



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

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3 **Compliance with a Time-out Procedure to Prevent Wrong Surgery in Hospitals: Results**  
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5 **of a National Patient Safety Program**  
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45 **Keywords.** *patient safety, compliance, time-out procedure, wrong surgery, checklist*  
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3 **Compliance with a Time-out Procedure to Prevent Wrong Surgery in Hospitals: Results**  
4 **of a National Patient Safety Program**  
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9 **Abstract** (*word count: 244*)

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11 **Objective.** To prevent wrong surgery, the WHO “Safe Surgery Checklist” was introduced in  
12 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of  
13 the surgical procedure where the patient, surgical procedure and side/site are reviewed by the  
14 surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the  
15 TOP before anesthesia in the operating room, whether compliance has changed over time, and  
16 to determine factors that are associated with compliance.  
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24 **Design.** Evaluation study involving observations.

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

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27 **Participants.** A random selection was made from all adult patients scheduled for elective  
28 surgery on the day of the observation, preferably involving different surgeons and different  
29 procedures.  
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36 **Results.** Mean compliance with the TOP was 71.3%. Large differences between hospitals  
37 were observed. No linear trend was found in compliance during the study period. Compliance  
38 at general and teaching hospitals was higher than at academic hospitals. Compliance  
39 decreased with the age of the patient, general surgery showed lower compliance in  
40 comparison with other specialties and compliance was higher when the team was focused on  
41 the TOP.  
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49 **Conclusions.** Large differences in compliance with the TOP were observed between  
50 participating hospitals which can be attributed at least in part to the type of hospital, surgical  
51 specialty, and patient characteristics. Hospitals do not comply consistently with national  
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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*

For peer review only

## 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.<sup>1</sup> 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.<sup>1</sup> As a result, patient safety became a major topic on the healthcare agenda.<sup>2-4</sup> Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.<sup>5</sup> 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.<sup>6</sup> 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.<sup>6</sup> More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> In the United States, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5 per 10,000 operations.<sup>3 8-13</sup>

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

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3 Commission in the United States.<sup>14</sup> Consequently, the World Health Organization (WHO)  
4 introduced a checklist in 2008 for worldwide use, called the “Safe Surgery Checklist”. In  
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7 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated  
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9 with a significant decrease in postoperative complication (30%) and mortality rates (50%).<sup>15</sup>  
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11 Based on these results, the WHO estimated that implementing the checklist could save  
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13 500,000 lives every year worldwide.<sup>15</sup> Other studies provided evidence supporting the use of  
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15 surgical checklists as well.<sup>16-19</sup> In the Netherlands, the SURgical PATient Safety System  
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17 (SURPASS) was developed with the same intention. It is based on safety checks used in the  
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19 aviation industry to reduce human error.<sup>20</sup> Research on the external validation of the  
20  
21 SURPASS shows a reduction in unintentional harm.<sup>21-23</sup>  
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25 Each of the checklists mentioned above comprises a time-out procedure (TOP). Errors  
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27 can be avoided by including a preoperative discussion just before the start of the surgical  
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29 procedure. This takes place during a time-out involving a review of the names and roles of all  
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31 team members, characteristics of the patient, the operation plan, familiarity with the  
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33 procedure, the presence of the correct materials/equipment, and potential issues for the  
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35 patient.<sup>24,25</sup> It is likely that these TOPs reduce uncertainties in the OR among the surgical team  
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37 and reduce the risk of wrong surgery. The TOP is the final step before the start of the surgical  
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39 procedure and is therefore crucial in preventing wrong surgery. A TOP is carried out just  
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41 before anesthesia,<sup>26</sup> and consists of three checks (the patient, the procedure and the side/site),  
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43 all of equal importance in preventing wrong surgery.  
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48 The aim of this study is to evaluate the extent to which hospitals carry out the TOP before  
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50 anesthesia in the OR, whether compliance has changed over time, and to determine factors  
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52 that are associated with the TOP compliance. Insights into compliance with the TOP and the  
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54 factors associated with compliance are important because they have the potential to improve  
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56 the TOP and reduce adverse events in surgical processes throughout the world. This study was  
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3 carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital  
4 Patient Safety Program (hereinafter “Safety Program”) that was carried out during the final  
5 year of the program. (Box 1.).  
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12 *Box 1. The Dutch Hospital Patient Safety Program*

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14 The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce  
15 preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.<sup>26</sup>  
16 The Safety Program consisted of ten patient safety themes and clinical guidelines were  
17 developed for each theme. Hospitals were given five years to implement these guidelines.  
18 One of the themes was prevention of wrong surgery. There are several risk factors for wrong  
19 surgery, e.g. insufficient compliance, inadequate identification and verification and bad  
20 preoperative planning.<sup>27 28</sup> The Safety Program therefore instructed the participating Dutch  
21 hospitals to implement several steps to decrease wrong surgery, based on the SURPASS  
22 checklist. One of the steps is identification and verification by means of a TOP consisting of  
23 checks on the correct patient, correct side, and correct intervention.<sup>29</sup>  
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27 Based on the goals of the Safety Program, it was expected that the compliance with the TOP  
28 increased over time and became more visible during the final year of the program when hospitals  
29 approached the public deadline at the end of 2012.  
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32 The research questions are:

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

48 *Study design*

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50 This study was part of a larger evaluation study of the Safety Program that was carried out  
51 between November 2011 and December 2012 in eighteen Dutch hospitals (about 20% of all  
52 Dutch hospitals). The study protocol was granted approval by the VU University Medical  
53 Center ethical review board in Amsterdam. Hospitals were randomly selected using a  
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3 stratified sample based on geographical regions and hospital type. Two academic hospitals,  
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5 four teaching hospitals and twelve general hospitals were included in this study. All hospitals  
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7 consented to the study and were informed about further practical issues. A random selection  
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9 was made on the day of the observation from all adult patients scheduled for elective surgery  
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11 on the day of the observation. The goal was to have ten observation days per hospital at  
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13 intervals of four to six weeks, and to observe six to ten surgical procedures per day, preferably  
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15 involving different surgeons and different procedures. One observer per surgical procedure  
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17 evaluated whether the TOP was carried out before anesthesia, using a standardized recording  
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19 form that covered the various aspects of doing the TOP: checking the patient, procedure, and  
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21 side/site, attention of the team (focus), completeness of the team, interruptions, and several  
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23 background variables such as the type of surgical procedure, the patient's age, and sex. The  
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25 OR team was not aware of the exact subject matter of the observation; the observer was  
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27 instructed to introduce the study in abstract terms, referring to it as a study about the surgical  
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29 process in general.  
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### 36 *TOP compliance*

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38 The dependent variable was whether the TOP was done correctly and was dichotomous  
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40 (yes/no). This variable was used to examine mean TOP compliance and the changes in  
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42 compliance during the study period. A correct TOP consists of three checks: patient,  
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44 procedure, and side/site. Since all three checks are equally important for preventing wrong  
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46 surgery, the TOP was only deemed correct when all three checks were performed. The entire  
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48 OR team gathers around the patient during a TOP and the surgeon asks the patient his/her  
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50 name, the type of procedure and the side/site of the procedure.  
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54 Four independent variables were included so that any relationship with compliance could be  
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56 determined. The type of hospital was categorized into academic, teaching, and general.  
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3 Hospital size was operationalized as the number of beds in the hospital (a continuous  
4 variable). Surgical specialty was added as a categorical variable with general surgery as the  
5 reference category. Focus (yes/no) was included to measure the degree to which the OR team  
6 was paying full attention to the TOP and was not performing any other activities during the  
7 TOP. In addition, the patient characteristics 'age' and 'sex' were included as covariates.  
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14 Completeness of the team (yes/no) was added as a explorative analysis.  
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### 16 17 18 *Statistical analyses* 19

