospital and surgical procedure level. An ICC of 20% was seen as moderate.[30] The changes over time were also analyzed for the different hospital types to determine the relationship between hospital type and the changes in TOP compliance. Separate logistic multilevel analyses were performed for each independent variable to analyze the effects of the independent variables 'hospital size' and 'surgical specialty'; this was necessary because not enough units at the highest level (hospitals) were available to have more than one independent variable in a model.[30] There were not enough units at the highest level (hospitals) to model the effect of hospital type on the TOP score in the pooled analyses. Age and sex of the patient were added as covariates in all analyses. All descriptive analyses were performed using SPSS version PASW Statistics 18. The multilevel analyses were performed using MlwiN version 2.24 (using PQL, second order, unconstrained level 1 variance, options).

Results

Descriptive analyses

1281 surgical procedures were observed at the participating hospitals. After patients younger than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96. The gender distribution was 41.4% male, 53.8% female, and 4.8% not registered. The range in types of surgical procedures was broad; observers had been instructed to observe different

procedures and observed surgical procedures of in total 13 different specialties. Mean compliance with the TOP during the total study period was 71.3%. Descriptive analyses showed that TOP compliance did not improve during the study period. There was a large spread between hospitals: one of the hospitals never performed the TOP correctly and two had mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at the ninth measuring moment for all the participating hospitals. The academic hospitals had a mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%. Differences between specialties were shown to exist: trauma, gastroenterology and hepatology, and Ear, Nose and Throat medicine (ENT) had the highest compliance rates. Anesthesiology, cardiothoracic surgery, and cosmetic surgery had the lowest compliance rates. In 44% of the observations the team was not focused on the TOP and in 56%, the team was incomplete.

Multilevel regression analyses

In the first multilevel regression analysis, the changes in TOP compliance were tested. The effect was statistically significant for the fourth-order polynomial ($p < 0.01$), meaning that TOP compliance was not linear but fluctuated over time and no clear trend was observed. Furthermore, there were large differences between the measuring moments and between individual hospitals. See Figure 1. The multilevel analysis shows that 44% (ICC = 44.01) of the total variance in TOP compliance can be attributed to the differences between the individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11 (40%). See Table 1.

When correcting for age and sex of the patient, the ICC dropped to 26% (ICC = 26.58). The relationship between the age of the patient and the TOP was found to be significant ($p < 0.05$). This relationship was tested and found to be linear. Based on the results

described above, there was no rationale to correct for time (measurement moments) in further analyses. Observations from the different measurement moments were pooled in the remaining analyses.

Separate analyses were performed for the independent variables 'hospital size', 'surgical specialty', and 'focus'. No statistically significant relationship was found between hospital size and TOP compliance (data not shown in tables). A positive relationship was found between patients undergoing ENT surgery and the TOP (reference = general surgery; $p < 0.01$). Another positive relationship was found between patients undergoing ophthalmic surgery and the TOP (reference = general surgery; $p < 0.05$). See Table 2. This indicates that TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic surgery compared to patients undergoing general surgery. The relationship between the age of the patient and TOP compliance was found to be significant ($p < 0.05$) in all analyses. This indicates that TOP compliance decreases with the patient age. The TOP is performed correctly less often for older patients. An additional analysis was performed based on these results to determine which of the three individual checks of the TOP attributed most to the negative relationship between the age of the patient and TOP compliance. Table 3 shows the results of the additional analysis. The check procedure contributes most to the negative relationship between age of the patient and TOP compliance, this check is more often skipped when an older patient is involved. The relationship between the focus of the team during the TOP and the correct execution of the TOP is shown in Table 4. There is a positive significant relationship between focus and TOP compliance, which indicates that the TOP is more often correctly executed when the entire team is focused on the TOP and not performing any other activities at the same time.

Discussion

The objective of this study was to investigate the compliance at Dutch hospitals with the national guidelines of a TOP set by the Safety Program and how this changed over the final year of the program. Furthermore, we studied variables that might be associated with compliance. This study found a mean TOP compliance of 71.3%. There was no linear trend in the TOP compliance during the study period. Large differences were found between and within individual hospitals, which were partly influenced by age of the patient. The type of hospital was associated with the TOP compliance: academic hospitals had lower compliance rates than general and teaching hospitals. Given the low number of academic hospitals in this study (N=2), these findings cannot be generalized to academic hospitals as a whole. ENT medicine and ophthalmological surgery had higher TOP compliance than the reference group (general surgery). No statistically significant relationship between TOP compliance and hospital size was found. The TOP was correctly performed more often when the OR team was focused on it. The negative relationship between age of the patient and the TOP indicates that greater patient age is associated with lower TOP compliance. Of all the observed TOPs, 44% were performed without the focus of the entire team, and the team was not complete in 56% of the TOPs.

A wide range in compliance rates for surgical checklists can be found in previous studies, ranging from 12% to 99% with a mean of 75%.[31-33] The compliance rate (71.3%) found in our study is slightly lower than the mean rate found in other studies.

We found a difference in TOP compliance between the different types of hospitals. The general and teaching hospitals hardly differed from each other, which is interesting because a previous study [34] found teaching hospitals to be better at implementing checklists than general hospitals. According to the organizational learning theory, the availability of knowledge in an organization contributes to the adoption of innovations.[34 35] Teaching hospitals are learning environments, aimed at spreading and developing knowledge; better compliance can therefore

be expected in teaching hospitals. We found that academic hospitals showed lower TOP compliance.

The literature is inconsistent about the influence of hospital size on the use of checklists. Some argue that larger hospitals are better developed and use standardized processes, which increases the quality of the hospital more often,[36-38] whereas others conclude that smaller hospitals implement checklists better.[39] We found no relationship between TOP compliance and hospital size. The high ICC rates found in this study suggest that the differences between individual hospitals are high, and differences in compliance cannot be explained by general hospital characteristics such as hospital size. The differences between individual hospitals need to be examined in further research, but possible explanations might be found in different organizational structures, the creation of awareness amongst healthcare staff and differences in speaking-up cultures between hospitals.

The relationship found between surgical specialties and the TOP is different from the results of previous studies. One study showed a difference between surgeons and anesthesiologists[40] and another study showed no difference between surgical specialties at all.[41] The TOP is a standardized procedure, and the way in which it should be carried out does not depend on the surgical specialty performing the procedure or the patient characteristics. Compliance with the TOP varied between different specialties and was lowest among general surgery teams. One explanation for these differences could be that not all medical disciplines and their scientific communities have placed the same amount of weight on a thorough implementation of the Safety Program. If so, this could have had an influence on the sense of urgency experienced by different specialties to comply with TOP in their daily functioning. Further research that includes specialty-specific factors is needed to verify and deepen our findings. The negative relationship between TOP compliance and the age of the patient was an unexpected result, since the TOP should be executed in the same way for all patients. In

particular, the exact surgical procedure that would be carried out was less often verified with elderly patients. Explanations might be found in factors inherently associated with the elderly patient themselves. For example, elderly patients might be less able to verbally express themselves to healthcare staff. On the other hand, explanations might be found in factors that are associated with the medical procedure itself. For example, the level of standardization of procedures that are commonly performed in the elderly population (such as hip- replacement surgery or cataract surgery) is relatively high and it is unclear what effect this has on compliance with TOP. Elderly people are a vulnerable group with a higher risk of complications after surgery, therefore further in-depth research is important to explain the differences in compliance for different age groups.

