Effects of the Introduction of the WHO "Surgical Safety Checklist" on In-Hospital Mortality

A Cohort Study

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Objective: To evaluate the effect of implementation of the WHO's Surgical Safety Checklist on mortality and to determine to what extent the potential effect was related to checklist compliance.

Background: Marked reductions in postoperative complications after implementation of a surgical checklist have been reported. As compliance to the checklists was reported to be incomplete, it remains unclear whether the benefits obtained were through actual completion of a checklist or from an increase in overall awareness of patient safety issues.

Methods: This retrospective cohort study included 25,513 adult patients undergoing non-day case surgery in a tertiary university hospital. Hospital administrative data and electronic patient records were used to obtain data. In-hospital mortality within 30 days after surgery was the main outcome and effect estimates were adjusted for patient characteristics, surgical specialty and comorbidity.

Results: After checklist implementation, crude mortality decreased from 3.13% to 2.85% ($P = 0.19$). After adjustment for baseline differences, mortality was significantly decreased after checklist implementation (odds ratio [OR] 0.85; 95% CI, 0.73–0.98). This effect was strongly related to checklist compliance: the OR for the association between full checklist completion and outcome was 0.44 (95% CI, 0.28–0.70), compared to 1.09 (95% CI, 0.78–1.52) and 1.16 (95% CI, 0.86–1.56) for partial or noncompliance, respectively.

Conclusions: Implementation of the WHO Surgical Checklist reduced in-hospital 30-day mortality. Although the impact on outcome was smaller than previously reported, the effect depended crucially upon checklist compliance.

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Ethical approval: According to Dutch law, as only routinely collected patient data were used and data were anonymized before analysis, hospital ethics board approval was not required.

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Although surgical and anesthetic caregivers seek to deliver optimal quality in perioperative service, surgery still carries considerable risks for individual patients.[1–3] As with the aviation industry, checklists have been developed to enhance teamwork and improve handover, thereby minimizing avoidable errors and complications including mortality.[4,5] Both public opinion and health authorities increasingly demand that professionals use such checklists in perioperative care. For example, the British National Patient Safety Agency issued an alert requiring all National Health Services to use a checklist by 2010.[6] The Dutch Health Care Inspectorate mandated nationwide perioperative checklist implementation in late 2008 and now measures compliance through spot audit.[7]

The marked reduction in postoperative complications recently reported after implementation of an elaborate checklist (SURgical PAtient Safety System: SURPASS) further supports enforced implementation of perioperative checklists.[8] The SURPASS study confirmed the results of the WHO Surgical Safety Checklist study, which reported a mortality reduction from 1.5% to 0.8% in hospitals around the globe.[9,10] However, the size of these checklists differ markedly; whereas the WHO checklist comprises just 19 items that need to be checked at 3 points around the time of surgery, the SURPASS checklist contains 124 items that need to be collected at 6 time points from hospital admission to discharge. It remains unclear what constitutes an optimal surgical checklist.[11] Both studies used mortality and complication rates as outcome measures. However, as compliance was incomplete in both, it remains unclear whether the benefit obtained was through actual completion of the checklist or from an increase in overall awareness of patient safety issues.

In accordance with the requirements from the Dutch Health Care Inspectorate, our hospital has implemented the WHO checklist. This study aimed to evaluate the effect of this checklist on in-hospital 30-day mortality, and in particular the impact of compliance.

METHODS

Patients

This retrospective cohort study included all adult patients who underwent a surgical procedure requiring hospital admission to the University Medical Center Utrecht (The Netherlands) in the period between January 1, 2007 and September 30, 2010. The last procedure was counted in patients undergoing more than 1 procedure within that period.