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21 Descriptive analyses were performed to obtain a picture of the study population, mean TOP  
22 compliance, changes in compliance over time, mean compliance for the different hospital  
23 types, mean compliance for the different surgical specialties, and the focus and completeness  
24 of the team during the TOP.  
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30 A multilevel logistic regression analysis with two levels was used to determine  
31 whether TOP compliance changed between the ten measuring moments. Multilevel analysis  
32 was chosen to correct for the fact that the surgical procedures are not independent from each  
33 other, but clustered within hospitals. Time was modeled by adding ten indicator variables for  
34 the time points (removing the intercept from the model); trends were tested using polynomial  
35 contrasts (to the 4<sup>th</sup> order) to study changes over time. Variance and intraclass correlations  
36 (ICCs) were calculated to assess the clustering of TOP compliance at the hospital and surgical  
37 procedure level. An ICC of 20% was seen as moderate.<sup>30</sup> The changes over time were also  
38 analyzed for the different hospital types to determine the relationship between hospital type  
39 and the changes in TOP compliance. Separate logistic multilevel analyses were performed for  
40 each independent variable to analyze the effects of the independent variables 'hospital size'  
41 and 'surgical specialty'; this was necessary because not enough units at the highest level  
42 (hospitals) were available to have more than one independent variable in a model.<sup>30</sup> Age and  
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3 sex of the patient were added as covariates in all analyses. All descriptive analyses were  
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5 performed using SPSS version PASW Statistics 18. The multilevel analyses were performed  
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7 using MLwiN version 2.24 (using PQL, second order, unconstrained level 1 variance, options).  
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## 10 11 **Results**

### 12 *Descriptive analyses*

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15 1281 surgical procedures were observed at the participating hospitals. After patients younger  
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17 than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96.  
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19 The gender distribution was 41.4% male, 53.8% female, and 4.8% unknown. The range in  
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21 types of surgical procedures was broad; observers had been instructed to observe different  
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23 procedures and observed surgical procedures of in total 13 different specialties. Mean  
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25 compliance with the TOP during the total study period was 71.3%. Descriptive analyses  
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27 showed that TOP compliance did not improve during the study period. There was a large  
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29 spread between hospitals: one of the hospitals never performed the TOP correctly and two had  
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31 mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at  
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33 the ninth measuring moment for all the participating hospitals. The academic hospitals had a  
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35 mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%.  
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37 Differences between specialties were shown to exist: trauma, gastroenterology and  
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39 hepatology, and ENT medicine had the highest compliance rates. Anesthesiology,  
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41 cardiothoracic surgery, and cosmetic surgery had the lowest compliance rates. In 44% of the  
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43 observations the team was not focused on the TOP and in 56%, the team was incomplete.  
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### 50 *Multilevel regression analyses*

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52 In the first multilevel regression analysis, the changes in TOP compliance were tested. The  
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54 effect was statistically significant for the fourth-order polynomial ( $p < 0.01$ ), meaning that  
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3 TOP compliance was not linear but fluctuated over time and no clear trend was observed.  
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5 Furthermore, there were large differences between the measuring moments and between  
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7 individual hospitals. See Figure 1. The multilevel analysis shows that 44% (ICC = 44.01) of  
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9 the total variance in TOP compliance can be attributed to the differences between the  
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11 individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11  
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13 (40%). See Table 1.

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16 When correcting for age and sex of the patient, the ICC dropped to 26% (ICC =  
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18 26.58). The relationship between the age of the patient and the TOP was found to be  
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20 significant ( $p < 0.05$ ). This relationship was tested and found to be linear. Based on the results  
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22 described above, there was no rationale to correct for time (measurement points) in further  
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24 analyses. Observations from the different measurement points were pooled in the remaining  
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26 analyses.  
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30 Separate analyses were performed for the independent variables 'hospital size',  
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32 'surgical specialty', and 'focus'. No statistically significant relationship was found between  
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34 hospital size and TOP compliance (data not shown in tables). A positive relationship was  
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36 found between patients undergoing ENT surgery and the TOP (reference = general surgery;  
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38  $p < 0.01$ ). Another positive relationship was found between patients undergoing ophthalmic  
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40 surgery and the TOP (reference = general surgery;  $p < 0.05$ ). See Table 2. This indicates that  
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42 TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic  
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44 surgery compared to patients undergoing general surgery. The relationship between the age of  
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46 the patient and TOP compliance was found to be significant ( $p < 0.05$ ) in all analyses. This  
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48 indicates that TOP compliance decreases with the patient age in all analyses. The TOP is  
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50 performed less often for older patients. An additional analysis was performed based on these  
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52 results to determine which of the three individual checks of the TOP attributed most to the  
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54 negative relationship between the age of the patient and TOP compliance. Table 3 shows the  
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3 results of the additional analysis. The check procedure contributes most to the negative  
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5 relationship between age of the patient and TOP compliance, this check is more often skipped  
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7 when an older patient is involved. The relationship between the focus of the team during the  
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9 TOP and the correct execution of the TOP is shown in Table 4. There is a positive significant  
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11 relationship between focus and TOP compliance, which indicates that the TOP is more often  
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13 correctly executed when the entire team is focused on the TOP and not performing any other  
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15 activities at the same time.  
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## 21 Discussion

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24 The objective of this study was to investigate the compliance at Dutch hospitals with the  
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26 national guidelines of a TOP set by the Safety Program and how this changed over the final  
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28 year of the program. Furthermore, we studied variables that might be associated with  
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30 compliance. This study found a mean TOP compliance of 71.3%. There was no linear trend in  
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32 the TOP compliance during the study period. Large differences were found between  
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34 individual hospitals, which were partly influenced by age of the patient. The type of hospital  
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36 was associated with the TOP compliance: academic hospitals had lower compliance rates than  
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38 general and teaching hospitals. Given the low number of academic hospitals in this study  
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40 (N=2), these findings cannot be generalized to academic hospitals as a whole. ENT medicine  
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42 and ophthalmological surgery had higher TOP compliance than the reference group (general  
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44 surgery). No statistically significant relationship between TOP compliance and hospital size  
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46 was found. The TOP was correctly performed more often when the OR team was focused on  
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48 it. The negative relationship between age of the patient and the TOP indicates that greater  
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50 patient age is associated with lower TOP compliance. Of all the observed TOPs, 44% were  
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52 performed without the focus of the entire team, and the team was not complete in 56% of the  
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54 TOPs.  
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3 A wide range in compliance rates for surgical checklists can be found in previous studies,  
4 ranging from 12% to 99% with a mean of 75%.<sup>31-33</sup> The compliance rate (71.3%) found in our study is  
5 slightly lower than the mean rate found in other studies.  
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9 We found a difference in TOP compliance between the different types of hospitals. The  
10 general and teaching hospitals hardly differed from each other, which is interesting because a  
11 previous study<sup>34</sup> found teaching hospitals to be better at implementing checklists than general  
12 hospitals. According to the organizational learning theory, the availability of knowledge in an  
13 organization contributes to the adoption of innovations.<sup>34 35</sup> Teaching hospitals are learning  
14 environments, aimed at spreading and developing knowledge; better compliance can therefore  
15 be expected in teaching hospitals. However, we found that academic hospitals showed lower  
16 TOP compliance.  
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20 The literature is inconsistent about the influence of hospital size on the use of  
21 checklists. Some argue that larger hospitals are better developed and use standardized  
22 processes, which increases the quality of the hospital more often,<sup>36-38</sup> whereas others conclude  
23 that smaller hospitals implement checklists better.<sup>39</sup> We found no relationship between TOP  
24 compliance and hospital size. The high ICC rates found in this study suggest that the  
25 differences between individual hospitals is high, and differences in compliance can not be  
26 explained by general hospital characteristics such as hospital size.  
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30 The relationship found between surgical specialties and the TOP is different from the  
31 results of previous studies. One study showed a difference between surgeons and  
32 anesthesiologists<sup>40</sup> and another study showed no difference between surgical specialties at  
33 all.<sup>41</sup> The TOP is a standardized procedure, and the way in which it should be carried out does  
34 not depend on the surgical specialty performing the procedure or the patient characteristics.  
35 We found that other surgical specialties teams performed the TOP more often than general  
36 surgery teams. Further research is needed to verify these results.  
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3 The negative relationship between TOP compliance and the age of the patient was an  
4 unexpected result, since the TOP should be executed in the same way for all patients. We  
5 found lower TOP compliance for older patients, in particular that the surgical procedure is  
6 verified less often with the patient. Elderly people are a vulnerable group with a higher risk of  
7 complications after surgery. Further in-depth research is needed to explain the differences in  
8 compliance for different age groups.  
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16 Completeness and focus are important factors in the TOP and performing it when team  
17 members are busy with other activities creates a risk. Our study showed that focus in the team  
18 contributes to the TOP being performed correctly. However, there was poor focus on the TOP  
19 in almost half of the surgical procedures observed. Based on these results, it seems that  
20 hospitals still have a lot to gain by carrying out the TOP properly.  
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### 28 29 30 *Strengths and limitations*