Completeness and focus are important factors in the TOP and performing it when team members are busy with other activities creates a risk. Our study showed that focus in the team contributes to the TOP being performed correctly. However, there was poor focus on the TOP in almost half of the surgical procedures observed. Several possible causes could be underlying to poor focus during the TOP, which was observed frequently in our study. Firstly, there could have been a lack of awareness of the importance of the TOP amongst healthcare staff. Regular emphasis on the importance of the TOP during team meetings or during the joint briefing at the start of a new working day could help raise awareness. Secondly, when surgery schedules are tight, healthcare staff might experience time pressure. In trying to keep up with the schedule and being efficient, healthcare staff might be tempted to perform multiple tasks simultaneously which in turn could negatively affect compliance with TOP.

Based on these results, it seems that hospitals still have a lot to gain by carrying out the TOP properly. Qualitative research methods could provide insight into the underlying reasons and incentives of why healthcare staff perform the TOP in the way they currently do.

This type of research could complement and deepen the findings that were presented in the current study.

Strengths and limitations

Our study was the first to evaluate TOP compliance over time through observations in the OR and look at the factors associated with compliance. Our dependent variable was a process indicator, because the incidence of wrong surgery is too low to be observed with our study design. Based on the literature, it seems fair to assume that higher TOP compliance can contribute to a decrease in the incidence of wrong surgery,[15] although this study gives no information about the actual number of wrong surgeries and TOP compliance might not be the only factor in the reduction of wrong surgery.

This study has several limitations. Firstly, the presence of the observer might have influenced the behavior of the OR staff and indirectly of our dependent variable TOP. However, the design of our study aimed to prevent this potential observer bias, because the precise goal of the observations was not known to the OR team. Secondly, a potential selection bias can be found in the selection of surgical procedures on the observation days. Surgical procedures were selected based on practical considerations: the day of the week, the duration of the procedure, and the OR schedule. The relationships found between different specialisms might be partially overestimated, because the same surgical teams were sometimes observed on the same day or on different observation days. However, the overall goal was to observe as may different surgical procedures with different teams as possible, in order to limit potential selection bias. Thirdly, there is no information available about the changes in compliance during the first period of the Safety Program, and hospitals may have made progress during this period.

Conclusions

The mean TOP compliance was 71.3% during the final year of the Safety Program and no improvement in compliance over time was found. Large differences were found between hospitals, and these differences were influenced by age of the patient. Compliance was influenced by several factors: hospital type, surgical specialty, age of the patient and focus of the team during the TOP. Furthermore, in almost half the TOPs, the team was not focused on the TOP or the team was incomplete. Despite the fact that almost three quarter of operations are preceded by a TOP, hospitals need to make an effort to improve TOP compliance and the way in which the TOP is carried out in order to prevent wrong surgery from happening in the future.

Figure legend

Figure 1. Trend in the time-out procedure compliance per hospital type, and overall mean (n=1232)

Tables

Table 1. Trend in the time-out procedure per hospital type (n=1232; 18 hospitals)

	Trend overall			Trend per hospital type								
				General hospitals			Teaching hospitals			Academic hospitals		
Fixed effects	N	Mean %	95% CI	N	Mean %	95% CI	N	Mean %	95% CI	N	Mean %	95% CI
TOP (constant)												
MM 1	121	73.52	53.20-87.14	85	85.18	2.00-94.35	25	59.00	21.26-88.46	11	16.48	0.91-80.91
MM 2	137	71.64	51.26-85.85	91	76.73	54.48-90.09	33	75.65	36.60-94.36	13	45.91	2.90-96.02
MM 3	134	66.79	45.78-82,73	87	67.09	42.94-84.66	33	82.19	44.85-96.32	14	23.86	1.55-86.19
MM 4	118	76.77	57.01-89.17	75	82.01	60.92-93.02	27	80.40	41.08-96.02	16	25.73	1.76-87.03
MM 5	125	77.26	57.99-89.32	85	87.56	70.27-95.44	30	72.30	32.65-93.36	10	5.97	0.29-57.90
MM 6	127	82.18	64.73-92.05	85	81.27	60.55-92.46	27	94.63	65.68-99.39	15	59.61	5.32-97.48
MM 7	114	81.20	62.89-91.67	78	82.23	61.44-93.07	26	91.13	57.87-98.72	10	46.67	2.40-96.89
MM 8	112	79.41	60.46-90.68	82	82.59	62.33-93.16	22	85.56	46.93-97.54	8	45.42	1.80-97.43
MM 9	129	48.44	28.65-68.74	89	52.86	29.81-74.75	25	66.00	26.36-91.33	15	6.00	0.40-50.29
MM 10	115	69.68	48.46-84.88	85	71.32	47.57-87.20	21	83.56	43.24-97.13	9	48.84	2.39-97.38
Random effects Variance components:												
ICC	44.056			40.106								
hospital (level 2)	2.591 (0.916) *			2.203 (0.798) *								
surgical procedure (level 1)	0.988 (0.040)			0.984 (0.040)								

MM = Measurement moment, TOP = Time-out procedure, 95% CI = 95% confidence interval, ICC = Intraclass correlation

*p<0.05

Raw data for the remaining variables (specialty, focus and individual checks) is available with the author upon request.

Table 2. Relationship between surgical specialties (n=1130; 18 hospitals) and compliance with the time-out procedure.

	Model 0 (time-out procedure + age + sex)	**Model 1 (model 0 + specialties)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties - General surgery	-	*Reference*
Specialties - Gynecology	-	0.050 (0.264)
Specialties – ENT	-	0.905 (0.316) *
Specialties - Ophthalmology	-	0.616 (0.302) *
Specialties – Orthopedic surgery	-	0.163 (0.241)
Specialties – Urology	-	0.084 (0.287)
Specialties – other	-	0.046 (0.279)
Patient age	-0.011 (0.004) *	-0.011 (0.004) *
Patient sex	0.064 (0.153)	0.074 (0.155)
Random effects		
Variance components:		
Intraclass correlation	25.331	25.499
hospital (level 2)	1.116 (0.422) *	1.126 (0.426) *
surgical procedure (level 1)	0.996 (0.042)	1.006 (0.043)

*p<0.05

Table 3. Age effects for the three different checks in the time-out procedure: checking the patient (n=1074), the procedure (n=1074), and the side/site (n=1074)

	Model 0 (check patient + age + sex)	**Model 1 (check procedure + age + sex)**	**Model 2 (check side/site + age + sex)**
Fixed effects	Estimate (SE)	Estimate (SE)	Estimate (SE)
Check patient (constant)	3.499 (0.334)	-	-
Check procedure (constant)	-	2.276 (0.282)	-
Check side/site (constant)	-	-	2.739 (0.204)
Patient's age	0.008 (0.008)	-0.021 (0.006)*	0.012 (0.007)*
Patient's sex	-0.185 (0.288)	0.124 (0.198)	0.160 (0.246)
Random effects			
Variance components:			
Intraclass correlation	27.172	24.990	10.854
hospital (level 2)	1.228 (0.623) *	1.096 (0.464) *	0.401 (0.236) *
surgical procedure (level 1)	0.834 (0.036)	0.922 (0.040)	0.950 (0.041)

*p<0.05

Table 4. Relationship between focus (n=1074; 18 hospitals) during the time-out procedure and compliance with the time-out procedure.

