

SPECIAL ARTICLE

Effect of a Comprehensive Surgical Safety System on Patient Outcomes

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ABSTRACT

BACKGROUND

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Adverse events in patients who have undergone surgery constitute a large proportion of iatrogenic illnesses. Most surgical safety interventions have focused on the operating room. Since more than half of all surgical errors occur outside the operating room, it is likely that a more substantial improvement in outcomes can be achieved by targeting the entire surgical pathway.

METHODS

We examined the effects on patient outcomes of a comprehensive, multidisciplinary surgical safety checklist, including items such as medication, marking of the operative side, and use of postoperative instructions. The checklist was implemented in six hospitals with high standards of care. All complications occurring during admission were documented prospectively. We compared the rate of complications during a baseline period of 3 months with the rate during a 3-month period after implementation of the checklist, while accounting for potential confounders. Similar data were collected from a control group of five hospitals.

RESULTS

In a comparison of 3760 patients observed before implementation of the checklist with 3820 patients observed after implementation, the total number of complications per 100 patients decreased from 27.3 (95% confidence interval [CI], 25.9 to 28.7) to 16.7 (95% CI, 15.6 to 17.9), for an absolute risk reduction of 10.6 (95% CI, 8.7 to 12.4). The proportion of patients with one or more complications decreased from 15.4% to 10.6% ($P < 0.001$). In-hospital mortality decreased from 1.5% (95% CI, 1.2 to 2.0) to 0.8% (95% CI, 0.6 to 1.1), for an absolute risk reduction of 0.7 percentage points (95% CI, 0.2 to 1.2). Outcomes did not change in the control hospitals.

CONCLUSIONS

Implementation of this comprehensive checklist was associated with a reduction in surgical complications and mortality in hospitals with a high standard of care. (Netherlands Trial Register number, NTR1943.)

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HOSPITALS ARE NOT THE SAFE PLACES we would like them to be. A systematic review has shown that 1 in every 150 patients admitted to a hospital dies as a consequence of an adverse event and that almost two thirds of in-hospital events are associated with surgical care.¹ In recognition of the disproportionate number of such events that are associated with surgical care, several interventions have been proposed to increase patient safety, including relegating surgical procedures to high-volume centers, establishing training programs for laparoscopic surgery, and improving the quality of teamwork in the operating room.²⁻⁴ In addition, a number of surgical checklists have been developed.⁵⁻⁹

The Safe Surgery Saves Lives Study Group at the World Health Organization (WHO) recently published the results of instituting a perioperative surgical safety checklist.⁵ The use of this checklist in eight hospitals around the world was associated with a reduction in major complications from 11.0% before introduction of the checklist to 7.0% afterward. However, the standardization of surgical processes should not be limited to the operating room: several studies have shown that the majority of surgical errors (53 to 70%) occur outside the operating room, before or after surgery, making it likely that a more substantial improvement in safety could be achieved by targeting the entire surgical pathway.¹⁰⁻¹²

This awareness has led to the development of the Surgical Patient Safety System (SURPASS) checklist, a multidisciplinary checklist that follows the surgical pathway from admission to discharge. We evaluated the effect of the use of this checklist on patient outcomes in a controlled, multicenter setting in teaching and academic hospitals with high baseline standards of health care.

METHODS

CHECKLIST AND STUDY DESIGN

The development and validation of the checklist have been described elsewhere.¹⁰ The checklist is divided into parts that correspond to the stages of care in the surgical pathway (preoperative, operative, recovery or intensive care, and postoperative), and it is multidisciplinary — the ward doctor, nurse, surgeon, anesthesiologist, and operating assistant are all responsible for completion of parts of the checklist. Items on the check-

list include, among others, a review of imaging studies, an accounting of all necessary equipment and materials, the marking of the patient's operative side, the hand-off of postoperative instructions, and the provision of medication prescriptions to the patient at discharge (for details, see part 1 of the Supplementary Appendix, available with the full text of this article at NEJM.org).