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32 Our study was the first to evaluate TOP compliance over time through observations in the OR  
33 and look at the factors associated with compliance. Our dependent variable was a process  
34 indicator, because the incidence of wrong surgery is too low to be observed with our study  
35 design. Based on the literature, it is fair to assume that higher TOP compliance will decrease  
36 the incidence of wrong surgery,<sup>15</sup> although this study gives no information about the actual  
37 number of wrong surgeries.  
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45 This study has several limitations. Firstly, the presence of the observer might have  
46 influenced the behavior of the OR staff and indirectly of our dependent variable TOP.  
47 However, the design of our study aimed to prevent this potential observer bias, because the  
48 precise goal of the observations was not known to the OR team. Secondly, a potential  
49 selection bias can be found in the selection of surgical procedures on the observation days.  
50 Surgical procedures were selected based on practical considerations: the day of the week, the  
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3 duration of the procedure, and the OR schedule. The relationships found between different  
4 specialisms might be partially overestimated, because the same surgical teams were  
5 sometimes observed on the same day or on different observation days. However, the overall  
6 goal was to observe as many different surgical procedures with different teams as possible, in  
7 order to limit potential selection bias. Thirdly, there is no information available about the  
8 changes in compliance during the first period of the Safety Program, and hospitals may have  
9 made progress during this period.  
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### 20 *Conclusions*

21  
22 The mean TOP compliance was 71.3% during the final year of the Safety Program and no  
23 improvement in compliance over time was found. Large differences were found between  
24 hospitals, and these differences were influenced by age of the patient. Compliance was  
25 influenced by several factors: academic hospitals performed the TOP less often than general  
26 and teaching hospitals, different surgical specialties showed different compliances with the  
27 TOP, the TOP was performed less often for older patients, and TOP compliance was higher  
28 when the entire team was focused on the TOP. Furthermore, in almost half the TOPs, the team  
29 was not focused on the TOP or the team was incomplete. Despite the fact that almost three  
30 quarter of operations are preceded by a TOP, hospitals need to make an effort to improve TOP  
31 compliance and the way in which the TOP is carried out in order to prevent wrong surgery  
32 from happening in the future.  
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3 **Figure legend**  
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6 **Figure 1.** Trend in the time-out procedure compliance per hospital type, and overall mean  
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8 (n=1232)  
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Tables

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

	Trend		Trend per hospital type		Teaching hospital		Academic hospital	
	Mean percentage	95% CI	Mean percentage	95% CI	Mean percentage	95% CI	Mean percentage	95% CI
<i>Fixed effects</i>								
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
<i>Random effects</i>								
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.

	<b>Model 0 (time-out procedure + age + sex)</b>	<b>Model 1 (model 0 + specialties)</b>
<i>Fixed effects</i>	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties - General surgery	-	<i>Reference</i>
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)
<i>Random effects</i>		
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&lt;0.05

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**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)

	<b>Model 0</b> <b>(check patient + age + sex)</b>	<b>Model 1</b> <b>(check procedure + age + sex)</b>	<b>Model 2</b> <b>(check side/site + age + sex)</b>
<i>Fixed effects</i>			
	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)
<i>Random effects</i>			
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.

		<b>Model 0</b>	<b>Model 1</b>
		<b>(time-out procedure + age + sex)</b>	<b>(model 0 + focus)</b>
<i>Fixed effects</i>		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)
<i>Random effects</i>			
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&lt;0.05

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### **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.

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### **Data sharing statement**

No additional data are available.

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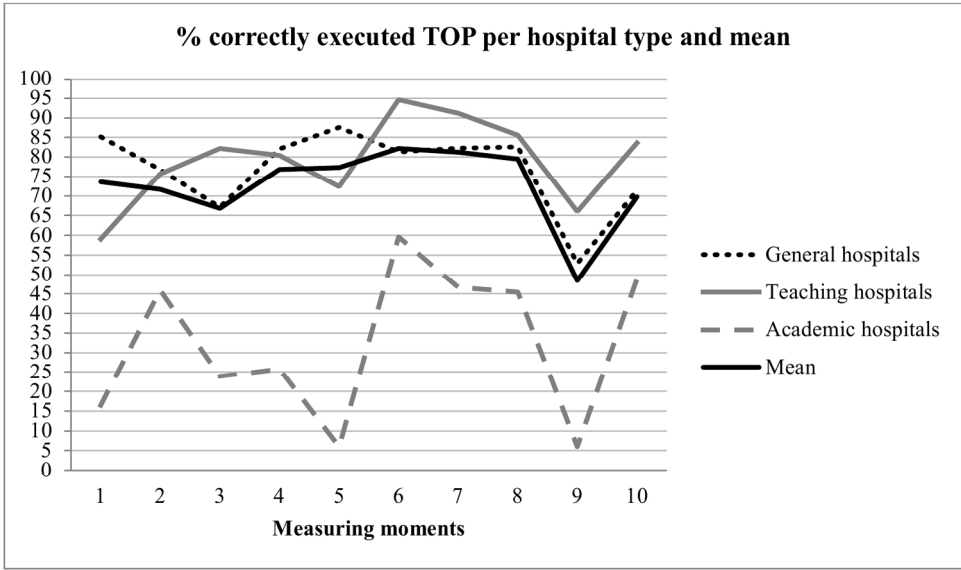


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# BMJ Open

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

Journal:	<i>BMJ Open</i>
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
<b>Primary Subject Heading</b>:	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

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Manuscripts

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3 **Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in**  
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5 **Hospitals: Results of a National Patient Safety Program in the Netherlands**  
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47  
48 **Keywords.** *patient safety, compliance, time-out procedure, wrong surgery, checklist*  
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51 **Word count.** 3906  
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10 **Abstract** (*word count: 244*)

11 **Objective.** To prevent wrong surgery, the WHO “Safe Surgery Checklist” was introduced in  
12 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of  
13 the surgical procedure where the patient, surgical procedure and side/site are reviewed by the  
14 surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the  
15 TOP before anesthesia in the operating room, whether compliance has changed over time, and  
16 to determine factors that are associated with compliance.  
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25 **Design.** Evaluation study involving observations.  
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27 **Setting.** Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals.  
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30 **Participants.** A random selection was made from all adult patients scheduled for elective  
31 surgery on the day of the observation, preferably involving different surgeons and different  
32 procedures.  
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36 **Results.** Mean compliance with the TOP was 71.3%. Large differences between hospitals  
37 were observed. No linear trend was found in compliance during the study period. Compliance  
38 at general and teaching hospitals was higher than at academic hospitals. Compliance  
39 decreased with the age of the patient, general surgery showed lower compliance in  
40 comparison with other specialties and compliance was higher when the team was focused on  
41 the TOP.  
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49 **Conclusions.** Large differences in compliance with the TOP were observed between  
50 participating hospitals which can be attributed at least in part to the type of hospital, surgical  
51 specialty, and patient characteristics. Hospitals do not comply consistently with national  
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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*