	Model 0 (time-out procedure + age + sex)	**Model 1 (model 0 + focus)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time-out procedure (constant)	1.540 (0.163)	1.471 (0.156)
Focus	-	0.567 (0.171)*
Patient's age	-0.006 (0.005)	-0.005 (0.005)
Patient's sex	-0.012 (0.162)	-0.016 (0.163)
Random effects		
Variance components:		
Intraclass correlation	8.971	7.991
hospital (level 2)	0.324 (0.154) *	0.286 (0.140) *
surgical procedure (level 1)	0.968 (0.042)	0.966 (0.042)

*p<0.05

Acknowledgements

We wish to thank the participating hospitals, their contact persons and employees who participated in our study.

Competing interests

The authors declare that they have no competing interests.

Contributions

SS and VK did the statistical analyses, interpreted the results of the analyses and drafted the manuscript. SS took part in the data collection. CB was involved in the design of the study, organized the data collection and critically revised the manuscript. PS did the statistical analyses and reviewed the parts of the manuscript that involved the statistical analyses. PG was involved in the design of the study, advised on the statistical analyses and critically revised the manuscript. CW was involved in the design of the study and critically revised the manuscript. All authors meet the criteria for authorship, were involved in revising and approving the final manuscript and accept responsibility for the data presented.

Funding

This research was funded by the Ministry of Education, Culture and Science in the Netherlands.

Data sharing statement

No additional data are available.

Reference List

1 Kohn LT, Corrigan J, Donaldson MS. To err is human: building a safer health system. 6 ed. Joseph Henry Press; 2000.

2 See LC, Chang YH, Chuang KL, *et al*. Animation program used to encourage patients or family members to take an active role for eliminating wrong-site, wrong-person, wrong-procedure surgeries: Preliminary evaluation. *Int J Surg* 2011; 9(3):241-247.

3 Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? *Arch Surg* 2006; 141(9):931.

4 Zhan C, Kelley E, Yang HP, *et al*. Assessing patient safety in the United States: challenges and opportunities. *Med Care* 2005; 43(3):I-42.

5 WHO. Patient Safety. 2013.
Ref Type: Online Source

6 Zegers M, De Bruijne MC, Wagner C, *et al*. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care* 2009; 18(4):297-302.

7 Gibbs VC. Thinking in three's: Changing surgical patient safety practices in the complex modern operating room. *World J Gastroenterol* 2012; 18(46):6712.

8 DeVine J, Chutkan N, Norvell DC, *et al*. Avoiding wrong site surgery: a systematic review. *Spine* 2010; 35(9S):S28.

9 Ammerman JM, Ammerman MD, Dambrosia J, *et al*. A prospective evaluation of the role for intraoperative x-ray in lumbar discectomy. Predictors of incorrect level exposure. *Surg Neurol* 2006; 66(5):470-473.

10 Kwaan MR, Studdert DM, Zinner MJ, *et al*. Incidence, patterns, and prevention of wrong-site surgery. *Arch Surg* 2006; 141(4):353.

11 Jhawar BS, Mitsis D, Duggal N. Wrong-sided and wrong-level neurosurgery: a national survey. 2007.

12 Mody MG, Nourbakhsh A, Stahl DL, *et al*. The prevalence of wrong level surgery among spine surgeons. *Spine* 2008; 33(2):194.

13 Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007; 246(3):395.

14 Angle JF, Nemcek AA, Jr., Cohen AM, *et al*. Quality improvement guidelines for preventing wrong site, wrong procedure, and wrong person errors: application of the joint commission "universal protocol for preventing wrong site, wrong procedure, wrong person surgery" to the practice of interventional radiology. *J Vasc Interv Radiol* 2009; 20(7 Suppl):S256-S262.

15 World Health Organization. New scientific evidence supports WHO findings: a surgical safety checklist could save hundreds of thousands of lives. 2011. 2011.
Ref Type: Generic

16 Haynes AB, Weiser TG, Berry WR, *et al*. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Eng J Med* 2009; 360(5):491-499.

17 Mazzocco K, Petitti DB, Fong KT, *et al*. Surgical team behaviors and patient outcomes. *AM J Surg* 2009; 197(5):678-685.

18 Gawande AA, Zinner MJ, Studdert DM, *et al*. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery* 2003; 133(6):614.

19 Lübbeke A, Hovaguimian F, Wickboldt N, *et al*. Effectiveness of the surgical safety checklist in a high standard care environment. *Med Care* 2013; 51(5):425-429.

20 Hales BM, Pronovost PJ. The checklist: a tool for error management and performance improvement. *J Crit Care* 2006; 21(3):231-235.

21 De Vries EN, Prins HA, Crolla RM, *et al*. Effect of a comprehensive surgical safety system on patient outcomes. *N Eng J Med* 2010; 363(20):1928-1937.

22 De Vries EN, Eikens-Jansen MP, Hamersma AM, *et al*. Prevention of surgical malpractice claims by use of a surgical safety checklist. *Ann Surg* 2011; 253(3):624.

23 De Vries EN, Prins HA, Bennink MC, *et al*. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. *BMJ Qual Saf* 2012; 21(6):503-508.

24 DeFontes J, Surbida S. Preoperative safety briefing project. *Perm J* 2004; 8(2):21-27.

25 Nederlandse Vereniging voor Anesthesiologie, Nederlandse Vereniging voor Heelkunde. Richtlijn: Het peroperatieve traject. 2011.
Ref Type: Report

26 VMS Safety Program. Prevention of wrong surgery. 2009.

27 Joint commission. Lessons learned: Wrong site surgery. 28-8-1998.
Ref Type: Report

28 MediRisk. OK-project: Schadecategoriën en vangnetcriteria voor de operatieafdeling. 2007.
Ref Type: Report

29 De Blok C, Koster E, Schilp J, *et al*. Implementatie VMS Veiligheidsprogramma. Evaluatieonderzoek in Nederlandse Ziekenhuizen. (In Dutch). 2013. Utrecht/Amsterdam: NIVEL en EMGO+ Instituut.
Ref Type: Report

30 Twisk JW. Applied multilevel analysis: a practical guide. Cambridge University Press; 2006.

31 Spence J, Goodwin B, Enns C, *et al*. Student-observed surgical safety practices across an urban regional health authority. *BMJ Qual Saf* 2011; 20(7):580-586.

32 Altpeter T, Luckhardt K, Lewis JN, *et al*. Expanded surgical time out: a key to real-time data collection and quality improvement. *J Am Coll Surg* 2007; 204(4):527-532.

33 Borchard A, Schwappach DL, Barbir A, *et al*. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012; 256(6):925-933.

34 Dijkstra R, Wensing M, Thomas R, *et al*. The relationship between organisational characteristics and the effects of clinical guidelines on medical performance in hospitals, a meta-analysis. *BMC Health Serv Res* 2006; 6(1):53.

35 Nevis EC, DiBella AJ, Gould JM. Understanding organizations as learning systems. *Sloan Manage Rev* 1997; 36(2).

36 Zuiderent-Jerak T, Kool T, Rademakers J. De relatie tussen volume en kwaliteit van zorg: tijd voor een brede benadering. 2012.

37 Mutter RL, Wong HS, Goldfarb MG. The effects of hospital competition on inpatient quality of care. *Inquiry* 2008; 45(3):263-279.

38 Sari N. Do competition and managed care improve quality? *Health Econ* 2002; 11(7):571-584.

39 Soria-Aledo V, Da Silva ZA, Saturno PJ, *et al*. Difficulties in implementing a surgical check list in operating theatres. *Cir Esp* 2012; 90(3):180.