The effects of the checklist on patient outcomes were studied in a controlled, multicenter, prospective study comparing outcomes before and after implementation of the intervention, from October 2007 through March 2009. The checklist was implemented in two academic centers and four teaching hospitals in the Netherlands, all representing a high standard of health care (Table 1). Before implementation of the checklist, all hospitals used numerous separate checks and protocols for various parts of the surgical pathway, including protocols for marking the operative side and medication checks. In each participating hospital, a project team was assembled, consisting of a surgeon, an anesthesiologist, and a quality-control officer. The implementation was presented to all departments as a quality-improvement project, without emphasizing its research aspect.

The amount of time required to implement the checklist was estimated at 6 to 9 months. The baseline measurement period was 3 months. Complications were documented in all adults who underwent general surgery and were discharged during this period. Patients who were discharged without having undergone surgery and patients with a hospital stay of less than 24 hours were excluded. After implementation of the checklist during a 9-month period, a postimplementation assessment was conducted for 3 months. All adults with a minimum hospital stay of 24 hours who underwent general surgery were included in the postimplementation cohort, not just the patients whose checklist had been completed.

A random sample of checklists from each hospital was entered into an online central database to estimate compliance rates. Compliance was expressed as the percentage of items that had been completed per checklist, and complication rates were compared between the group of patients whose checklists were above the median percentage of completed items and the group whose checklists were at or below the median.

Five control hospitals were selected — one

Table 1. Characteristics of the Hospitals.*

Hospital	Type of Hospital	No. of Beds	Level of Specialized Care and Accreditation
Intervention hospitals			
Academic Medical Center, Amsterdam	Academic	1002	NFU hospital
Amphia Hospital, Breda	Tertiary teaching	954	STZ hospital, NIAZ accreditation
Jeroen Bosch Hospital, Den Bosch	Tertiary teaching	560	STZ hospital
Maastricht University Medical Center, Maastricht	Academic	715	NFU hospital, NIAZ accreditation
Onze Lieve Vrouwe Gasthuis, Amsterdam	Tertiary teaching	555	STZ hospital, NIAZ accreditation
Rijnland Hospital, Leiderdorp	Regional teaching	470	NIAZ accreditation
Control hospitals			
Deventer Hospital, Deventer	Tertiary teaching	380	STZ hospital
Gelre Hospital, Apeldoorn	Tertiary teaching	622	STZ hospital, NIAZ accreditation
Leiden University Medical Center, Leiden	Academic	882	NFU hospital, NIAZ accreditation
Reinier de Graaf Hospital, Delft	Tertiary teaching	817	STZ hospital
Tergooi Hospital, Hilversum	Regional teaching	440	NIAZ accreditation pending

* All hospitals are in the Netherlands. Hospitals that belong to the Dutch Federation of University Medical Centers (NFU),¹³ which account for 9% of all the hospitals in the Netherlands, provide the most specialized care. The Dutch Institute for Health Care Accreditation (NIAZ), part of the International Society for Quality in Healthcare,¹⁴ provides accreditation to hospitals that meet international standards developed and tested for external evaluation of health care organizations. Hospitals that belong to the Association of Tertiary Medical Teaching Hospitals (STZ),¹⁵ which account for 29% of hospitals in the Netherlands, provide highly specialized medical care (the next level of specialization below that of NFU hospitals).

academic center and four teaching hospitals — all of which had high standards of care and were qualitatively similar to the six intervention hospitals (Table 1). In the control hospitals, data on patients and outcomes were collected in the same manner over the same periods of time as in the intervention hospitals.

The study was reviewed by the institutional review board of the Academic Medical Center and conducted in accordance with the protocol. Because this was an observational study in which the effect of a quality-improvement intervention was assessed with the use of outcome measures that are already routinely collected, the board determined that formal review and informed consent were not required.

DATA COLLECTION

Data on age, sex, American Society of Anesthesiologists (ASA) score (a measure of coexisting conditions), length of stay, and number and type of surgical procedures were collected from hospital administrative data. Outcome data were collected from the prospective Dutch National Surgical Adverse Event Registration System (LHCR),

a nationwide registration system that has been in use for more than 10 years.¹⁶⁻¹⁸ The outcome grades in this system correspond to grades in the recently described Accordion Severity Grading System of Surgical Complications.¹⁹ All postoperative complications are prospectively registered by ward doctors during the patient's hospital stay, discussed by staff at the time of discharge, and entered into an electronic database. The LHCR system is comprehensive. All complications are registered, including, for example, a postponed procedure, and more than one complication per patient can be registered. Complications that arose after discharge were not documented.

