DEPARTMENT OF ANESTHESIOLOGY

JOURNAL CLUB

Wednesday April 23, 2014
1800 HOURS

LOCATION:
Thai House Cuisine
183-185 Sydenham Street, Kingston

PRESENTING ARTICLES:
Dr. Brian Mahoney & Dr. Tanya Griffiths

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SUGGESTED GUIDELINES FOR CRITICAL APPRAISAL OF PAPERS
ANESTHESIOLOGY JOURNAL CLUB
QUEEN'S UNIVERSITY

Two presenters will be assigned to choose and present summaries of their papers. Ideally the two papers will represent similar topics but contrasting research methodologies. The focus remains on critical appraisal of the research and manuscript, more than on the actual contents of the article. Each presenter will then lead an open discussion about the article, based around the guidelines below. The object is to open up the appraisal to wide discussion involving all participants, who will be expected to contribute pending suspension of bar privileges.

GENERAL

1. Title of paper: Does it seem like an important problem? Does it reflect the purpose/results?
2. Authors, institution and country of origin

INTRODUCTION

1. What is the problem being addressed?
2. What is the current state of knowledge of the problem studied?
3. What is the hypothesis being tested?
4. How does testing the hypothesis help solve the stated problem?

METHODOLOGY

1. Study design:
   a) Clinical trial vs. systematic review/meta-analysis
   b) Prospective vs. retrospective
   c) Observational vs. Experimental
   d) Randomized or not
   e) Blinded or not

2. Population studied:
   a) Human, animal, other
   b) Justification
   c) Control groups: experimental vs. historical
   d) Is the sample size/power calculated, and how?
   e) Is the population similar to your own practice?
   f) Single vs. multi-centre

3. Is the study ethically sound?
   a) Clinical equipoise
   b) Does treatment meet standard of care (esp controls)?
   c) Appropriate consent and institutional ethics approval

4. Exclusions: what groups are excluded and why?

5. Experimental protocol
   a) Is it designed to test the hypothesis?

b) Is it detailed enough to be reproducible?
c) Is the methodology validated?
d) Are the drugs/equipment used detailed?
e) How does the randomization take place?

6. What are the primary endpoints?
7. Is power sufficient to justify secondary endpoints?
8. Is the protocol clinically relevant?
9. Data collection and analysis
10. Statistical analysis: Is it appropriate? Are results

RESULTS

1. Are the groups comparable?
2. Were any subjects/data eliminated?
3. Analyzed by intent to treat?
4. Are adequate details of results provided? - data, graphs, tables

DISCUSSION

1. What is the main conclusion of the study?
2. Do the results support this conclusion?
3. Do the results address the stated purpose/hypothesis of the study?
4. How do the authors explain the results obtained?
5. Are there any alternative interpretations to the data?
6. Are the results clinically as well statistically relevant?
7. How do the results compare with those of previous studies?
8. What do the results add to the existing literature?
9. What are the limitations of the methods or analysis used?
10. What are the unanswered questions for future work?

APPLICABILITY OF THE PAPER

1. Have you learned something important from reading this paper?
2. Will the results of this study alter your clinical practice?
3. Was the food and wine up to the high standards expected by self-respecting anesthesiologists?

SPECIAL ARTICLE

Introduction of Surgical Safety Checklists in Ontario, Canada

David R. Urbach, M.D., Anand Govindarajan, M.D., Refik Saskin, M.Sc., Andrew S. Wilton, M.Sc., and Nancy N. Baxter, M.D., Ph.D.

ABSTRACT

BACKGROUND

Evidence from observational studies that the use of surgical safety checklists results in striking improvements in surgical outcomes led to the rapid adoption of such checklists worldwide. However, the effect of mandatory adoption of surgical safety checklists is unclear. A policy encouraging the universal adoption of checklists by hospitals in Ontario, Canada, provided a natural experiment to assess the effectiveness of checklists in typical practice settings.

METHODS

We surveyed all acute care hospitals in Ontario to determine when surgical safety checklists were adopted. Using administrative health data, we compared operative mortality, rate of surgical complications, length of hospital stay, and rates of hospital readmission and emergency department visits within 30 days after discharge among patients undergoing a variety of surgical procedures before and after adoption of a checklist.

RESULTS

During 3-month periods before and after adoption of a surgical safety checklist, a total of 101 hospitals performed 109,341 and 106,370 procedures, respectively. The adjusted risk of death during a hospital stay or within 30 days after surgery was 0.71% (95% confidence interval [CI], 0.66 to 0.76) before implementation of a surgical checklist and 0.65% (95% CI, 0.60 to 0.70) afterward (odds ratio, 0.91; 95% CI, 0.80 to 1.03; P=0.13). The adjusted risk of surgical complications was 3.86% (95% CI, 3.76 to 3.96) before implementation and 3.82% (95% CI, 3.71 to 3.92) afterward (odds ratio, 0.97; 95% CI, 0.90 to 1.03; P=0.29).

CONCLUSIONS

Implementation of surgical safety checklists in Ontario, Canada, was not associated with significant reductions in operative mortality or complications. (Funded by the Canadian Institutes of Health Research.)