40 De Vries EN, Hollmann MW, Smorenburg SM, *et al*. Development and validation of the SURgical PAtient Safety System (SURPASS) checklist. *Qual Saf Health Care* 2009; 18(2):121-126.

41 Blanco M, Clarke JR, Martindell D. Wrong site surgery near misses and actual occurrences. *AORN J* 2009; 90(2):215-222.

Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program

Steffie M. van Schoten MSc [1*], Veerle Kop BSc[1], Carolien de Blok PhD[12], Peter Spreeuwenberg[1], Prof. Peter P. Groenewegen PhD [1,32], Prof. Cordula Wagner PhD[1,43]

[1] NIVEL – Netherlands Institute for Health Services Research, Utrecht, Netherlands

[2] Department Operations, Faculty Economics and Business, University of Groningen, Groningen, Netherlands

[23] Department of Sociology, Department of Human Geography, Utrecht University, Utrecht, Netherlands

[34] Department of Public and Occupational Health & EMGO Institute for Health and Care Research, Vrije Universiteit Medical Center (VUmc), Amsterdam, Netherlands

* Corresponding author

NIVEL – Netherlands Institute for Health Services Research.

PO Box 1568, 3500 BN Utrecht, Netherlands

E-Mail address: s.vanschoten@nivel.nl

Tel: +31 30 2729 730

Fax: +31 30 2729 729

Keywords. *patient safety, compliance, time-out procedure, wrong surgery, checklist*

Word count. ~~3410~~3906

Formatted: Font: Times New Roman, 12 pt, Not Italic

Formatted: Comment Text

Formatted: German (Germany)

Field Code Changed

Formatted: English (U.S.)

Formatted: English (U.S.)

Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in Hospitals: Results of a National Patient Safety Program

Abstract *(word count: 244)*

Objective. To prevent wrong surgery, the WHO "Safe Surgery Checklist" was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Design. Evaluation study involving observations.

Setting. Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals.

Participants. A random selection was made from all adult patients scheduled for elective surgery on the day of the observation, preferably involving different surgeons and different procedures.

Results. Mean compliance with the TOP was 71.3%. Large differences between hospitals were observed. No linear trend was found in compliance during the study period. Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.

Conclusions. Large differences in compliance with the TOP were observed between participating hospitals which can be attributed at least in part to the type of hospital, surgical specialty, and patient characteristics. Hospitals do not comply consistently with national

guidelines to prevent wrong surgery and further implementation as well as further research into non-compliance is needed.

K**eywords.** *patient safety, compliance, time-out procedure, wrong surgery, checklist*

Article Summary

Article focus

- To prevent wrong surgery, the WHO "Safe Surgery Checklist" was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team.
- The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Key message

- Mean compliance with the TOP was 71.3%, large differences between hospitals were observed.
- Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.
- Hospitals do not comply consistently with national guidelines to prevent wrong surgery and further implementation as well as further research into non-compliance is needed.

Strengths and limitations of this study

- Structured observations of compliance with TOP ~~at operating rooms (OR)OR~~ and factors that are associated with compliance at operating rooms (ORs).
- The presence of the observer might have influenced the behavior of the OR staff, a potential selection bias in the surgical procedures on the observation days, no outcome data are available.

Introduction

Ideally, hospitals should be safe environments for their patients. However, making errors is inherent in all humans.[1] The report "To Err is Human" showed that errors cause 44,000 to 98,000 deaths and over one million injuries each year in American hospitals.[1] As a result, patient safety became a major topic on the healthcare agenda.[2-4] Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.[5] An adverse event is unintentional harm caused by healthcare management rather than by the patient's underlying disease that results in a prolonged hospital stay, temporary or permanent disability, or death.[6] In 2004, adverse events occurred in approximately 5.7% of hospital admissions in the Netherlands: approximately 2.3% of the adverse events were potentially preventable.[6] More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.[6] It is therefore important to ensure and improve patient safety during surgery.

Patient safety in surgery has several aspects. One of these aspects is wrong surgery, which can be classified into three groups: surgery at the wrong site, surgery on the wrong patient, and carrying out the wrong procedure.[7] Wrong site surgery occurs whenever a planned surgical procedure is performed at or on the wrong place, part, side or site. Wrong patient surgery refers to a procedure performed on the wrong patient. Wrong procedure surgery refers to a different procedure being performed than the one planned for the patient. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event database ranked wrong site surgery as the second most frequently reported adverse event between 1995 and 2005.[8] In the United States, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5 per 10,000 operations.[3 8-13]

To prevent wrong surgery, the JCAHO guideline "Universal protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery" was adopted in 2003 by the Joint

Commission in the United States.[14] Consequently, the World Health Organization (WHO) introduced a checklist in 2008 for worldwide use, called the "Safe Surgery Checklist". In 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated with a significant decrease in postoperative complication (30%) and mortality rates (50%).[15] Based on these results, the WHO estimated that implementing the checklist could save 500,000 lives every year worldwide.[15] Other studies provided evidence supporting the use of surgical checklists as well.[16-19] In the Netherlands, the SURgical PAtient Safety System (SURPASS) was developed with the same intention. It is based on safety checks used in the aviation industry to reduce human error.[20] Research on the external validation of the SURPASS shows a reduction in unintentional harm.[21-23]

Each of the checklists mentioned above comprises a time-out procedure (TOP). Errors can be avoided by including a preoperative discussion just before the start of the surgical procedure. This takes place during a time-out involving a review of the names and roles of all team members, characteristics of the patient, the operation plan, familiarity with the procedure, the presence of the correct materials/equipment, and potential issues for the patient.[24,25] Although evidence is scarce, ~~I~~it is likely that these TOPs reduce uncertainties in the OR among the surgical team and reduce the risk of wrong surgery. The TOP is the final step before the start of the surgical procedure and is therefore crucial in preventing wrong surgery. A TOP is carried out just before anesthesia,[26] and consists of three checks (the patient, the procedure and the side/site), all of equal importance in preventing wrong surgery.

The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the OR, whether compliance has changed over time, and to determine factors that are associated with the TOP compliance. Insights into compliance with the TOP and the factors associated with compliance are important because they have the potential to improve the TOP and reduce adverse events in surgical processes throughout the world. This study was

carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital Patient Safety Program (hereinafter "Safety Program") that was carried out during the final year of the program. (Box 1.).

Box1. The Dutch Hospital Patient Safety Program

The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.[26] The Safety Program consisted of ten patient safety themes and clinical guidelines were developed for each theme. Hospitals were given five years to implement these guidelines. One of the themes was prevention of wrong surgery. There are several risk factors for wrong surgery, e.g. insufficient compliance, inadequate identification and verification and bad preoperative planning.[27 28] The Safety Program therefore instructed the participating Dutch hospitals to implement several steps to decrease wrong surgery, based on the SURPASS checklist. One of the steps is identification and verification by means of a TOP consisting of checks on the correct patient, correct side, and correct intervention.[29]

Based on the goals of the Safety Program, it was expected that the compliance with the TOP would increase~~d~~ over time and would bec~~o~~me more visible during the final year of the program when hospitals approached the public deadline at the end of 2012.