STATISTICAL ANALYSIS

All recorded complications were classified into 12 categories (part 2 of the Supplementary Appendix). The number of complications per 100 patients per category and the proportion of patients with one or more complications were reported. Differences between patients undergoing surgery during the baseline and postimplementation periods were assessed with the use of the Mann-Whitney U-test (for age and length of stay) or the

Pearson chi-square test (for sex, ASA score, type of surgical procedure [or type of first procedure, in the case of patients who underwent more than one], and urgency of medical need) to identify potential confounders. Zero-inflated negative binomial (ZINB) regression analyses were performed to assess the effect of the checklist on the number of complications while accounting for potential confounders. ZINB regression analysis is a suitable approach to counting data when there is overdispersion (the variance is greater than the mean), an excess of zero counts, or concern that complications may be correlated.²⁰ Two ZINB models were tested to assess the robustness of the influence of the checklist. The first model addressed the checklist alone; the second accounted for all potential confounders (sex, age, ASA score, hospital, type of surgical procedure, and urgency of medical need). Two-tailed tests of significance were used, and a P value of less than 0.05 was considered to indicate statistical significance. Exact 95% confidence intervals were calculated for the rate of complications (expressed as the number of complications per 100 patients) and the rate ratio. Confidence intervals for the absolute reduction in the risk of complications were calculated with the use of Wilson scores.²¹ Logistic-regression analysis was performed to assess the effect of the checklist on mortality, with correction for the same potential confounders. The analyses were performed with the use of SPSS software, version 16.0, and SAS software, version 9.1.

RESULTS

STUDY COHORTS

The preimplementation cohort consisted of 3760 patients, of whom 10.2% underwent more than one procedure; the total number of surgical procedures was 4364 (Table 2). In the postimplementation cohort, 3820 patients underwent 4387 procedures; 9.7% underwent more than one procedure.

Characteristics of the patients are listed in Table 2. Some differences between the preimplementation and postimplementation cohorts were observed. Patients in the postimplementation cohort were more likely to undergo surgery for a gastrointestinal condition or for trauma and less likely to undergo surgery for a vascular condition ($P < 0.001$).

A random sample of checklists used for pro-

cedures in the postimplementation period (1146 of 4387 procedures, or 26%) was entered into the central database (Table 2). Among these checklists, a median of 80% (interquartile range, 69 to 91) of items per checklist had been completed (Table 2, and part 3 of the Supplementary Appendix).

OUTCOMES IN INTERVENTION HOSPITALS

During the 3-month preimplementation period, complication rates were stable (Fig. 1). After implementation of the checklist, the total number of complications decreased from 27.3 per 100 patients (95% confidence interval [CI], 25.9 to 28.7) to 16.7 per 100 patients (95% CI, 15.6 to 17.9), corresponding to an absolute reduction of 10.6 complications (95% CI, 8.7 to 12.4) (Table 3 and Fig. 1) and to an uncorrected rate ratio of 0.613 (95% CI, 0.545 to 0.681). There were differences among hospitals in the effect of the checklist. The absolute reduction in the number of complications ranged from 0.3 to 19.5 per 100 patients (part 4 of the Supplementary Appendix). The proportion of patients with one or more complications was 15.4% in the preimplementation period versus 10.6% in the postimplementation period ($P < 0.001$) (Fig. 2).

The complication rate was 7.1 per 100 patients among the 566 patients for whom the extent of checklist completion was above the median, as compared with a rate of 18.8 per 100 among the 580 patients for whom checklist completion was at or below the median (absolute risk reduction, 11.7 complications; 95% CI, 7.9 to 15.6).

In-hospital mortality decreased from 1.5% (95% CI, 1.2 to 2.0) to 0.8%, with an absolute risk reduction of 0.7 percentage points (95% CI, 0.2 to 1.2) (Table 3) and an uncorrected rate ratio of 0.52 (95% CI, 0.34 to 0.81). The proportion of patients who had temporary disability and the proportion of patients requiring a second surgical procedure to resolve a complication also decreased significantly, by 2.7 percentage points (95% CI, 1.5 to 4.0) and 1.1 percentage points (95% CI, 0.4 to 1.9), respectively (Table 3).