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## 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.<sup>1</sup> 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.<sup>1</sup> As a result, patient safety became a major topic on the healthcare agenda.<sup>2-4</sup> Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.<sup>5</sup> 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.<sup>6</sup> 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.<sup>6</sup> More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> In the United States, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5 per 10,000 operations.<sup>3 8-13</sup>

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

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3 Commission in the United States.<sup>14</sup> Consequently, the World Health Organization (WHO)  
4 introduced a checklist in 2008 for worldwide use, called the “Safe Surgery Checklist”. In  
5 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated  
6 with a significant decrease in postoperative complication (30%) and mortality rates (50%).<sup>15</sup>  
7 Based on these results, the WHO estimated that implementing the checklist could save  
8 500,000 lives every year worldwide.<sup>15</sup> Other studies provided evidence supporting the use of  
9 surgical checklists as well.<sup>16-19</sup> In the Netherlands, the SURgical PATient Safety System  
10 (SURPASS) was developed with the same intention. It is based on safety checks used in the  
11 aviation industry to reduce human error.<sup>20</sup> Research on the external validation of the  
12 SURPASS shows a reduction in unintentional harm.<sup>21-23</sup>

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25 Each of the checklists mentioned above comprises a time-out procedure (TOP). Errors  
26 can be avoided by including a preoperative discussion just before the start of the surgical  
27 procedure. This takes place during a time-out involving a review of the names and roles of all  
28 team members, characteristics of the patient, the operation plan, familiarity with the  
29 procedure, the presence of the correct materials/equipment, and potential issues for the  
30 patient.<sup>24,25</sup> Although evidence is scarce, it is likely that these TOPs reduce uncertainties in the  
31 OR among the surgical team and reduce the risk of wrong surgery. The TOP is the final step  
32 before the start of the surgical procedure and is therefore crucial in preventing wrong surgery.  
33 A TOP is carried out just before anesthesia,<sup>26</sup> and consists of three checks (the patient, the  
34 procedure and the side/site), all of equal importance in preventing wrong surgery.  
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48 The aim of this study is to evaluate the extent to which hospitals carry out the TOP before  
49 anesthesia in the OR, whether compliance has changed over time, and to determine factors  
50 that are associated with the TOP compliance. Insights into compliance with the TOP and the  
51 factors associated with compliance are important because they have the potential to improve  
52 the TOP and reduce adverse events in surgical processes throughout the world. This study was  
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3 carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital  
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5 Patient Safety Program (hereinafter “Safety Program”) that was carried out during the final  
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7 year of the program. (Box 1.).  
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12 *Box 1. The Dutch Hospital Patient Safety Program*

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14 The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce  
15 preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.<sup>26</sup>  
16 The Safety Program consisted of ten patient safety themes and clinical guidelines were  
17 developed for each theme. Hospitals were given five years to implement these guidelines.  
18 One of the themes was prevention of wrong surgery. There are several risk factors for wrong  
19 surgery, e.g. insufficient compliance, inadequate identification and verification and bad  
20 preoperative planning.<sup>27 28</sup> The Safety Program therefore instructed the participating Dutch  
21 hospitals to implement several steps to decrease wrong surgery, based on the SURPASS  
22 checklist. One of the steps is identification and verification by means of a TOP consisting of  
23 checks on the correct patient, correct side, and correct intervention.<sup>29</sup>  
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27 Based on the goals of the Safety Program, it was expected that the compliance with the TOP  
28 would increase over time and would become more visible during the final year of the program when  
29 hospitals approached the public deadline at the end of 2012.  
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32 The research questions are:

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

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51 *Study design*

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

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3 procedure, and side/site. Since all three checks are equally important for preventing wrong  
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5 surgery, the TOP was only deemed correct when all three checks were performed.  
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7 Furthermore, during a TOP the entire OR team gathers around the patient and the surgeon  
8  
9 asks the patient his/her name, the type of procedure and the side/site of the procedure.  
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12 Four independent variables were included so that any association with compliance  
13  
14 could be determined. The type of hospital was categorized into academic, teaching, and  
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16 general. In the Netherlands, teaching hospitals provide specialized medical care and are  
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18 committed to training and education. The level of care can be characterized as complex and  
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20 lies between that of general hospitals and academic centers. Hospital size was operationalized  
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22 as the number of beds in the hospital (a continuous variable). Surgical specialty was added as  
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24 a categorical variable with general surgery as the reference category. Focus (yes/no) was  
25  
26 included to measure the degree to which the OR team was paying full attention to the TOP  
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28 and was not performing any other activities during the TOP. In addition, the patient  
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30 characteristics 'age' and 'sex' were included as covariates. Completeness of the team (yes/no)  
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32 was added as a explorative analysis. The complete team in this study was seen as the group of  
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34 persons that performed the surgery on the patient. To be able to perform a TOP correctly, the  
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36 complete team was present during the TOP. When this was not the case, meaning that one or  
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38 more persons joint the team after the TOP had been completed, team completeness was scores  
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40 as 'no'.  
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#### 47 *Statistical analyses*

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49 Descriptive analyses were performed to obtain a picture of the study population, mean TOP  
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51 compliance, changes in compliance over time, mean compliance for the different hospital  
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53 types, mean compliance for the different surgical specialties, and the focus and completeness  
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55 of the team during the TOP.  
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3 A multilevel logistic regression analysis with two levels was used to determine  
4 whether TOP compliance changed between the ten measuring moments. Multilevel analysis  
5 was chosen to correct for the fact that the surgical procedures are not independent from each  
6 other, but clustered within hospitals. Time was modeled by adding ten indicator variables for  
7 the measurement moments (removing the intercept from the model); trends were tested using  
8 polynomial contrasts (to the 4<sup>th</sup> order) to study changes over time. Variance and intraclass  
9 correlations (ICCs) were calculated to assess the clustering of TOP compliance at the hospital  
10 and surgical procedure level. An ICC of 20% was seen as moderate.<sup>30</sup> The changes over time  
11 were also analyzed for the different hospital types to determine the relationship between  
12 hospital type and the changes in TOP compliance. Separate logistic multilevel analyses were  
13 performed for each independent variable to analyze the effects of the independent variables  
14 ‘hospital size’ and ‘surgical specialty’; this was necessary because not enough units at the  
15 highest level (hospitals) were available to have more than one independent variable in a  
16 model.<sup>30</sup> There were not enough units at the highest level (hospitals) to model the effect of  
17 hospital type on the TOP score in the pooled analyses. Age and sex of the patient were added  
18 as covariates in all analyses. All descriptive analyses were performed using SPSS version  
19 PASW Statistics 18. The multilevel analyses were performed using MlwiN version 2.24 (using  
20 PQL, second order, unconstrained level 1 variance, options).  
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## 45 **Results**

### 46 *Descriptive analyses*

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48 1281 surgical procedures were observed at the participating hospitals. After patients younger  
49 than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96.  
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51 The gender distribution was 41.4% male, 53.8% female, and 4.8% not registered. The range  
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53 in types of surgical procedures was broad; observers had been instructed to observe different  
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3 procedures and observed surgical procedures of in total 13 different specialties. Mean  
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5 compliance with the TOP during the total study period was 71.3%. Descriptive analyses  
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7 showed that TOP compliance did not improve during the study period. There was a large  
8  
9 spread between hospitals: one of the hospitals never performed the TOP correctly and two had  
10  
11 mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at  
12  
13 the ninth measuring moment for all the participating hospitals. The academic hospitals had a  
14  
15 mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%.  
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17 Differences between specialties were shown to exist: trauma, gastroenterology and  
18  
19 hepatology, and Ear, Nose and Throat medicine (ENT) had the highest compliance rates.  
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21 Anesthesiology, cardiothoracic surgery, and cosmetic surgery had the lowest compliance  
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23 rates. In 44% of the observations the team was not focused on the TOP and in 56%, the team  
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25 was incomplete.  
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### 32 *Multilevel regression analyses*