The research questions are:

1. *To what extent do Dutch hospitals comply with the time-out procedure before anesthesia in the operating room?*
2. *How has the compliance with the time-out procedure changed during the final year of the Safety Program?*
3. *What factors are associated with compliance with the time-out procedure?*

Methods

Study design

This study was part of a larger evaluation study of the Safety Program that was carried out between November 2011 and December 2012 in eighteen Dutch hospitals (about 20% of all Dutch hospitals). The study protocol was granted approval by the VU University Medical

Center ethical review board in Amsterdam. Hospitals were randomly selected using a stratified sample based on geographical regions and hospital type. Two academic hospitals, four teaching hospitals and twelve general hospitals were included in this study. All hospitals consented to the study and were informed about further practical issues. Twelve observers participated in this study. To limit inter observer variability, all observers were trained prior to the start of the observations. Moreover, ~~and~~ regular feedback meetings were held where observers exchanged experiences and discussed how to deal with certain situations and observations at the OR. A random selection was made on the day of the observation from all adult patients scheduled for elective surgery on the day of the observation. The goal was to have ten observation days per hospital at intervals of four to six weeks, and to observe six to ten surgical procedures per day, preferably involving different surgeons and different procedures. One observer per surgical procedure evaluated whether the TOP was carried out before anesthesia, using a standardized recording form that covered the various aspects of doing the TOP: checking the patient, procedure, and side/site, attention of the team (focus), completeness of the team, interruptions, and several background variables such as the type of surgical procedure, the patient's age, and sex. The OR team was not aware of the exact subject matter of the observation; the observer was instructed to introduce the study in abstract terms, referring to it as a study about the surgical process in general.

TOP compliance

The dependent variable was whether the TOP was done correctly and was dichotomous (yes/no). This variable was used to examine mean TOP compliance and the changes in compliance during the study period. A correct TOP consists of three checks: patient, procedure, and side/site. Since all three checks are equally important for preventing wrong surgery, the TOP was only deemed correct when all three checks were performed. ~~The~~ Furthermore, during a TOP the entire OR team gathers around the patient ~~during a TOP~~ and

the surgeon asks the patient his/her name, the type of procedure and the side/site of the procedure.

Four independent variables were included so that any ~~relationship~~ association with compliance could be determined. The type of hospital was categorized into academic, teaching, and general. In the Netherlands, teaching hospitals provide specialized medical care and are committed to training and education. The level of care can be characterized as complex and lies between that of general hospitals and academic centers. Hospital size was operationalized as the number of beds in the hospital (a continuous variable). Surgical specialty was added as a categorical variable with general surgery as the reference category. Focus (yes/no) was included to measure the degree to which the OR team was paying full attention to the TOP and was not performing any other activities during the TOP. In addition, the patient characteristics 'age' and 'sex' were included as covariates. Completeness of the team (yes/no) was added as a explorative analysis. The complete team in this study was seen as the group of persons that performed the surgery on the patient. To be able to perform a TOP correctly, the complete team was present during the TOP. When this was not the case, ~~and~~meaning that one or more persons joint the team after the TOP had been completed, team completeness was scores as 'no'.

Formatted: Indent: First line: 0.49"
Formatted: Font: 12 pt, English (U.S.)
Formatted: Font: 12 pt, English (U.S.)
Formatted: Font: 12 pt
Formatted: Font: 12 pt, English (U.S.)
Formatted: Font: 12 pt
Formatted: Font: 12 pt, English (U.S.)
Formatted: Font: 12 pt, English (U.S.)
Formatted: Font: 12 pt

Statistical analyses

Descriptive analyses were performed to obtain a picture of the study population, mean TOP compliance, changes in compliance over time, mean compliance for the different hospital types, mean compliance for the different surgical specialties, and the focus and completeness of the team during the TOP.

A multilevel logistic regression analysis with two levels was used to determine whether TOP compliance changed between the ten measuring moments. Multilevel analysis

was chosen to correct for the fact that the surgical procedures are not independent from each other, but clustered within hospitals. Time was modeled by adding ten indicator variables for the ~~time points~~measurement moments (removing the intercept from the model); trends were tested using polynomial contrasts (to the 4th order) to study changes over time. Variance and intraclass correlations (ICCs) were calculated to assess the clustering of TOP compliance at the hospital and surgical procedure level. An ICC of 20% was seen as moderate.[30] The changes over time were also analyzed for the different hospital types to determine the relationship between hospital type and the changes in TOP compliance. Separate logistic multilevel analyses were performed for each independent variable to analyze the effects of the independent variables 'hospital size' and 'surgical specialty'; this was necessary because not enough units at the highest level (hospitals) were available to have more than one independent variable in a model.[30] There were not enough units at the highest level (hospitals) to model the effect of hospital type on the TOP score in the pooled analyses. Age and sex of the patient were added as covariates in all analyses. All descriptive analyses were performed using SPSS version PASW Statistics 18. The multilevel analyses were performed using MlwiN version 2.24 (using PQL, second order, unconstrained level 1 variance, options).

Formatted: Font: 12 pt, English (U.S.)

Formatted: English (U.S.)

Results

Descriptive analyses

1281 surgical procedures were observed at the participating hospitals. After patients younger than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96. The gender distribution was 41.4% male, 53.8% female, and 4.8% not registered~~unknown~~. The range in types of surgical procedures was broad; observers had been instructed to observe different procedures and observed surgical procedures of in total 13 different specialties. Mean compliance with the TOP during the total study period was 71.3%. Descriptive analyses

showed that TOP compliance did not improve during the study period. There was a large spread between hospitals: one of the hospitals never performed the TOP correctly and two had mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at the ninth measuring moment for all the participating hospitals. The academic hospitals had a mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%. Differences between specialties were shown to exist: trauma, gastroenterology and hepatology, and Ear, Nose and Throat medicine (ENT) had the highest compliance rates. Anesthesiology, cardiothoracic surgery, and cosmetic surgery had the lowest compliance rates. In 44% of the observations the team was not focused on the TOP and in 56%, the team was incomplete.

Multilevel regression analyses

In the first multilevel regression analysis, the changes in TOP compliance were tested. The effect was statistically significant for the fourth-order polynomial ($p < 0.01$), meaning that TOP compliance was not linear but fluctuated over time and no clear trend was observed. Furthermore, there were large differences between the measuring moments and between individual hospitals. See Figure 1. The multilevel analysis shows that 44% (ICC = 44.01) of the total variance in TOP compliance can be attributed to the differences between the individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11 (40%). See Table 1.

When correcting for age and sex of the patient, the ICC dropped to 26% (ICC = 26.58). The relationship between the age of the patient and the TOP was found to be significant ($p < 0.05$). This relationship was tested and found to be linear. Based on the results described above, there was no rationale to correct for time (measurement momentspoints) in

further analyses. Observations from the different measurement ~~points~~ moments were pooled in the remaining analyses.

Separate analyses were performed for the independent variables 'hospital size', 'surgical specialty', and 'focus'. No statistically significant relationship was found between hospital size and TOP compliance (data not shown in tables). A positive relationship was found between patients undergoing ENT surgery and the TOP (reference = general surgery; $p < 0.01$). Another positive relationship was found between patients undergoing ophthalmic surgery and the TOP (reference = general surgery; $p < 0.05$). See Table 2. This indicates that TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic surgery compared to patients undergoing general surgery. The relationship between the age of the patient and TOP compliance was found to be significant ($p < 0.05$) in all analyses. This indicates that TOP compliance decreases with the patient age. ~~in all analyses.~~ The TOP is performed correctly less often for older patients. An additional analysis was performed based on these results to determine which of the three individual checks of the TOP attributed most to the negative relationship between the age of the patient and TOP compliance. Table 3 shows the results of the additional analysis. The check procedure contributes most to the negative relationship between age of the patient and TOP compliance, this check is more often skipped when an older patient is involved. The relationship between the focus of the team during the TOP and the correct execution of the TOP is shown in Table 4. There is a positive significant relationship between focus and TOP compliance, which indicates that the TOP is more often correctly executed when the entire team is focused on the TOP and not performing any other activities at the same time.