The ZINB model showed that the checklist, when controlled for potential confounding factors (i.e., sex, age, ASA score, hospital, type of surgical procedure, and urgency of medical need), was associated with an absolute reduction of 9.7 complications (95% CI, 7.8 to 11.5) and a rate

Table 2. Characteristics of Patients in Intervention and Control Hospitals before and after Implementation of the Surgical Safety Checklist.*

Characteristic	Intervention Hospitals (N=6)			Control Hospitals (N=5)		
	Before Implementation	After Implementation	P Value	Before Implementation	After Implementation	P Value
No. of patients	3760	3820		2592	2664	
No of procedures†	4364	4387		2924	3058	
Mean length of stay (days)	9.1	8.5	0.15	7.0	7.4	0.052
Mean age (yr)	57.7±17.8	56.8±18.7	0.11	58.8±17.9	59.5±17.7	0.16
Male sex (%)	49.3	47.4	0.10	46.6	46.8	0.93
ASA score (%)‡			0.84			0.39
1	29.8	29.9		30.0	29.6	
2	41.8	41.2		49.9	48.2	
3	25.1	25.5		18.8	20.3	
4	2.9	3.1		1.2	1.8	
5	0.4	0.3		0.1	0.1	
No documented ASA score (no.)	452	362		840	561	
Surgical intervention required in <24 hr (%)	19.5	21.2	0.09	19.9	21.2	0.24
Surgical procedures (%)§			<0.001			0.005
Gastrointestinal procedures, including relaparotomies	36.0	39.2		34.6	31.9	
Procedures for treatment of trauma	18.2	20.6		19.2	22.5	
Vascular or renal procedures, amputation	16.5	11.6		16.2	15.1	
Abdominal-wall procedures, diagnostic laparoscopy	13.2	13.6		12.2	10.9	
Endocrine procedures, including breast surgery	6.1	6.1		10.2	10.7	
Other or unknown	9.9	8.9		7.5	8.9	
Checklist sample¶						
No. of checklists		1146				
Items completed (%)						
Median		80				
Interquartile range		69–91				

* Plus–minus values are means ±SD. Data on individual hospitals can be found in part 4 of the Supplementary Appendix. ASA denotes American Society of Anesthesiologists.

† Some patients underwent more than one procedure; the data include all procedures.

‡ The ASA score is a measure of physical status for patients undergoing surgery. A score of 1 denotes a healthy condition, a score of 2 mild systemic disease, a score of 3 severe, systemic, function-limiting disease, a score of 4 life-threatening disease, and a score of 5 terminal disease.

§ For cases in which there was more than one procedure per patient, only the initial procedure was reported.

¶ Checklists in this sample, which represented 26% of all procedures performed during the postimplementation period, were entered, item by item, into a central online database.

ratio for total complications of 0.646 (95% CI, 0.579 to 0.714), which are similar to the crude results of 10.6 and 0.613, respectively. The corrected rate ratio for mortality was 0.54 (95% CI, 0.33 to 0.88).

OUTCOMES IN CONTROL HOSPITALS

In the five control hospitals, complication rates and mortality did not change significantly throughout the study period (Table 3 and Fig. 1 and 2). The number of complications was 30.4 per 100