Data Collection

Patients fulfilling the inclusion criteria were selected from the hospital's intraoperative record-keeping system (Vierkleurenpen, The Netherlands). This system contains procedure-related data such as date and time of surgery and type of anesthesia. The unique hospital patient identifier was used to merge these data with those from the hospital information system, the surgical scheduling system

(CS-OK Chipsoft, The Netherlands) and the electronic preoperative record. These latter systems contain patient demographic data, surgical specialty, WHO checklist compliance, date of outpatient preanesthesia evaluation (if any), American Society of Anesthesiologists (ASA) physical status classification and date of hospital discharge or date of in-hospital death, whichever is applicable. Causes of death were obtained from discharge letters to the family physician describing diagnoses that were found during the admission. All diagnoses extracted from these letters by hospital administrators and stored using ICD-9 codes were downloaded from the hospital information system. Multiple diagnoses were summarized into 1 "main diagnosis."

Intervention

The WHO checklist was formally introduced into our hospital on April 1, 2009.[10] As encouraged by the WHO, we made adaptations to the checklist to enhance local applicability, resulting in a 22 item checklist (see Supplemental Digital Content, available at: http://links.lww.com/SLA/A185). The "sign-in" part of the original checklist was replaced by a team briefing at 8.00 a.m. where each operative patient was briefly reviewed by the entire surgical and anesthesia team, using the "sign-in" items. To ensure that some important checklist items (eg, patient identity, planned or performed procedure, known allergies) were also available to caregivers before a patient entered and after a patient left the operating room, structured handovers were implemented from ward to operating room holding area, and from operating room to recovery room. In addition to the WHO checklist implementation, strict hygiene rules were re-enforced.

Besides encouraging implementation by making adaptations to the checklist, information was provided both in regular meetings as well as in extra meetings with the entire operating room staff (surgeons, anesthesiologists, and nurses), in which the importance of the checklist was emphasized. In addition, the checklist was made available in poster format in every operating room as well as electronically in the scheduling system. Moreover, compliance was evaluated monthly by analyzing the data in the scheduling system and providing an overview of this analysis to team managers.

Finally, operating room circulating nurses were made responsible for documentation of compliance with each individual checklist item in the surgical scheduling system. At the time of documentation, these nurses were unaware of the study. Checklist compliance was defined as "not completed" (none of the 22 items documented), "partially completed" (at least 1 item documented but not all) and "fully completed" (all items documented). Only the briefing (sign-in), time-out and sign-out procedures (see Supplemental Digital Content, available at: http://links.lww.com/SLA/A185) were documented electronically and available for analysis.

Main Outcome Measures

The primary outcome was in-hospital mortality within 30 days after surgery.

Confounders

The association between checklist introduction and in-hospital 30-day mortality may have been influenced by temporal changes in baseline characteristics of the patient population. We therefore considered gender, age, emergency surgery, type of anesthesia, availability of an outpatient preanesthesia evaluation record, ASA physical status and surgical specialty as potential confounding factors in the analyses. All procedures performed within a dedicated emergency operating room, as well as those performed in any operating room with a start time after 4.59 PM or before 7.30 AM or during the weekend were considered to be emergency surgery. The type of anesthesia was defined as either general (with or without any regional technique) or regional. The ASA physical status classification is a 5-point scale ranging from ASA 1 (healthy patient) to ASA 5 (moribund patient not expected to survive without surgery, such as a patient with a ruptured aortic aneurysm).[12] As the rate of death during the 45-month study period could have fluctuated due to other circumstances, in the final analysis "time" (included as 15 trimesters) was also considered as a potential confounder.

Statistical Analysis

Analysis was performed using SPSS release 17.0 for Windows. Baseline characteristics of patients operated before and after implementation of the checklist were compared with Pearson's χ^2-test or with Student's t-test where appropriate. A P value below 0.05 was considered statistically significant. To determine compliance with the particular parts of the total checklist, the percentages of completed sign-in, time-out, and sign out forms were calculated separately. Differences in causes of death between the intervention periods were compared with univariable logistic regression analysis.

Multivariable logistic regression analysis was used to adjust the association between intervention and outcome for confounding factors. First, the intervention was included as a binary variable (surgery pre- or postchecklist implementation). Secondly, the intervention was included based on checklist compliance (either preimplementation, or postimplementation noncompleted, completed in part, or fully completed). In this analysis, "time" was included as an additional confounder. The analysis was repeated after imputing missing values for ASA classification, using multiple imputations.