Discussion

The objective of this study was to investigate the compliance at Dutch hospitals with the national guidelines of a TOP set by the Safety Program and how this changed over the final year of the program. Furthermore, we studied variables that might be associated with compliance. This study found a mean TOP compliance of 71.3%. There was no linear trend in the TOP compliance during the study period. Large differences were found between and within individual hospitals, which were partly influenced by age of the patient. The type of hospital was associated with the TOP compliance: academic hospitals had lower compliance rates than general and teaching hospitals. Given the low number of academic hospitals in this study (N=2), these findings cannot be generalized to academic hospitals as a whole. ENT medicine and ophthalmological surgery had higher TOP compliance than the reference group (general surgery). No statistically significant relationship between TOP compliance and hospital size was found. The TOP was correctly performed more often when the OR team was focused on it. The negative relationship between age of the patient and the TOP indicates that greater patient age is associated with lower TOP compliance. Of all the observed TOPs, 44% were performed without the focus of the entire team, and the team was not complete in 56% of the TOPs.

A wide range in compliance rates for surgical checklists can be found in previous studies, ranging from 12% to 99% with a mean of 75%.[31-33] The compliance rate (71.3%) found in our study is slightly lower than the mean rate found in other studies.

We found a difference in TOP compliance between the different types of hospitals. The general and teaching hospitals hardly differed from each other, which is interesting because a previous study [34] found teaching hospitals to be better at implementing checklists than general hospitals. According to the organizational learning theory, the availability of knowledge in an organization contributes to the adoption of innovations.[34 35] Teaching hospitals are learning environments, aimed at spreading and developing knowledge; better compliance can therefore

Formatted: Font: 12 pt

be expected in teaching hospitals. ~~However, w~~We found that academic hospitals showed lower TOP compliance.

The literature is inconsistent about the influence of hospital size on the use of checklists. Some argue that larger hospitals are better developed and use standardized processes, which increases the quality of the hospital more often,[36-38] whereas others conclude that smaller hospitals implement checklists better.[39] We found no relationship between TOP compliance and hospital size. The high ICC rates found in this study suggest that the ~~differences between individual hospitals is~~differences between individual hospitals are high, and differences in compliance ~~can not~~cannot be explained by general hospital characteristics such as hospital size. The differences between individual hospitals need to be examined in further research~~–~~, but possible explanations might be found in different organizational structures, the creation of awareness amongst healthcare staff~~, or~~and differences in speaking-up cultures between hospitals.

The relationship found between surgical specialties and the TOP is different from the results of previous studies. One study showed a difference between surgeons and anesthesiologists[40] and another study showed no difference between surgical specialties at all.[41] The TOP is a standardized procedure, and the way in which it should be carried out does not depend on the surgical specialty performing the procedure or the patient characteristics. ~~We found that other surgical specialties teams performed the TOP more often than general surgery teams~~Compliance with the TOP varied between different specialties and was lowest among general surgery teams. One explanation for these differences could be that not all medical disciplines and their scientific communities have placed the same amount of weight on a thorough implementation of the Safety Program. If so, this could have had an influence on the sense of urgency experienced by different specialties to comply with TOP in their daily

functioning. Further research that includes specialty-specific factors is needed to verify and deepen our findings. ~~Further research is needed to verify these results.~~

The negative relationship between TOP compliance and the age of the patient was an unexpected result, since the TOP should be executed in the same way for all patients. In particular, the exact surgical procedure that would be carried out was less often verified with elderly patients. Explanations might be found in factors inherently associated with the elderly patient themselves. For example, elderly patients might be less able to verbally express themselves to healthcare staff. On the other hand, explanations might be found in factors that are associated with the medical procedure itself. For example, the level of standardization of procedures that are commonly performed in the elderly population (such as hip- replacement surgery or cataract surgery) is relatively high and it is unclear what effect this has on compliance with TOP. Elderly people are a vulnerable group with a higher risk of complications after surgery, therefore. ~~F~~ further in-depth research is ~~needed~~ important to explain the differences in compliance for different age groups.

Completeness and focus are important factors in the TOP and performing it when team members are busy with other activities creates a risk. Our study showed that focus in the team contributes to the TOP being performed correctly. However, there was poor focus on the TOP in almost half of the surgical procedures observed. Several possible causes could be underlying to poor focus during the TOP, which was observed frequently in our study. Firstly, there could have been a lack of awareness of the importance of the TOP amongst healthcare staff. Regular emphasis on the importance of the TOP during team meetings or during the joint briefing at the start of a new working day could help raise awareness. Secondly, when surgery schedules are tight, healthcare staff might experience time pressure. In trying to keep up with the schedule and being efficient, healthcare staff might be tempted to perform multiple tasks simultaneously which in turn could negatively affect compliance with TOP.

Formatted: No Spacing2, Indent: First line: 0.49"

Based on these results, it seems that hospitals still have a lot to gain by carrying out the TOP properly. Qualitative research methods could provide insight into the underlying reasons and incentives of why healthcare staff perform the TOP in the way they currently do. This type of research could complement and deepen the findings that were presented in the current study.

-

Formatted: Indent: First line: 0"

Strengths and limitations

Our study was the first to evaluate TOP compliance over time through observations in the OR and look at the factors associated with compliance. Our dependent variable was a process indicator, because the incidence of wrong surgery is too low to be observed with our study design. Based on the literature, it ~~is~~ seems fair to assume that higher TOP compliance ~~will~~ can contribute to~~decrease~~ a decrease in the incidence of wrong surgery,[15] although this study gives no information about the actual number of wrong surgeries and TOP compliance might not be the only factor in the reduction of wrong surgery. ~~-~~

This study has several limitations. Firstly, the presence of the observer might have influenced the behavior of the OR staff and indirectly of our dependent variable TOP. However, the design of our study aimed to prevent this potential observer bias, because the precise goal of the observations was not known to the OR team. Secondly, a potential selection bias can be found in the selection of surgical procedures on the observation days. Surgical procedures were selected based on practical considerations: the day of the week, the duration of the procedure, and the OR schedule. The relationships found between different specialisms might be partially overestimated, because the same surgical teams were sometimes observed on the same day or on different observation days. However, the overall goal was to observe as may different surgical procedures with different teams as possible, in

order to limit potential selection bias. Thirdly, there is no information available about the changes in compliance during the first period of the Safety Program, and hospitals may have made progress during this period.

Conclusions

The mean TOP compliance was 71.3% during the final year of the Safety Program and no improvement in compliance over time was found. Large differences were found between hospitals, and these differences were influenced by age of the patient. Compliance was influenced by several factors: ~~academic hospitals performed the TOP less often than general and teaching hospitals~~hospital type, ~~different~~ surgical specialty~~ies showed different compliances with the TOP~~, age of the patient~~the TOP was performed less often for older patients, and TOP compliance was higher when the entire team~~and focus of the team during the TOP ~~was focused on the TOP~~.~~ Furthermore, in almost half the TOPs, the team was not focused on the TOP or the team was incomplete. Despite the fact that almost three quarter of operations are preceded by a TOP, hospitals need to make an effort to improve TOP compliance and the way in which the TOP is carried out in order to prevent wrong surgery from happening in the future.