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34 In the first multilevel regression analysis, the changes in TOP compliance were tested. The  
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36 effect was statistically significant for the fourth-order polynomial ( $p < 0.01$ ), meaning that  
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38 TOP compliance was not linear but fluctuated over time and no clear trend was observed.  
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40 Furthermore, there were large differences between the measuring moments and between  
41  
42 individual hospitals. See Figure 1. The multilevel analysis shows that 44% (ICC = 44.01) of  
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44 the total variance in TOP compliance can be attributed to the differences between the  
45  
46 individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11  
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48 (40%). See Table 1.  
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52 When correcting for age and sex of the patient, the ICC dropped to 26% (ICC =  
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54 26.58). The relationship between the age of the patient and the TOP was found to be  
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56 significant ( $p < 0.05$ ). This relationship was tested and found to be linear. Based on the results  
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3 described above, there was no rationale to correct for time (measurement moments) in further  
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5 analyses. Observations from the different measurement moments were pooled in the  
6  
7 remaining analyses.  
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10 Separate analyses were performed for the independent variables 'hospital size',  
11  
12 'surgical specialty', and 'focus'. No statistically significant relationship was found between  
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14 hospital size and TOP compliance (data not shown in tables). A positive relationship was  
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16 found between patients undergoing ENT surgery and the TOP (reference = general surgery;  
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18  $p < 0.01$ ). Another positive relationship was found between patients undergoing ophthalmic  
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20 surgery and the TOP (reference = general surgery;  $p < 0.05$ ). See Table 2. This indicates that  
21  
22 TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic  
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24 surgery compared to patients undergoing general surgery. The relationship between the age of  
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26 the patient and TOP compliance was found to be significant ( $p < 0.05$ ) in all analyses. This  
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28 indicates that TOP compliance decreases with the patient age. The TOP is performed correctly  
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30 less often for older patients. An additional analysis was performed based on these results to  
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32 determine which of the three individual checks of the TOP attributed most to the negative  
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34 relationship between the age of the patient and TOP compliance. Table 3 shows the results of  
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36 the additional analysis. The check procedure contributes most to the negative relationship  
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38 between age of the patient and TOP compliance, this check is more often skipped when an  
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40 older patient is involved. The relationship between the focus of the team during the TOP and  
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42 the correct execution of the TOP is shown in Table 4. There is a positive significant  
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44 relationship between focus and TOP compliance, which indicates that the TOP is more often  
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46 correctly executed when the entire team is focused on the TOP and not performing any other  
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48 activities at the same time.  
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## 57 Discussion

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3 The objective of this study was to investigate the compliance at Dutch hospitals with the  
4 national guidelines of a TOP set by the Safety Program and how this changed over the final  
5 year of the program. Furthermore, we studied variables that might be associated with  
6 compliance. This study found a mean TOP compliance of 71.3%. There was no linear trend in  
7 the TOP compliance during the study period. Large differences were found between and  
8 within individual hospitals, which were partly influenced by age of the patient. The type of  
9 hospital was associated with the TOP compliance: academic hospitals had lower compliance  
10 rates than general and teaching hospitals. Given the low number of academic hospitals in this  
11 study (N=2), these findings cannot be generalized to academic hospitals as a whole. ENT  
12 medicine and ophthalmological surgery had higher TOP compliance than the reference group  
13 (general surgery). No statistically significant relationship between TOP compliance and  
14 hospital size was found. The TOP was correctly performed more often when the OR team was  
15 focused on it. The negative relationship between age of the patient and the TOP indicates that  
16 greater patient age is associated with lower TOP compliance. Of all the observed TOPs, 44%  
17 were performed without the focus of the entire team, and the team was not complete in 56%  
18 of the TOPs.  
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38 A wide range in compliance rates for surgical checklists can be found in previous  
39 studies, ranging from 12% to 99% with a mean of 75%.<sup>31-33</sup> The compliance rate (71.3%)  
40 found in our study is slightly lower than the mean rate found in other studies.  
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45 We found a difference in TOP compliance between the different types of hospitals. The  
46 general and teaching hospitals hardly differed from each other, which is interesting because a  
47 previous study<sup>34</sup> found teaching hospitals to be better at implementing checklists than general  
48 hospitals. According to the organizational learning theory, the availability of knowledge in an  
49 organization contributes to the adoption of innovations.<sup>34 35</sup> Teaching hospitals are learning  
50 environments, aimed at spreading and developing knowledge; better compliance can therefore  
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3 be expected in teaching hospitals. We found that academic hospitals showed lower TOP  
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5 compliance.  
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8 The literature is inconsistent about the influence of hospital size on the use of  
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10 checklists. Some argue that larger hospitals are better developed and use standardized  
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12 processes, which increases the quality of the hospital more often,<sup>36-38</sup> whereas others conclude  
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14 that smaller hospitals implement checklists better.<sup>39</sup> We found no relationship between TOP  
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16 compliance and hospital size. The high ICC rates found in this study suggest that the  
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18 differences between individual hospitals are high, and differences in compliance cannot be  
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20 explained by general hospital characteristics such as hospital size. The differences between  
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22 individual hospitals need to be examined in further research, but possible explanations might  
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24 be found in different organizational structures, the creation of awareness amongst healthcare  
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26 staff and differences in speaking-up cultures between hospitals.  
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30 The relationship found between surgical specialties and the TOP is different from the  
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32 results of previous studies. One study showed a difference between surgeons and  
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34 anesthesiologists<sup>40</sup> and another study showed no difference between surgical specialties at  
35  
36 all.<sup>41</sup> The TOP is a standardized procedure, and the way in which it should be carried out does  
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38 not depend on the surgical specialty performing the procedure or the patient characteristics.  
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40 Compliance with the TOP varied between different specialties and was lowest among general  
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42 surgery teams. One explanation for these differences could be that not all medical disciplines  
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44 and their scientific communities have placed the same amount of weight on a thorough  
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46 implementation of the Safety Program. If so, this could have had an influence on the sense of  
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48 urgency experienced by different specialties to comply with TOP in their daily functioning.  
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50 Further research that includes specialty-specific factors is needed to verify and deepen our  
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52 findings. The negative relationship between TOP compliance and the age of the patient was an  
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54 unexpected result, since the TOP should be executed in the same way for all patients. In  
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3 particular, the exact surgical procedure that would be carried out was less often verified with  
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5 elderly patients. Explanations might be found in factors inherently associated with the elderly  
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7 patient themselves. For example, elderly patients might be less able to verbally express  
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9 themselves to healthcare staff. On the other hand, explanations might be found in factors that  
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11 are associated with the medical procedure itself. For example, the level of standardization of  
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13 procedures that are commonly performed in the elderly population (such as hip- replacement  
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15 surgery or cataract surgery) is relatively high and it is unclear what effect this has on  
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17 compliance with TOP. Elderly people are a vulnerable group with a higher risk of  
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19 complications after surgery, therefore further in-depth research is important to explain the  
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21 differences in compliance for different age groups.  
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25 Completeness and focus are important factors in the TOP and performing it when team  
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27 members are busy with other activities creates a risk. Our study showed that focus in the team  
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29 contributes to the TOP being performed correctly. However, there was poor focus on the TOP  
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31 in almost half of the surgical procedures observed. Several possible causes could be  
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33 underlying to poor focus during the TOP, which was observed frequently in our study. Firstly,  
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35 there could have been a lack of awareness of the importance of the TOP amongst healthcare  
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37 staff. Regular emphasis on the importance of the TOP during team meetings or during the  
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39 joint briefing at the start of a new working day could help raise awareness. Secondly, when  
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41 surgery schedules are tight, healthcare staff might experience time pressure. In trying to keep  
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43 up with the schedule and being efficient, healthcare staff might be tempted to perform  
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45 multiple tasks simultaneously which in turn could negatively affect compliance with TOP.  
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50 Based on these results, it seems that hospitals still have a lot to gain by carrying out  
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52 the TOP properly. Qualitative research methods could provide insight into the underlying  
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54 reasons and incentives of why healthcare staff perform the TOP in the way they currently do.  
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3 This type of research could complement and deepen the findings that were presented in the  
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5 current study.  
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### 8 9 10 *Strengths and limitations*