To exclude any remaining selection bias due to emergency patients with a lower level of preparation, the analysis was repeated in patients for whom an outpatient preanesthesia evaluation record was available as such patients can be assumed to have been adequately prepared for elective surgery. Moreover, to compare the different levels of compliance after implementation, and to further eliminate any possible "time" effect, the analysis was repeated separately for the postimplementation period. Finally, as we considered that it takes time to effectively implement a checklist, the analysis was repeated separately for the first 9 months and last 9 months after implementation.

Results of the logistic regression analysis are expressed as odds ratios (OR) with 95% confidence intervals (95% CI).

RESULTS

During the study period, 25,513 patients underwent surgery, of which 11,151 (43.7%) were operated in the period after checklist implementation (Table 1). In this latter period, the checklist was fully completed (all 22 items) in 4353 (39.0%) of the 11,151 patients (Table 1). Sign-in was completed in 6537 patients (58.6%), time-out in 6598 patients (59.2%), and sign-out in 4977 patients (44.6%). Checklist compliance increased over time (Figure 1). The median number of items documented was 16 (interquartile range 0–22).

After implementation of the checklist, mortality decreased from 3.13% to 2.85% (OR 0.91; 95% CI, 0.78–1.05; Table 2). Most causes of death did not significantly differ between the implementation periods, except for multiorgan failure (OR 0.28; 95% CI, 0.14–0.58) and major bleeding (OR 2.58; 95% CI, 1.10–6.03; Table 2).

Figure 2 shows the unadjusted mortality rate per trimester and the unadjusted mortality rates for the 3 compliance groups after April 1, 2009. Adjustment of the association between implementation period and outcome for all variables listed in Table 1 revealed a decreased mortality after checklist implementation (OR 0.85; 95% CI, 0.73–0.98).

When studying actual checklist compliance and its association with outcome, univariable analysis yielded ORs of 0.23 (95% CI, 0.16–0.33), 1.16 (95% CI, 0.95–1.41), and 1.57 (95% CI, 1.31–1.89)

TABLE 1. Baseline Characteristics of the Cohort (N = 25,513) by Period

	Preimplementation *N = 14,362*	Postimplementation *N = 11,151*	*P*
Male gender	7380 (51.4)	5,861 (52.6)	0.062
Mean age in years (SD)	53.7 (17.9)	54.2 (17.7)	0.057
Emergency surgery	2391 (16.6)	1894 (17.0)	0.475
General anesthesia	13,190 (91.8)	10,363 (92.9)	0.001
Preanesthesia record available	9816 (68.3)	7389 (66.3)	0.001
ASA classification			0.001
I	3480 (24.2)	2459 (22.1)	
II	4883 (34.0)	3903 (35.0)	
III	1175 (8.2)	917 (8.2)	
IV	41 (0.3)	44 (0.4)	
Not specified	4783 (33.3)	3828 (34.3)	
Surgical specialty			0.001
General surgery	2629 (18.3)	1934 (17.3)	
Cardiothoracic surgery	2085 (14.3)	1636 (14.7)	
Neurosurgery	1813 (12.6)	1524 (13.7)	
Ear–nose–throat surgery	1770 (12.3)	1391 (12.5)	
Orthopedic surgery	1229 (8.6)	882 (7.9)	
Gynecology	1059 (7.4)	729 (6.5)	
Plastic surgery	887 (6.2)	707 (6.3)	
Vascular surgery	865 (6.0)	771 (6.9)	
Eye surgery	705 (4.9)	501 (4.5)	
Dental surgery	686 (4.8)	591 (5.3)	
Urology	661 (4.6)	485 (4.3)	
Checklist compliance			n.a.
Before implementation, not completed	14,362 (100)	—	
After implementation, not completed	—	3304 (29.6)	
After implementation, partly completed	—	3494 (31.3)	
After implementation, fully completed	—	4353 (39.0)	

Preimplementation: from January 1, 2007 to March 31, 2009 and postimplementation: from April 1, 2009 to September 30, 2010. Data are absolute numbers (column%), unless otherwise specified.