Figure legend

Figure 1. Trend in the time-out procedure compliance per hospital type, and overall mean (n=1232)

Tables

Table 1. Trend in the time-out procedure per hospital type (n=1232; 18 hospitals)

	Trend overall			Trend per hospital type								
				General hospitals			Teaching hospitals			Academic hospitals		
Fixed effects	N	Mean %	95% CI	N	Mean %	95% CI	N	Mean %	95% CI	N	Mean %	95% CI
TOP (constant)												
MM 1	121	73.52	53.20-87.14	85	85.18	2.00-94.35	25	59.00	21.26-88.46	11	16.48	0.91-80.91
MM 2	137	71.64	51.26-85.85	91	76.73	54.48-90.09	33	75.65	36.60-94.36	13	45.91	2.90-96.02
MM 3	134	66.79	45.78-82.73	87	67.09	42.94-84.66	33	82.19	44.85-96.32	14	23.86	1.55-86.19
MM 4	118	76.77	57.01-89.17	75	82.01	60.92-93.02	27	80.40	41.08-96.02	16	25.73	1.76-87.03
MM 5	125	77.26	57.99-89.32	85	87.56	70.27-95.44	30	72.30	32.65-93.36	10	5.97	0.29-57.90
MM 6	127	82.18	64.73-92.05	85	81.27	60.55-92.46	27	94.63	65.68-99.39	15	59.61	5.32-97.48
MM 7	114	81.20	62.89-91.67	78	82.23	61.44-93.07	26	91.13	57.87-98.72	10	46.67	2.40-96.89
MM 8	112	79.41	60.46-90.68	82	82.59	62.33-93.16	22	85.56	46.93-97.54	8	45.42	1.80-97.43
MM 9	129	48.44	28.65-68.74	89	52.86	29.81-74.75	25	66.00	26.36-91.33	15	6.00	0.40-50.29
MM 10	115	69.68	48.46-84.88	85	71.32	47.57-87.20	21	83.56	43.24-97.13	9	48.84	2.39-97.38
Random effects Variance components:												
ICC	44.056			40.106								
hospital (level 2)	2.591 (0.916) *			2.203 (0.798) *								
surgical procedure (level 1)	0.988 (0.040)			0.984 (0.040)								

MM = Measurement~~ing~~ moment, TOP = Time-out procedure, 95% CI = 95% confidence interval, ICC = Intraclass correlation

*p<0.05

Formatted Table

Table 2. Relationship between surgical specialties (n=1130; 18 hospitals) and compliance with the time-out procedure.

	Model 0 (time-out procedure + age + sex)	**Model 1 (model 0 + specialties)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties - General surgery	-	*Reference*
Specialties - Gynecology	-	0.050 (0.264)
Specialties – ENT	-	0.905 (0.316) *
Specialties - Ophthalmology	-	0.616 (0.302) *
Specialties – Orthopedic surgery	-	0.163 (0.241)
Specialties – Urology	-	0.084 (0.287)
Specialties – other	-	0.046 (0.279)
Patient age	-0.011 (0.004) *	-0.011 (0.004) *
Patient sex	0.064 (0.153)	0.074 (0.155)
Random effects		
Variance components:		
Intraclass correlation	25.331	25.499
hospital (level 2)	1.116 (0.422) *	1.126 (0.426) *
surgical procedure (level 1)	0.996 (0.042)	1.006 (0.043)

*p<0.05

Table 3. Age effects for the three different checks in the time-out procedure: checking ~~the patient~~the patient (n=1074), the procedure (n=1074), and the side/site (n=1074)

	Model 0 (check patient + age + sex)	**Model 1 (check procedure + age + sex)**	**Model 2 (check side/site + age + sex)**
Fixed effects	Estimate (SE)	Estimate (SE)	Estimate (SE)
Check patient (constant)	3.499 (0.334)	-	-
Check procedure (constant)	-	2.276 (0.282)	-
Check side/site (constant)	-	-	2.739 (0.204)
Patient's age	0.008 (0.008)	-0.021 (0.006)*	0.012 (0.007)*
Patient's sex	-0.185 (0.288)	0.124 (0.198)	0.160 (0.246)
Random effects			
Variance components:			
Intraclass correlation	27.172	24.990	10.854
hospital (level 2)	1.228 (0.623) *	1.096 (0.464) *	0.401 (0.236) *
surgical procedure (level 1)	0.834 (0.036)	0.922 (0.040)	0.950 (0.041)

*p<0.05

Table 4. Relationship between focus (n=1074; 18 hospitals) during the time-out procedure and compliance with the time-out procedure.

	Model 0 (time-out procedure + age + sex)	**Model 1 (model 0 + focus)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time-out procedure (constant)	1.540 (0.163)	1.471 (0.156)
Focus	-	0.567 (0.171)*
Patient's age	-0.006 (0.005)	-0.005 (0.005)
Patient's sex	-0.012 (0.162)	-0.016 (0.163)
Random effects		
Variance components:		
Intraclass correlation	8.971	7.991
hospital (level 2)	0.324 (0.154) *	0.286 (0.140) *
surgical procedure (level 1)	0.968 (0.042)	0.966 (0.042)

*p<0.05

Acknowledgements

We wish to thank the participating hospitals, their contact persons and employees who participated in our study.

Competing interests

The authors declare that they have no competing interests.

Contributions

SS and VK did the statistical analyses, interpreted the results of the analyses and drafted the manuscript. SS took part in the data collection. CB was involved in the design of the study, organized the data collection and critically revised the manuscript. PS did the statistical analyses and reviewed the parts of the manuscript that involved the statistical analyses. PG was involved in the design of the study, advised on the statistical analyses and critically revised the manuscript. CW was involved in the design of the study and critically revised the manuscript. All authors meet the criteria for authorship, were involved in revising and approving the final manuscript and accept responsibility for the data presented.

Funding

This research was funded by the Ministry of Education, Culture and Science in the Netherlands.

Data sharing statement

No additional data are available.

Reference List

1 Kohn LT, Corrigan J, Donaldson MS. To err is human: building a safer health system. 6 ed. Joseph Henry Press; 2000.

2 See LC, Chang YH, Chuang KL, *et al*. Animation program used to encourage patients or family members to take an active role for eliminating wrong-site, wrong-person, wrong-procedure surgeries: Preliminary evaluation. *Int J Surg* 2011; 9(3):241-247.

3 Seiden SC, Barach P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? *Arch Surg* 2006; 141(9):931.

4 Zhan C, Kelley E, Yang HP, *et al*. Assessing patient safety in the United States: challenges and opportunities. *Med Care* 2005; 43(3):I-42.

5 WHO. Patient Safety. 2013.
Ref Type: Online Source

6 Zegers M, De Bruijne MC, Wagner C, *et al*. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care* 2009; 18(4):297-302.

7 Gibbs VC. Thinking in three's: Changing surgical patient safety practices in the complex modern operating room. *World J Gastroenterol* 2012; 18(46):6712.