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12 Our study was the first to evaluate TOP compliance over time through observations in the OR  
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14 and look at the factors associated with compliance. Our dependent variable was a process  
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16 indicator, because the incidence of wrong surgery is too low to be observed with our study  
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18 design. Based on the literature, it seems fair to assume that higher TOP compliance can  
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20 contribute to a decrease in the incidence of wrong surgery,<sup>15</sup> although this study gives no  
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22 information about the actual number of wrong surgeries and TOP compliance might not be the  
23  
24 only factor in the reduction of wrong surgery.  
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27  
28 This study has several limitations. Firstly, the presence of the observer might have  
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30 influenced the behavior of the OR staff and indirectly of our dependent variable TOP.  
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32 However, the design of our study aimed to prevent this potential observer bias, because the  
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34 precise goal of the observations was not known to the OR team. Secondly, a potential  
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36 selection bias can be found in the selection of surgical procedures on the observation days.  
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38 Surgical procedures were selected based on practical considerations: the day of the week, the  
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40 duration of the procedure, and the OR schedule. The relationships found between different  
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42 specialisms might be partially overestimated, because the same surgical teams were  
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44 sometimes observed on the same day or on different observation days. However, the overall  
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46 goal was to observe as many different surgical procedures with different teams as possible, in  
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48 order to limit potential selection bias. Thirdly, there is no information available about the  
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50 changes in compliance during the first period of the Safety Program, and hospitals may have  
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52 made progress during this period.  
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### *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.

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3 **Figure legend**  
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6 **Figure 1.** Trend in the time-out procedure compliance per hospital type, and overall mean  
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For peer review only

## Tables

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

<i>Fixed effects</i>	<b>Trend overall</b>			<b>Trend per hospital type</b>			<b>Teaching hospitals</b>			<b>Academic hospitals</b>		
	<b>N</b>	<b>Mean %</b>	<b>95% CI</b>	<b>N</b>	<b>Mean %</b>	<b>95% CI</b>	<b>N</b>	<b>Mean %</b>	<b>95% CI</b>	<b>N</b>	<b>Mean %</b>	<b>95% CI</b>
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
<i>Random effects</i>												
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.

	<b>Model 0 (time-out procedure + age + sex)</b>	<b>Model 1 (model 0 + specialties)</b>
<i>Fixed effects</i>	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties - General surgery	-	<i>Reference</i>
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)
<i>Random effects</i>		
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&lt;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)

	<b>Model 0</b> <b>(check patient + age + sex)</b>	<b>Model 1</b> <b>(check procedure + age + sex)</b>	<b>Model 2</b> <b>(check side/site + age + sex)</b>
<i>Fixed effects</i>			
	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)
<i>Random effects</i>			
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.

		<b>Model 0</b>	<b>Model 1</b>
		<b>(time-out procedure + age + sex)</b>	<b>(model 0 + focus)</b>
<i>Fixed effects</i>		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)
<i>Random effects</i>			
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&lt;0.05

### **Acknowledgements**

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### **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.

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### **Data sharing statement**

No additional data are available.

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

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

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7 **Compliance with a Time-out Procedure intended to Prevent Wrong Surgery in**  
8 **Hospitals: Results of a National Patient Safety Program**  
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12 **Abstract** (*word count: 244*)  
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14 **Objective.** To prevent wrong surgery, the WHO “Safe Surgery Checklist” was introduced in  
15 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of  
16 the surgical procedure where the patient, surgical procedure and side/site are reviewed by the  
17 surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the  
18 TOP before anesthesia in the operating room, whether compliance has changed over time, and  
19 to determine factors that are associated with compliance.  
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22 **Design.** Evaluation study involving observations.  
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25 **Setting.** Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals.  
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28 **Participants.** A random selection was made from all adult patients scheduled for elective  
29 surgery on the day of the observation, preferably involving different surgeons and different  
30 procedures.  
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34 **Results.** Mean compliance with the TOP was 71.3%. Large differences between hospitals  
35 were observed. No linear trend was found in compliance during the study period. Compliance  
36 at general and teaching hospitals was higher than at academic hospitals. Compliance  
37 decreased with the age of the patient, general surgery showed lower compliance in  
38 comparison with other specialties and compliance was higher when the team was focused on  
39 the TOP.  
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43 **Conclusions.** Large differences in compliance with the TOP were observed between  
44 participating hospitals which can be attributed at least in part to the type of hospital, surgical  
45 specialty, and patient characteristics. Hospitals do not comply consistently with national  
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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*

For peer review only

## 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.<sup>1</sup> 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.<sup>1</sup> As a result, patient safety became a major topic on the healthcare agenda.<sup>2-4</sup> Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.<sup>5</sup> 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.<sup>6</sup> 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.<sup>6</sup> More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> In the United States, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5 per 10,000 operations.<sup>3 8-13</sup>

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

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7 Commission in the United States.<sup>14</sup> Consequently, the World Health Organization (WHO)  
8 introduced a checklist in 2008 for worldwide use, called the “Safe Surgery Checklist”. In  
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10 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated  
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12 with a significant decrease in postoperative complication (30%) and mortality rates (50%).<sup>15</sup>  
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14 Based on these results, the WHO estimated that implementing the checklist could save  
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16 500,000 lives every year worldwide.<sup>15</sup> Other studies provided evidence supporting the use of  
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18 surgical checklists as well.<sup>16-19</sup> In the Netherlands, the SURgical PATient Safety System  
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20 (SURPASS) was developed with the same intention. It is based on safety checks used in the  
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22 aviation industry to reduce human error.<sup>20</sup> Research on the external validation of the  
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24 SURPASS shows a reduction in unintentional harm.<sup>21-23</sup>  
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26 Each of the checklists mentioned above comprises a time-out procedure (TOP). Errors  
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28 can be avoided by including a preoperative discussion just before the start of the surgical  
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30 procedure. This takes place during a time-out involving a review of the names and roles of all  
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32 team members, characteristics of the patient, the operation plan, familiarity with the  
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34 procedure, the presence of the correct materials/equipment, and potential issues for the  
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36 patient.<sup>24,25</sup> Although evidence is scarce, ~~It~~ it is likely that these TOPs reduce uncertainties in  
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38 the OR among the surgical team and reduce the risk of wrong surgery. The TOP is the final  
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40 step before the start of the surgical procedure and is therefore crucial in preventing wrong  
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42 surgery. A TOP is carried out just before anesthesia,<sup>26</sup> and consists of three checks (the patient,  
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44 the procedure and the side/site), all of equal importance in preventing wrong surgery.