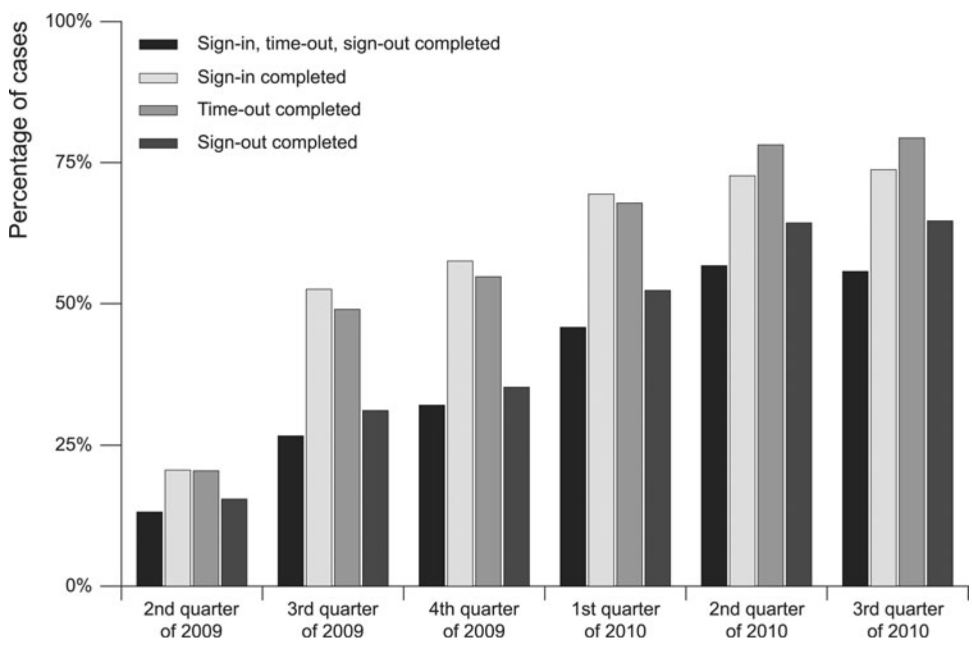

FIGURE 1. Checklist compliance per trimester after April 1, 2009.

TABLE 2. Summarized Diagnoses Documented During Admission of Those Patients Who Died In-Hospital Within 30 Days After Surgery (N = 768)

Diagnosis	Preimplementation *N = 14,362*	Postimplementation *N = 11,151*	Odds Ratio (95% CI)
Cancer	79 (0.55)	45 (0.40)	0.7 (0.5–1.1)
Septic shock/sepsis*	75 (0.52)	58 (0.52)	1.0 (0.7–1.4)
Neurologic†	69 (0.48)	68 (0.61)	1.3 (0.9–1.8)
Major adverse cardiac event‡	60 (0.42)	43 (0.39)	0.9 (0.6–1.4)
Major (multi-) trauma	50 (0.35)	35 (0.31)	0.9 (0.6–1.4)
Multiorgan failure	41 (0.29)	9 (0.08)	0.3 (0.1–0.6)
Minor trauma§	28 (0.19)	14 (0.13)	0.6 (0.3–1.2)
Ruptured aortic aneurysm	15 (0.10)	14 (0.13)	1.2 (0.6–2.5)
Respiratory¶	15 (0.10)	9 (0.08)	0.8 (0.3–1.8)
Major uncontrollable bleeding	8 (0.06)	16 (0.14)	2.6 (1.1–6.0)
Other/Unknown	10 (0.07)	7 (0.06)	0.9 (0.3–2.4)
Total	450 (3.13)	318 (2.85)	0.9 (0.8–1.0)

Results are subdivided by checklist implementation period. Data are absolute numbers (column%). The odds ratio's are unadjusted for baseline differences.
*Includes mediastinitis, peritonitis, pancreatitis, endocarditis, bowel ischemia, bowel perforation.
†Includes stroke, subarachnoid hemorrhage, obstructive hydrocephalus.
‡Includes cardiac arrest, myocardial infarction, sustained ventricular fibrillation or ventricular tachycardia.
§Includes hip fracture, subdural hematoma.
¶Includes pulmonary embolism, respiratory insufficiency unknown cause.