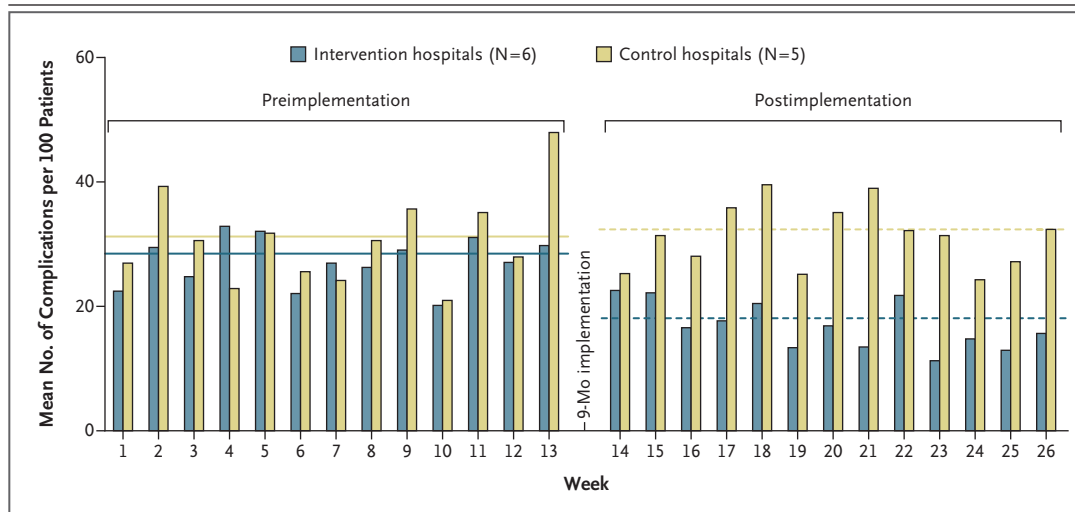


Figure 1. Mean Number of Complications in Intervention Hospitals and Control Hospitals before and after Implementation of the Surgical Safety Checklist.

The solid horizontal lines show the overall mean number of complications before implementation of the checklist, and the dashed horizontal lines show the mean number after implementation. The change in the mean number of complications from the preimplementation period to the postimplementation period was significant in the intervention hospitals ($P<0.001$) but not in the control hospitals ($P=0.81$).

patients during the first study period as compared with 31.2 per 100 during the second period (absolute risk reduction, -0.8 ; 95% CI, -3.2 to 1.7), and the proportions of patients with one or more complications in the first study period were 17.6% and 17.9%, respectively ($P=0.95$). Mortality was 1.2%, as compared with 1.1% in the second period (absolute risk reduction, 0.1 percentage points; 95% CI, -0.5 to 0.7).

DISCUSSION

In this multicenter study, implementation of the SURPASS checklist in six teaching and academic hospitals with a high baseline standard of care was associated with a reduction in the postoperative complication rate from 27.3 per 100 patients before implementation to 16.7 per 100 afterward and a reduction in in-hospital mortality from 1.5 to 0.8%. The reduction in complication rates was consistent over the 3 months of the postimplementation period and remained significant after adjustment for potential confounding factors. During the same study period, outcomes did not change in five control hospitals with similar characteristics, increasing the likelihood that the decrease in complication rates in the intervention

centers was a result of the use of the checklist. This hypothesis is further supported by the significantly lower complication rate among patients for whom 80% or more of the checklist items were completed than among those for whom a smaller proportion of the checklist items were completed.

Improved outcomes after implementation may be explained by a number of mechanisms. The checklist is designed to incorporate all existing protocols and checks in order to provide a comprehensive framework for the surgical pathway, minimize information loss during transfers from one stage of the pathway to the next, and promote interdisciplinary communication. Specific items on the checklist may directly prevent adverse events. For example, checking for timely cessation of anticoagulant agents may directly prevent perioperative bleeding. In addition, the implementation of the checklist triggers improvements in the entire surgical pathway. In all participating hospitals, many processes were optimized, including digital registration of blood-type cross-matching (incorporation into electronic records), standardization of protocols, and standardization of the timing of antibiotic prophylaxis. Finally, the checklist may lead to improved outcomes by

Table 3. Complication and Outcome Rates in Intervention and Control Hospitals before and after Implementation of the Surgical Safety Checklist.*