45 The aim of this study is to evaluate the extent to which hospitals carry out the TOP before  
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47 anesthesia in the OR, whether compliance has changed over time, and to determine factors  
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49 that are associated with the TOP compliance. Insights into compliance with the TOP and the  
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51 factors associated with compliance are important because they have the potential to improve  
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53 the TOP and reduce adverse events in surgical processes throughout the world. This study was  
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7 carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital  
8 Patient Safety Program (hereinafter “Safety Program”) that was carried out during the final  
9 year of the program. (Box 1.).  
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14 *Box 1. The Dutch Hospital Patient Safety Program*  
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16 The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce  
17 preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.<sup>26</sup>  
18 The Safety Program consisted of ten patient safety themes and clinical guidelines were  
19 developed for each theme. Hospitals were given five years to implement these guidelines.  
20 One of the themes was prevention of wrong surgery. There are several risk factors for wrong  
21 surgery, e.g. insufficient compliance, inadequate identification and verification and bad  
22 preoperative planning.<sup>27 28</sup> The Safety Program therefore instructed the participating Dutch  
23 hospitals to implement several steps to decrease wrong surgery, based on the SURPASS  
24 checklist. One of the steps is identification and verification by means of a TOP consisting of  
25 checks on the correct patient, correct side, and correct intervention.<sup>29</sup>  
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27 Based on the goals of the Safety Program, it was expected that the compliance with the TOP  
28 would increase over time and would become more visible during the final year of the program when  
29 hospitals approached the public deadline at the end of 2012.  
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32 The research questions are:  
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35 1. *To what extent do Dutch hospitals comply with the time-out procedure before anesthesia*  
36 *in the operating room?*  
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38 2. *How has the compliance with the time-out procedure changed during the final year of the*  
39 *Safety Program?*  
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41 3. *What factors are associated with compliance with the time-out procedure?*  
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46 **Methods**  
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48 *Study design*  
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50 This study was part of a larger evaluation study of the Safety Program that was carried out  
51 between November 2011 and December 2012 in eighteen Dutch hospitals (about 20% of all  
52 Dutch hospitals). The study protocol was granted approval by the VU University Medical  
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7 Center ethical review board in Amsterdam. Hospitals were randomly selected using a  
8 stratified sample based on geographical regions and hospital type. Two academic hospitals,  
9 four teaching hospitals and twelve general hospitals were included in this study. All hospitals  
10 consented to the study and were informed about further practical issues. Twelve observers  
11 participated in this study. To limit inter observer variability, all observers were trained prior to the start  
12 of the observations. Moreover, ~~and~~ regular feedback meetings were held where observers exchanged  
13 experiences and discussed how to deal with certain situations and observations at the OR. A random  
14 selection was made on the day of the observation from all adult patients scheduled for elective  
15 surgery on the day of the observation. The goal was to have ten observation days per hospital  
16 at intervals of four to six weeks, and to observe six to ten surgical procedures per day,  
17 preferably involving different surgeons and different procedures. One observer per surgical  
18 procedure evaluated whether the TOP was carried out before anesthesia, using a standardized  
19 recording form that covered the various aspects of doing the TOP: checking the patient,  
20 procedure, and side/site, attention of the team (focus), completeness of the team,  
21 interruptions, and several background variables such as the type of surgical procedure, the  
22 patient's age, and sex. The OR team was not aware of the exact subject matter of the  
23 observation; the observer was instructed to introduce the study in abstract terms, referring to it  
24 as a study about the surgical process in general.

#### 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 *TOP compliance*

44 The dependent variable was whether the TOP was done correctly and was dichotomous  
45 (yes/no). This variable was used to examine mean TOP compliance and the changes in  
46 compliance during the study period. A correct TOP consists of three checks: patient,  
47 procedure, and side/site. Since all three checks are equally important for preventing wrong  
48 surgery, the TOP was only deemed correct when all three checks were performed. The  
49 Furthermore, during a TOP the entire OR team gathers around the patient during a TOP and  
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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 an 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 join the team after the TOP had been completed, team completeness was scores as 'no'.

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### *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

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7 was chosen to correct for the fact that the surgical procedures are not independent from each  
8 other, but clustered within hospitals. Time was modeled by adding ten indicator variables for  
9 the ~~time points~~measurement moments (removing the intercept from the model); trends were  
10 tested using polynomial contrasts (to the 4<sup>th</sup> order) to study changes over time. Variance and  
11 intraclass correlations (ICCs) were calculated to assess the clustering of TOP compliance at  
12 the hospital and surgical procedure level. An ICC of 20% was seen as moderate.<sup>30</sup> The  
13 changes over time were also analyzed for the different hospital types to determine the  
14 relationship between hospital type and the changes in TOP compliance. Separate logistic  
15 multilevel analyses were performed for each independent variable to analyze the effects of the  
16 independent variables 'hospital size' and 'surgical specialty'; this was necessary because not  
17 enough units at the highest level (hospitals) were available to have more than one independent  
18 variable in a model.<sup>30</sup> There were not enough units at the highest level (hospitals) to model  
19 the effect of hospital type on the TOP score in the pooled analyses. Age and sex of the patient  
20 were added as covariates in all analyses. All descriptive analyses were performed using SPSS  
21 version PASW Statistics 18. The multilevel analyses were performed using MlwiN version  
22 2.24 (using PQL, second order, unconstrained level 1 variance, options).  
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## 40 Results

### 41 *Descriptive analyses*

42 1281 surgical procedures were observed at the participating hospitals. After patients younger  
43 than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96.  
44 The gender distribution was 41.4% male, 53.8% female, and 4.8% not registered~~unknown~~.  
45 The range in types of surgical procedures was broad; observers had been instructed to observe  
46 different procedures and observed surgical procedures of in total 13 different specialties.  
47 Mean compliance with the TOP during the total study period was 71.3%. Descriptive analyses  
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7 showed that TOP compliance did not improve during the study period. There was a large  
8 spread between hospitals: one of the hospitals never performed the TOP correctly and two had  
9 mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at  
10 the ninth measuring moment for all the participating hospitals. The academic hospitals had a  
11 mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%.  
12 Differences between specialties were shown to exist: trauma, gastroenterology and  
13 hepatology, and [Ear, Nose and Throat](#) medicine ([ENT](#)) had the highest compliance rates.  
14 Anesthesiology, cardiothoracic surgery, and cosmetic surgery had the lowest compliance  
15 rates. In 44% of the observations the team was not focused on the TOP and in 56%, the team  
16 was incomplete.  
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#### 28 *Multilevel regression analyses*

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30 In the first multilevel regression analysis, the changes in TOP compliance were tested. The  
31 effect was statistically significant for the fourth-order polynomial ( $p < 0.01$ ), meaning that  
32 TOP compliance was not linear but fluctuated over time and no clear trend was observed.  
33 Furthermore, there were large differences between the measuring moments and between  
34 individual hospitals. See Figure 1. The multilevel analysis shows that 44% (ICC = 44.01) of  
35 the total variance in TOP compliance can be attributed to the differences between the  
36 individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11  
37 (40%). See Table 1.  
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45 When correcting for age and sex of the patient, the ICC dropped to 26% (ICC =  
46 26.58). The relationship between the age of the patient and the TOP was found to be  
47 significant ( $p < 0.05$ ). This relationship was tested and found to be linear. Based on the results  
48 described above, there was no rationale to correct for time (measurement [momentspoints](#)) in  
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7 further analyses. Observations from the different measurement ~~points-moments~~ were pooled  
8 in the remaining analyses.  
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10 Separate analyses were performed for the independent variables 'hospital size',  
11 'surgical specialty', and 'focus'. No statistically significant relationship was found between  
12 hospital size and TOP compliance (data not shown in tables). A positive relationship was  
13 found between patients undergoing ENT surgery and the TOP (reference = general surgery;  
14  $p < 0.01$ ). Another positive relationship was found between patients undergoing ophthalmic  
15 surgery and the TOP (reference = general surgery;  $p < 0.05$ ). See Table 2. This indicates that  
16 TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic  
17 surgery compared to patients undergoing general surgery. The relationship between the age of  
18 the patient and TOP compliance was found to be significant ( $p < 0.05$ ) in all analyses. This  
19 indicates that TOP compliance decreases with the patient age, ~~in all analyses~~. The TOP is  
20 performed correctly less often for older patients. An additional analysis was performed based  
21 on these results to determine which of the three individual checks of the TOP attributed most  
22 to the negative relationship between the age of the patient and TOP compliance. Table 3  
23 shows the results of the additional analysis. The check procedure contributes most to the  
24 negative relationship between age of the patient and TOP compliance, this check is more often  
25 skipped when an older patient is involved. The relationship between the focus of the team  
26 during the TOP and the correct execution of the TOP is shown in Table 4. There is a positive  
27 significant relationship between focus and TOP compliance, which indicates that the TOP is  
28 more often correctly executed when the entire team is focused on the TOP and not performing  
29 any other activities at the same time.  
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## 51 Discussion