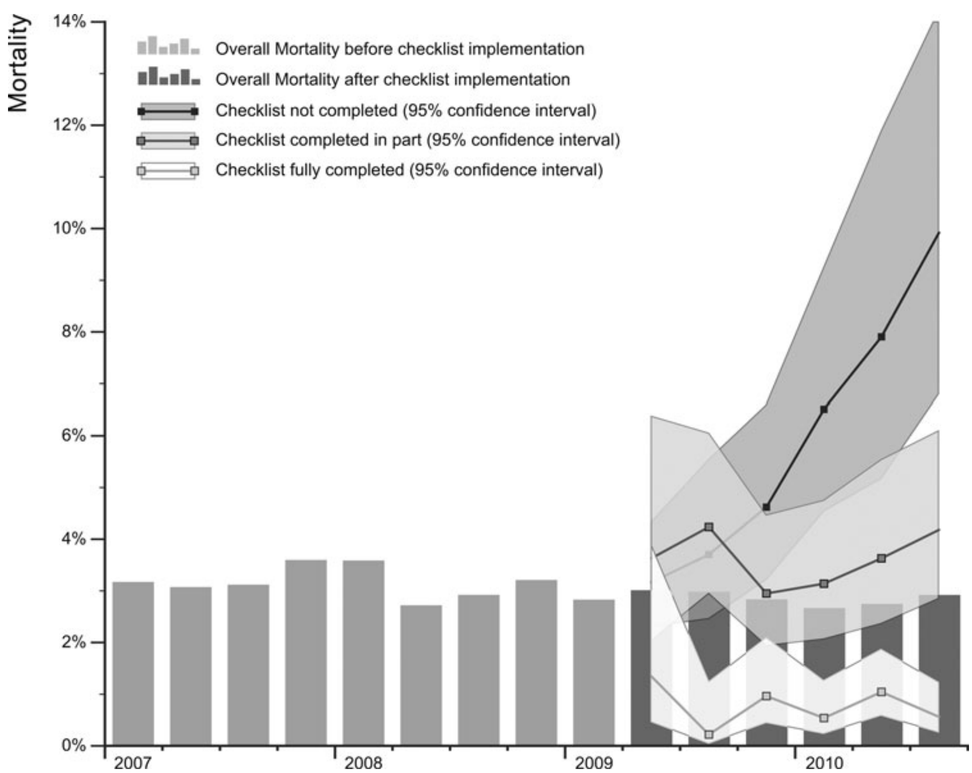

FIGURE 2. In-hospital 30-day mortality during the study period. Bars show overall mortality rate per trimester, lines show mortality rates with 95% confidence interval per trimester for the 3 compliance groups (completed, completed in part, and noncompleted checklists) after checklist implementation at April 1, 2009.

for completed, partially completed, and noncompleted checklists, respectively. After adjustment, checklist compliance remained significantly related to outcome, with ORs of 0.44 (95% CI, 0.28–0.70), 1.09 (95% CI, 0.78–1.52), and 1.16 (95% CI, 0.86–1.56) for completed, partially completed, and noncompleted checklists, respectively (Table 3).

Analysis after imputing missing values for ASA classification yielded similar results: the adjusted OR for implementation period was 0.82 (95% CI, 0.68–0.99) and the OR for a fully completed checklist was 0.41 (95% CI, 0.23–0.70).

In the 17,205 patients with a completed preanaesthesia evaluation record, 160 patients died within 30 days (0.93%). In these

TABLE 3. Association Between WHO's Checklist Compliance and 30-Day In-Hospital Mortality, Adjusted for Confounding Factors