Variable	Intervention Hospitals (N=6)			Control Hospitals (N=5)			
	Before Implementation <i>no./100 patients</i>	After Implementation	Absolute Risk Reduction (95% CI)	Before Implementation <i>no./100 patients</i>	After Implementation	Absolute Risk Reduction (95% CI)	P Value
Complications							
Respiratory complication	3.3	2.1		3.7	3.8		0.91
Pneumonia	2.0	1.4		2.2	2.3		
Other	1.3	0.7		1.5	1.5		
Cardiac complication	2.3	1.3	0.001	1.6	1.4		0.72
Arrhythmia	0.7	0.5		0.8	1.0		
Congestive heart failure	0.7	0.3		0.4	0.2		
Other	1.0	0.5		0.4	0.2		
Abdominal complication	3.5	2.4	0.04	3.1	3.1		0.56
Anastomotic leakage	1.3	0.7		0.9	0.9		
Other	2.2	1.6		2.2	2.3		
Infection	4.8	3.3	0.006	6.8	6.3		0.22
Surgical site	3.8	2.7		4.2	3.8		
Other	1.1	0.6		2.5	2.5		
Wound complication	1.5	0.8	0.008	1.0	1.2		0.56
Dehiscence	0.9	0.4		0.6	0.8		
Other	0.6	0.4		0.4	0.5		
Bleeding	2.0	0.9	0.001	2.0	2.7		0.12
Genitourinary complication	2.6	1.7	0.007	3.3	2.8		0.28
Urinary tract infection	1.4	1.0		1.7	1.5		
Other	1.2	0.7		1.6	1.3		
Nervous system complication	2.1	1.2	0.005	2.2	2.6		0.43
Delirium	1.0	0.7		1.4	1.6		
Other	1.1	0.5		0.9	1.0		
Technical or intraoperative problem†	1.2	0.8	0.08	1.2	1.7		0.25

Organizational problem‡	0.9	0.4	0.007	0.4	0.3	0.77
Disturbed function§	1.4	0.7	0.002	1.3	1.4	0.90
Other	1.7	1.2	0.15	3.7	3.9	0.89
Total	27.3	16.7	<0.001	30.4	31.2	-0.8 (-3.2 to 1.7)
Outcomes¶						
No disability	0.2	0.2	0.78	0.2	0.1	0.1 (-0.1 to 0.3)
Temporary disability, reoperation not required	9.4	6.6	<0.001	11.1	11.3	-0.2 (-1.8 to 1.5)
Temporary disability, reoperation required	3.7	2.5	0.005	4.6	4.8	-0.2 (-1.3 to 0.9)
Permanent disability	0.5	0.4	0.46	0.5	0.6	-0.1 (-0.5 to 0.3)
Death	1.5	0.8	0.003	1.2	1.1	0.1 (-0.5 to 0.7)

* Data on individual hospitals are available in part 4 of the Supplementary Appendix.

† Included in this category are intraoperative injuries and technical complications, such as fracture of osteosynthesis material (see part 2 of the Supplementary Appendix for details).

‡ Included in this category are cancellations of surgery for administrative reasons (see part 2 of the Supplementary Appendix for details).

§ This category includes conditions such as hypertension, hypokalemia, and disseminated intravascular coagulation (see part 2 of the Supplementary Appendix for details).

¶ Classifications for outcomes are from the Dutch National Surgical Adverse Event Registration System. For patients with multiple complications, the most severe outcome was reported.

improving teamwork, communication, and attitudes toward quality and safety.

A number of factors might account for the differences in baseline complication rates among the hospitals. One important factor is the difference in case mix. Patients at academic hospitals generally have a larger number of coexisting conditions and undergo more extensive procedures, increasing the likelihood of complications. Another factor that may account for the difference in complication rates is differences in aspects of registration. Although the hospitals' process of documenting complications was uniform, there might have been differences between hospitals in the vigilance and precision with which adverse outcomes were registered. In addition, there were considerable differences across hospitals in the effect of the checklist: the absolute reduction in the number of complications ranged from 19.5 to 0.3 per 100 patients. A number of reasons might account for this difference. First, there were differences in compliance with the use of the checklist at the hospitals. In addition, there might have been hospitals at which checklist integration was not yet optimal after 9 months owing to the existing culture in the hospital or department or to specific implementation strategies.