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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%.<sup>31-33</sup> 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<sup>34</sup> 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.<sup>34 35</sup> Teaching hospitals are learning environments, aimed at spreading and developing knowledge; better compliance can therefore

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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,<sup>36-38</sup> whereas others conclude that smaller hospitals implement checklists better.<sup>39</sup> 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 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<sup>40</sup> and another study showed no difference between surgical specialties at all.<sup>41</sup> 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

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

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

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

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7 Based on these results, it seems that hospitals still have a lot to gain by carrying out  
8 the TOP properly. [Qualitative research methods could provide insight into the underlying](#)  
9 [reasons and incentives of why healthcare staff perform the TOP in the way they currently do.](#)  
10 [This type of research could complement and deepen the findings that were presented in the](#)  
11 [current study.](#)  
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### 18 19 20 *Strengths and limitations*

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22 Our study was the first to evaluate TOP compliance over time through observations in the OR  
23 and look at the factors associated with compliance. Our dependent variable was a process  
24 indicator, because the incidence of wrong surgery is too low to be observed with our study  
25 design. Based on the literature, it ~~is seems~~ fair to assume that higher TOP compliance ~~will can~~  
26 ~~contribute to decrease a decrease in~~ the incidence of wrong surgery,<sup>15</sup> although this study gives  
27 no information about the actual number of wrong surgeries ~~and TOP compliance might not be~~  
28 ~~the only factor in the reduction of wrong surgery.~~ -  
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36 This study has several limitations. Firstly, the presence of the observer might have  
37 influenced the behavior of the OR staff and indirectly of our dependent variable TOP.  
38 However, the design of our study aimed to prevent this potential observer bias, because the  
39 precise goal of the observations was not known to the OR team. Secondly, a potential  
40 selection bias can be found in the selection of surgical procedures on the observation days.  
41 Surgical procedures were selected based on practical considerations: the day of the week, the  
42 duration of the procedure, and the OR schedule. The relationships found between different  
43 specialisms might be partially overestimated, because the same surgical teams were  
44 sometimes observed on the same day or on different observation days. However, the overall  
45 goal was to observe as many different surgical procedures with different teams as possible, in  
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7 order to limit potential selection bias. Thirdly, there is no information available about the  
8 changes in compliance during the first period of the Safety Program, and hospitals may have  
9 made progress during this period.  
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### 12 13 14 *Conclusions*

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16 The mean TOP compliance was 71.3% during the final year of the Safety Program and no  
17 improvement in compliance over time was found. Large differences were found between  
18 hospitals, and these differences were influenced by age of the patient. Compliance was  
19 influenced by several factors: ~~academic hospitals performed the TOP less often than general~~  
20 ~~and teaching hospitals~~ hospital type, ~~different surgical specialties showed different~~  
21 ~~compliances with the TOP~~, age of the patient ~~the TOP was performed less often for older~~  
22 ~~patients, and TOP compliance was higher when the entire team and focus of the team during~~  
23 ~~the TOP was focused on the TOP.~~ Furthermore, in almost half the TOPs, the team was not  
24 focused on the TOP or the team was incomplete. Despite the fact that almost three quarter of  
25 operations are preceded by a TOP, hospitals need to make an effort to improve TOP  
26 compliance and the way in which the TOP is carried out in order to prevent wrong surgery  
27 from happening in the future.  
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7 **Figure legend**  
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9 **Figure 1.** Trend in the time-out procedure compliance per hospital type, and overall mean  
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Tables

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

<i>Fixed effects</i>	<u>Trend overall</u>			<u>Trend per hospital type</u>			<u>Teaching hospitals</u>			<u>Academic hospitals</u>		
	<u>N</u>	<u>Mean %</u>	<u>95% CI</u>	<u>N</u>	<u>Mean %</u>	<u>95% CI</u>	<u>N</u>	<u>Mean %</u>	<u>95% CI</u>	<u>N</u>	<u>Mean %</u>	<u>95% CI</u>
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
<i>Random effects</i>												
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

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

	<b>Model 0</b> <b>(time-out procedure + age + sex)</b>	<b>Model 1</b> <b>(model 0 + specialties)</b>
<i>Fixed effects</i>	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties - General surgery	-	<i>Reference</i>
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)
<i>Random effects</i>		
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&lt;0.05

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**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)

	<b>Model 0 (check patient + age + sex)</b>	<b>Model 1 (check procedure + age + sex)</b>	<b>Model 2 (check side/site + age + sex)</b>
<i>Fixed effects</i>			
	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)
<i>Random effects</i>			
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.

	<b>Model 0 (time-out procedure + age + sex)</b>	<b>Model 1 (model 0 + focus)</b>
<i>Fixed effects</i>	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)
	Patient's sex	-0.012 (0.162)
<i>Random effects</i>		
Variance components:		
	Intraclass correlation	8.971
	hospital (level 2)	0.324 (0.154) *
	surgical procedure (level 1)	0.968 (0.042)

\*p&lt;0.05

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### **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.

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### **Data sharing statement**

No additional data are available.



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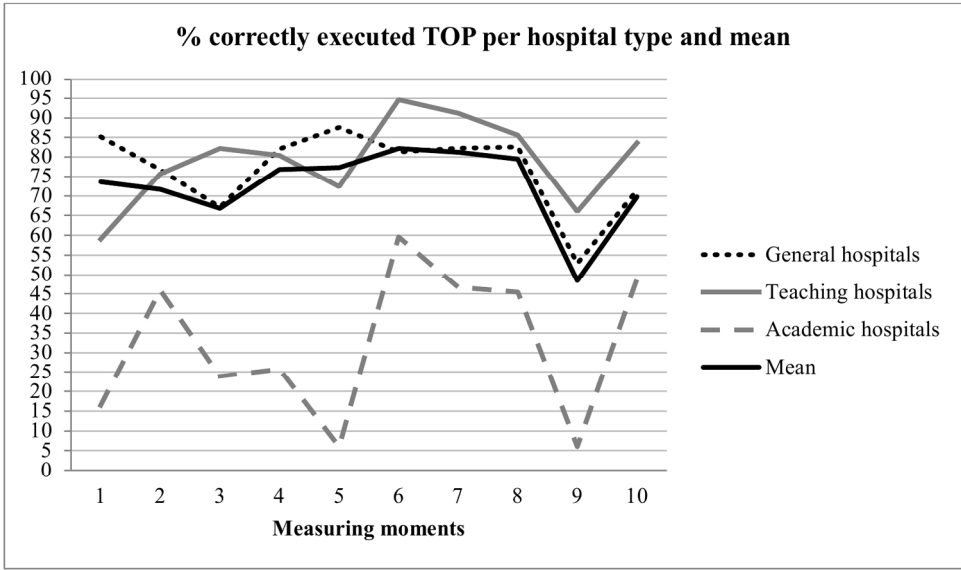
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