	Beta*	Odds Ratio (95% CI)
Checklist compliance		
Before implementation, not completed	Reference	
After implementation, fully completed	–0.81	0.44 (0.28–0.70)
After implementation, partly completed	0.09	1.09 (0.78–1.52)
After implementation, not completed	0.15	1.16 (0.86–1.56)
Age (per year >)	0.03	1.03 (1.02–1.04)
Male gender	–0.05	0.95 (0.81–1.11)
Emergency surgery	0.76	2.14 (1.76–2.61)
General anesthesia	–0.16	0.85 (0.62–1.16)
Preanesthesia record available	–1.30	0.27 (0.11–0.67)
ASA classification		
I	Reference	
II	0.85	2.35 (1.26–4.36)
III	1.86	6.40 (3.40–12.0)
IV	3.48	32.3 (13.9–75.2)
Not specified	1.37	3.93 (1.36–11.3)
Surgical specialty		
General surgery	Reference	
Cardiothoracic surgery	–0.54	0.58 (0.45–0.76)
Neurosurgery	0.34	1.40 (1.13–1.73)
Ear–nose–throat surgery	–0.26	0.77 (0.55–1.08)
Orthopedic surgery	–1.06	0.35 (0.22–0.54)
Gynecology	–1.27	0.28 (0.15–0.53)
Plastic surgery	–1.44	0.24 (0.11–0.51)
Vascular surgery	0.45	1.57 (1.22–2.02)
Eye surgery	–2.60	0.07 (0.02–0.30)
Dental surgery	–1.26	0.28 (0.15–0.53)
Urology	–1.24	0.29 (0.15–0.57)
Time (per 3 months >)	–0.02	0.98 (0.95–1.02)

*Beta is the regression coefficient from the logistic regression model.

patients, the OR for the period after checklist implementation compared to the preimplementation period was 0.82 (95% CI, 0.59–1.14) and the ORs ratios for a full, partial and noncompleted checklist were 0.54 (95% CI, 0.25–1.17), 0.66 (95% CI, 0.32–1.37), and 1.16 (95% CI, 0.59–2.29), respectively.

Similar results were found when analyzing only those patients who underwent surgery in the postimplementation period. Compared to noncompleted checklists, the OR for full and partial completed checklists were 0.34 (95% CI, 0.22–0.51) and 0.90 (95% CI, 0.69–1.17), respectively. The analysis of the first and last 9 months after implementation revealed ORs for fully completed checklists of 0.54 (95% CI, 0.27–1.10) and 0.21 (95% CI, 0.12–0.36), respectively compared to noncompleted checklists in these respective periods.

DISCUSSION

After implementation of the WHO Surgical Safety Checklist in our hospital, in-hospital 30-day mortality decreased from 3.13% to 2.85%. After adjustment for differences in case-mix before and after implementation, the difference did become statistically significant with an OR of 0.85 (95% CI, 0.73–0.98). This reduced mortality rate was strongly associated with checklist compliance: mortality was significantly lower in patients with completed checklists, whereas in those patients with partial or noncompleted checklists the mortality rate remained unchanged.

This study, in which we retrospectively compared mortality rates before and after implementation of a perioperative checklist in a single center, has some obvious limitations. First, although the effect measures were adjusted for known confounders and baseline differences, and the analysis on compliance with the checklist included "time" as a proxy for other changes, residual confounding might still exist. Second, a Hawthorne effect may be a factor related to implementation of the checklist. Despite the disadvantages of a retrospective design, in this type of research it actually might prove advantageous as it allowed us to assess checklist compliance through routinely collected data with the operating room team remaining unaware of any study participation. In contrast, in both the SURPASS and WHO checklist studies the caregivers were aware that their compliance was being recorded. The WHO study has been criticized for a potential Hawthorne effect arising from its study design.[9,10,13] Third, as the checklist was fully completed in only 39% of our patients and the median number of completed items was 16 (73% of the 22 items), checklist compliance was clearly far from perfect in our hospital. Moreover, actual adherence to the checklist may have been lower than documented adherence. Nevertheless, our results are comparable to those from the SURPASS study, where the median number of items completed was 80 (65% of the 124 items).