The improvements in outcome that we observed confirm the results that were achieved with the use of the WHO's surgical safety checklist. However, in the present study, only hospitals with a high baseline standard of care were included, whereas the hospitals included in the WHO study were more diverse. Another difference between this study and the WHO study is the scope of the intervention: the WHO's checklist is intended for use in the operating room only, whereas the SURPASS checklist covers the entire surgical pathway. Many of the risks along the surgical pathway should be corrected at an earlier stage than just before surgery. To delay certain checks until the patient is lying under the operating lights may lead to postponement of surgery, compromised safety, or both. In addition, many adverse events originate in the postoperative stage.^{10-12,22}

This study has several limitations. First, because it had preimplementation and postimplementation phases, any change that was observed in relation to the intervention might have been influenced by other changes in each hospital that occurred over time or by differences in case

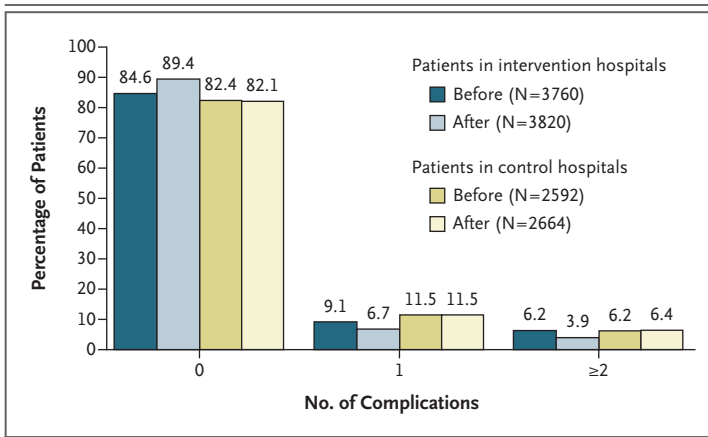


Figure 2. Number of Complications per Patient in Intervention Hospitals and Control Hospitals before and after Implementation of the Surgical Safety Checklist.

The change in the number of complications per patient from the preimplementation period to the postimplementation period was significant in the intervention hospitals ($P < 0.001$) but not in the control hospitals ($P = 0.95$).

mix. However, a randomized study design was not feasible because of the contamination effect in interventions of this kind: hospital personnel using the checklist for one patient will still work according to the checklist, consciously or subconsciously, when providing care for a patient not assigned to the checklist.²³ In an effort to minimize the influence of changes over time, the measurements performed before and after implementation took place within a year of each other. No other fundamental changes in policy or surgical care occurred in any of the participating hospitals during that year, making it unlikely that the decrease in complications was attributable to factors other than the introduction of the SURPASS checklist. This hypothesis is supported by the observation that in the control hospitals, outcomes did not change significantly from the first 3 months of the study (the baseline period) to the last 3 months (corresponding to the postimplementation period).

A second limitation is the manner in which outcome data were collected. Documentation of complications by physicians has proved to be subject to underreporting.^{24,25} However, the LHCR has been used to monitor the quality of surgical care in the Netherlands for more than 10

years and is well integrated into daily clinical care. It includes prospective documentation of complications during the hospital stay, with a daily plenary meeting at which staff and residents discuss all complications for patients being discharged. We have no reason to suspect that any possible underregistration was inconsistent over time.

Third, the documentation of complications was limited to the period of admission. Data on complications and deaths occurring after discharge were not collected.

Finally, in interpreting our results, it is important to note that health care providers did not fully comply with the checklist. Compliance rates were monitored in only a sample of patients for whom the checklist had been used. In this sample of 26% of patients who underwent surgical procedures in the postimplementation period, a median of 80% of items per checklist were completed. Although we have no reason to suspect that the checklist was not used at all for a large number of patients, suboptimal compliance during the study period may have led to an underestimation of the effect of the checklist.

The implementation of this checklist requires a considerable amount of time and effort. The checklist is quite comprehensive, requiring the input of care providers from multiple disciplines involved in the care of patients undergoing surgery. By providing a blueprint of the ideal situation, the system reveals safety risks and triggers improvements in all stages of the surgical pathway. These improvements are part of its beneficial effect; when a substantial improvement in patient safety is desired, merely developing and enforcing a checklist do not suffice.^{26,27} A “culture of safety” is required in the organization, with concerted efforts to reduce risks.