8 DeVine J, Chutkan N, Norvell DC, *et al*. Avoiding wrong site surgery: a systematic review. *Spine* 2010; 35(9S):S28.

9 Ammerman JM, Ammerman MD, Dambrosia J, *et al*. A prospective evaluation of the role for intraoperative x-ray in lumbar discectomy. Predictors of incorrect level exposure. *Surg Neurol* 2006; 66(5):470-473.

10 Kwaan MR, Studdert DM, Zinner MJ, *et al*. Incidence, patterns, and prevention of wrong-site surgery. *Arch Surg* 2006; 141(4):353.

11 Jhawar BS, Mitsis D, Duggal N. Wrong-sided and wrong-level neurosurgery: a national survey. 2007.

12 Mody MG, Nourbakhsh A, Stahl DL, *et al*. The prevalence of wrong level surgery among spine surgeons. *Spine* 2008; 33(2):194.

13 Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007; 246(3):395.

14 Angle JF, Nemcek AA, Jr., Cohen AM, *et al*. Quality improvement guidelines for preventing wrong site, wrong procedure, and wrong person errors: application of the joint commission "universal protocol for preventing wrong site, wrong procedure, wrong person surgery" to the practice of interventional radiology. *J Vasc Interv Radiol* 2009; 20(7 Suppl):S256-S262.

15 World Health Organization. New scientific evidence supports WHO findings: a surgical safety checklist could save hundreds of thousands of lives. 2011. 2011.
Ref Type: Generic

16 Haynes AB, Weiser TG, Berry WR, *et al*. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Eng J Med* 2009; 360(5):491-499.

17 Mazzocco K, Petitti DB, Fong KT, *et al*. Surgical team behaviors and patient outcomes. *AM J Surg* 2009; 197(5):678-685.

18 Gawande AA, Zinner MJ, Studdert DM, *et al*. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery* 2003; 133(6):614.

19 Lübbeke A, Hovaguimian F, Wickboldt N, *et al*. Effectiveness of the surgical safety checklist in a high standard care environment. *Med Care* 2013; 51(5):425-429.

20 Hales BM, Pronovost PJ. The checklist: a tool for error management and performance improvement. *J Crit Care* 2006; 21(3):231-235.

21 De Vries EN, Prins HA, Crolla RM, *et al*. Effect of a comprehensive surgical safety system on patient outcomes. *N Eng J Med* 2010; 363(20):1928-1937.

22 De Vries EN, Eikens-Jansen MP, Hamersma AM, *et al*. Prevention of surgical malpractice claims by use of a surgical safety checklist. *Ann Surg* 2011; 253(3):624.

23 De Vries EN, Prins HA, Bennink MC, *et al*. Nature and timing of incidents intercepted by the SURPASS checklist in surgical patients. *BMJ Qual Saf* 2012; 21(6):503-508.

24 DeFontes J, Surbida S. Preoperative safety briefing project. *Perm J* 2004; 8(2):21-27.

25 Nederlandse Vereniging voor Anesthesiologie, Nederlandse Vereniging voor Heelkunde. Richtlijn: Het peroperatieve traject. 2011.
Ref Type: Report

26 VMS Safety Program. Prevention of wrong surgery. 2009.

27 Joint commission. Lessons learned: Wrong site surgery. 28-8-1998.
Ref Type: Report

28 MediRisk. OK-project: Schadecategoriën en vangnetcriteria voor de operatieafdeling. 2007.
Ref Type: Report

29 De Blok C, Koster E, Schilp J, *et al*. Implementatie VMS Veiligheidsprogramma. Evaluatieonderzoek in Nederlandse Ziekenhuizen. (In Dutch). 2013. Utrecht/Amsterdam: NIVEL en EMGO+ Instituut.
Ref Type: Report

30 Twisk JW. Applied multilevel analysis: a practical guide. Cambridge University Press; 2006.

31 Spence J, Goodwin B, Enns C, *et al*. Student-observed surgical safety practices across an urban regional health authority. *BMJ Qual Saf* 2011; 20(7):580-586.

32 Altpeter T, Luckhardt K, Lewis JN, *et al*. Expanded surgical time out: a key to real-time data collection and quality improvement. *J Am Coll Surg* 2007; 204(4):527-532.

33 Borchard A, Schwappach DL, Barbir A, *et al*. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012; 256(6):925-933.

34 Dijkstra R, Wensing M, Thomas R, *et al*. The relationship between organisational characteristics and the effects of clinical guidelines on medical performance in hospitals, a meta-analysis. *BMC Health Serv Res* 2006; 6(1):53.

35 Nevis EC, DiBella AJ, Gould JM. Understanding organizations as learning systems. *Sloan Manage Rev* 1997; 36(2).

36 Zuiderent-Jerak T, Kool T, Rademakers J. De relatie tussen volume en kwaliteit van zorg: tijd voor een brede benadering. 2012.

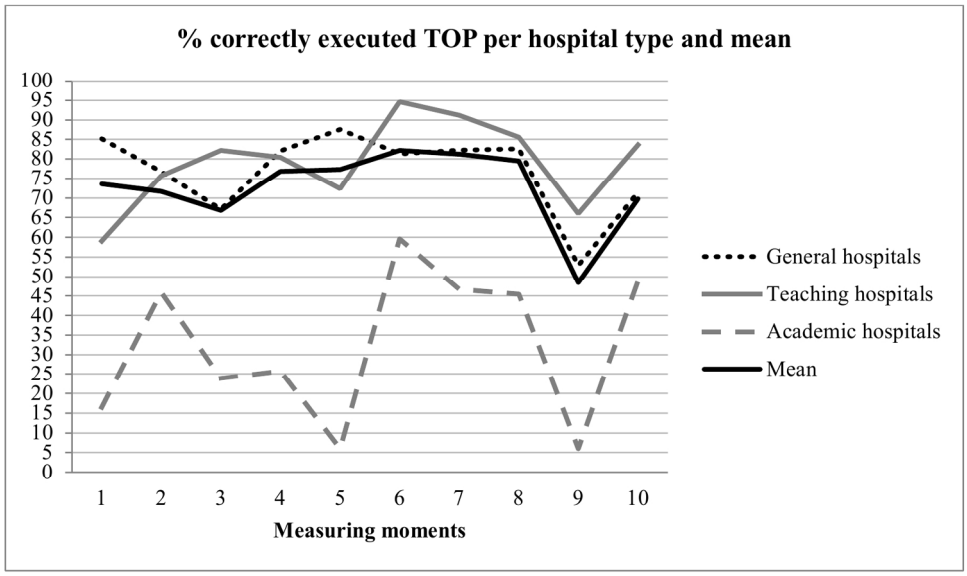
37 Mutter RL, Wong HS, Goldfarb MG. The effects of hospital competition on inpatient quality of care. *Inquiry* 2008; 45(3):263-279.

38 Sari N. Do competition and managed care improve quality? *Health Econ* 2002; 11(7):571-584.

39 Soria-Aledo V, Da Silva ZA, Saturno PJ, *et al*. Difficulties in implementing a surgical check list in operating theatres. *Cir Esp* 2012; 90(3):180.

40 De Vries EN, Hollmann MW, Smorenburg SM, *et al*. Development and validation of the SURgical PAtient Safety System (SURPASS) checklist. *Qual Saf Health Care* 2009; 18(2):121-126.

41 Blanco M, Clarke JR, Martindell D. Wrong site surgery near misses and actual occurrences. *AORN J* 2009; 90(2):215-222.



159x93mm (300 x 300 DPI)