In contrast to the WHO checklist study, we were able to adjust the effect estimates for surgical specialty and comorbidity by using the ASA physical status classification.[10,12] This latter variable had missing values in 34% of our patients, in large part due to cardiac and emergency surgical cases not having electronic registration of the ASA classification resulting from the absence of a preoperative screening visit. Obviously, such patients are sicker and more likely to die, and thus would have been classified as ASA 3, 4, or even 5. Although over time the checklist was completed in an increasing number of patients (Fig. 1), it was less often completed in these sicker and urgent/emergent patients. Figure 2 shows an increase in mortality over time in patients with noncompleted checklists. This suggests that the checklist was increasingly being completed in patients with a lower urgency and a lower chance of dying, whereas the checklist was still noncompleted in highly urgent patients with a greater chance of dying. This is confirmed by the analysis of the first and second 9 months after implementation. After adjustment, the association of compliance with outcome seems to be stronger over the second 9 months postimplementation (OR 0.21), as compared to the first 9 months (OR 0.54). The question arises whether selective noncompliance in urgent cases limited the adjustment effect for ASA classification in the multivariable analysis. Therefore, as a sensitivity analysis, we included patients with missing ASA values in an "ASA not specified" category (Table 3) and, in addition, performed a separate analysis after imputation of the missing values. Although residual confounding might still exist, the analysis for those cases with an available outpatient preanesthesia record was a complete case analysis and yielded comparable effect measures.

Our results seem to confirm those reported previously, albeit with a smaller effect. Both WHO and SURPASS studies showed a 47% reduction in-hospital mortality (from 1.5% to 0.8%).[8,10] In contrast, our results are highly comparable to the reported 18% reduction in postoperative mortality after the implementation of a surgical team training program, including operating room briefings and checklists, in the Veterans Health Administration facilities.[14] All these studies had lower absolute mortality rates than ours, most likely due to inclusion of nonuniversity hospitals with a different case-mix. In our study checklist compliance was lowest in the sicker and more urgent cases with the highest probability to die. Although the SURPASS authors reported that the degree of checklist compliance was related to the number of complications, we were unable to show any beneficial effect of partial checklist compliance on mortality (OR 1.09; 95% CI, 0.78–1.52).

As with these previous studies, we cannot explain precisely why implementation of a checklist would have an effect on surgical mortality. One could argue that the checklist was developed to prevent team-based problems requiring coordination of care, such as administration of antibiotics, as opposed to complications related to poor judgment or technical error. After implementation, we found a decrease in mortality due to multiorgan failure (from 0.29% to 0.08%), and a slight increase in mortality due to major bleeding (from 0.06% to 0.14%; Table 2). However, these numbers seem too small to draw solid inferences.

Simply enforcing the use of checklists will likely not suffice when substantial improvements in safety culture are desired.[15,16] Whether enforcing the use of checklists in emergency cases will have an impact—positive or negative—on mortality requires further study.

It is conceivable that surgical teams who work conscientiously and meticulously both on the ward and in the operating room are more likely to adopt and complete the checklist, even in emergency situations. Arguably, patients cared for by such teams may survive more often. Our results could therefore reflect a more general attitude of (surgical) teams towards patient safety and efforts to improve safety. To confirm or refute this hypothesis requires a qualitative approach to elicit facilitators and barriers to perioperative checklist implementation, and their relation with attitudes towards patient safety, especially in the sicker, more urgent patients with the highest risk of death.

This study showed that postoperative mortality was decreased after implementation of the WHO surgical checklist. Mortality was strongly associated with checklist compliance, suggesting that large variations in the level of implementation for different groups of patients need to be reduced. If reduced postoperative mortality is indeed related to safety culture and human factors, checklist compliance could be used as a performance indicator for multidisciplinary surgical teams. Which checklist should be chosen seems less important and may largely depend on local hospital culture. Although the SURPASS checklist is very comprehensive and prescriptive, we considered the WHO checklist simpler, more focused on teamwork, pragmatic and relatively easy to implement.

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WAvK designed the study. RGH, EEHLvA, RKJS, LPER, and WFB were responsible for implementation of the checklist. LvW was responsible for data collection and management. WAvK, THK, and LMP performed the data analysis, all authors contributed to the subsequent interpretation of the results. WAvK, RGH, THK, CJK, WFB, and LMP contributed equally to the writing of the manuscript, all authors contributed to the revision of the manuscript for important intellectual content. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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