In conclusion, our study shows that the use of the comprehensive SURPASS checklist is associated with reductions in complications and mortality among adults undergoing general surgery in hospitals that have a high baseline standard of care.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org

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REFERENCES

1. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care* 2008;17:216-23.
2. Gurusamy K, Aggarwal R, Palanivelu L, Davidson BR. Systematic review of randomized controlled trials on the effectiveness of virtual reality training for laparoscopic surgery. *Br J Surg* 2008;95:1088-97.
3. Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. *Ann Intern Med* 2002;137:511-20.
4. McCulloch P, Mishra A, Handa A, Dale T, Hirst G, Catchpole K. The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre. *Qual Saf Health Care* 2009;18:109-15.
5. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009;360:491-9.
6. Lingard L, Regehr G, Orser B, et al. Evaluation of a preoperative checklist and team briefing among surgeons, nurses, and anesthesiologists to reduce failures in communication. *Arch Surg* 2008;143:12-7.
7. Makary MA, Holzmüller CG, Thompson D, et al. Operating room briefings: working on the same page. *Jt Comm J Qual Patient Saf* 2006;32:351-5.
8. Paige JT, Aaron DL, Yang T, et al. Implementation of a preoperative briefing protocol improves accuracy of teamwork assessment in the operating room. *Am Surg* 2008;74:817-23.
9. Verdaasdonk EG, Stassen LP, Widhiamara PP, Dankelman J. Requirements for the design and implementation of checklists for surgical processes. *Surg Endosc* 2009;23:715-26.
10. de Vries EN, Hollmann MW, Smorenburg SM, Gouma DJ, Boermeester MA. Development and validation of the SURGical Patient Safety System (SURPASS) checklist. *Qual Saf Health Care* 2009;18:121-6.
11. Greenberg CC, Regenbogen SE, Studert DM, et al. Patterns of communication breakdowns resulting in injury to surgical patients. *J Am Coll Surg* 2007;204:533-40.
12. Griffen FD, Stephens LS, Alexander JB, et al. The American College of Surgeons' closed claims study: new insights for improving care. *J Am Coll Surg* 2007;204:561-9.
13. Dutch Federation for University Medical Centres home page. (<http://www.nfu.nl/index.php?id=21>)
14. International Society for Quality in Healthcare home page. (<http://www.isqua.org/>)
15. Association of Tertiary Medical Teaching Hospitals (STZ) home page. (<http://www.stz-ziekenhuizen.nl/english.html>)
16. Marang-van de Mheen PJ, Kievit J. Automated registration of adverse events in surgical patients in the Netherlands: current status. *Ned Tijdschr Geneesk* 2003;147:1273-7. (In Dutch.)
17. Marang-van de Mheen PJ, van Hane-gem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. *Qual Saf Health Care* 2005;14:378-82.
18. Marang-van de Mheen PJ, Stadlander MC, Kievit J. Adverse outcomes in surgical patients: implementation of a nationwide reporting system. *Qual Saf Health Care* 2006;15:320-4.
19. Strasberg SM, Linehan DC, Hawkins WG. The accordion severity grading system of surgical complications. *Ann Surg* 2009;250:177-86.
20. Elhai JD, Calhoun PS, Ford JD. Statistical procedures for analyzing mental health services data. *Psychiatry Res* 2008;160:129-36.
21. Bender R. Calculating confidence intervals for the number needed to treat. *Control Clin Trials* 2001;22:102-10.
22. Marang-van de Mheen PJ, van Duijn-Bakker N, Kievit J. Adverse outcomes after discharge: occurrence, treatment and determinants. *Qual Saf Health Care* 2008;17:47-52.
23. Brown C, Hofer T, Johal A, et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 2: study design. *Qual Saf Health Care* 2008;17:163-9.
24. Feldman L, Barkun J, Barkun A, Sampalis J, Rosenberg L. Measuring postoperative complications in general surgery patients using an outcomes-based strategy: comparison with complications presented at morbidity and mortality rounds. *Surgery* 1997;122:711-9.
25. Hutter MM, Rowell KS, Devaney LA, et al. Identification of surgical complications and deaths: an assessment of the traditional surgical morbidity and mortality conference compared with the American College of Surgeons–National Surgical Quality Improvement Program. *J Am Coll Surg* 2006;203:618-24.
26. Bosk CL, Dixon-Woods M, Goeschel CA, Pronovost PJ. Reality check for checklists. *Lancet* 2009;374:444-5.
27. Clarke JR, Johnston J, Finley ED. Getting surgery right. *Ann Surg* 2007;246:395-403.

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