From the Institute for Clinical Evaluative Sciences (D.R.U., A.G., R.S., A.S.W., N.N.B.), the Department of Surgery (D.R.U., A.G., N.N.B.) and Institute of Health Policy, Management and Evaluation (D.R.U., N.N.B.), University of Toronto, the University Health Network (D.R.U.), Mount Sinai Hospital (A.G.), and Keenan Research Centre, Li Ka Shing Knowledge Institute, Department of Surgery, St. Michael's Hospital (N.N.B.) — all in Toronto. Address reprint requests to Dr. Urbach at 200 Elizabeth St., 10-214, Toronto, ON M5G 2C4, Canada, or at david.urbach@uhn.ca.

Drs. Urbach and Baxter contributed equally to this article.

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A study published in 2009 showed that implementation of the 19-item World Health Organization (WHO) Surgical Safety Checklist substantially reduced the rate of surgical complications, from 11.0% to 7.0%, and reduced the rate of in-hospital death from 1.5% to 0.8%.[1] The WHO estimated that at least 500,000 deaths per year could be prevented through worldwide implementation of this checklist.[2] This dramatic effect of a relatively simple and accessible intervention resulted in its widespread adoption. In the United Kingdom, a nationwide program was implemented by the National Health Service within weeks after publication of the WHO study,[3] and almost 6000 hospitals worldwide are actively using or have expressed interest in using the checklist.[4]

The effect of mandatory checklist implementation is unclear. Studies of implementation have been observational,[5-11] have been limited to a small number of centers,[6-11] have not evaluated patient outcomes,[8-10] or have not shown the magnitude of effectiveness found in the WHO study.[6,7] Only studies including team training[11-13] or a more comprehensive safety system that includes multiple checklists[14] have shown effectiveness similar to that seen in the WHO study.

Implementation of surgical safety checklists is not uniform,[15,16] and performance quality may be lower when participation is not voluntary. In Ontario, a Canadian province with a population of more than 13 million people, the Ministry of Health and Long-Term Care mandated public reporting of adherence to surgical safety checklists for hospitals beginning in July 2010.[17] The rapid implementation of surgical safety checklists in Ontario provided a natural experiment to evaluate the effectiveness of checklist implementation at the population level.

METHODS

OVERVIEW

We analyzed the outcomes of surgical procedures performed before and after the adoption of surgical safety checklists, using population-based administrative health data (see the Supplementary Appendix, available with the full text of this article at NEJM.org). The study was approved by the research ethics board of Sunnybrook Health Sciences Centre.

SURGICAL SAFETY CHECKLISTS

We contacted all 133 surgical hospitals in Ontario to determine when the surgical safety checklist was introduced (the month, if the day was not known), whether a special intervention or educational program was used, and the specific checklist used (the Canadian Patient Safety Institute checklist, the WHO checklist, or a unique checklist devised by the hospital). Hospitals were required to report the number of surgical procedures for which a surgical safety checklist was used (numerator) as a proportion of the total number of surgical procedures performed (denominator) at the institution. Hospitals typically designate a checklist coordinator, often an operating-room nurse, to determine whether the checklist is completed for each surgical procedure performed.[18] Compliance with surgical safety checklists is reported publicly by the Ontario Ministry of Health and Long-Term Care at the level of the individual hospital.[19]

STUDY PERIODS

We studied 3-month intervals for each hospital, one ending 3 months before the introduction of a surgical checklist, and one starting 3 months after the introduction of the checklist. We conducted sensitivity analyses using different periods for comparison.

SURGICAL PROCEDURES

We included all surgical procedures performed during each study interval. Procedure types (see the Supplementary Appendix) were selected on the basis of Canadian Classification of Health Interventions codes.[20] Some patients underwent more than one surgical procedure in one or both periods; we limited the analysis to the first procedure per patient in each study interval.

OUTCOMES

Operative mortality, defined as the rate of death occurring in the hospital or within 30 days after surgery regardless of place, was the primary outcome. We used administrative data to assess the rates of complications occurring within 30 days after surgery (see the Supplementary Appendix). We also assessed length of hospital stay, rates of readmission within 30 days after discharge, and rates of emergency department visits within 30 days after discharge.

COVARIATES

We measured comorbidity using the resource utilization bands (simplified morbidity categories) of the Adjusted Clinical Group system (0, nonusers; 1, healthy users; 2, users with low morbidity; 3, users with moderate morbidity; 4, users with high morbidity; and 5, users with very high morbidity),[21] age (0 to 17, 18 to 39, 40 to 64, and 65 years of age or older), sex, urban or rural residence, and quintile of median neighborhood household income (an ecologic measure of socioeconomic status). We also assessed attributes of the surgical intervention: admission category (ambulatory or inpatient), procedure status (emergency or elective), and month performed.

STATISTICAL ANALYSIS

In analyses of the effect of checklists on surgical outcomes, we used generalized estimating equations to adjust for potentially confounding variables and to account for the clustering of observations within hospitals.[22] We used Poisson generalized-estimating-equation models to estimate length of stay for inpatient procedures and binomial (logistic-regression) models for other outcomes. Adjusted risks were estimated with the use of the average value of each adjustment variable in the study population (age, sex, procedure status [emergency vs. elective], admission category [inpatient vs. ambulatory], urban vs. rural residence, procedure type, month of surgery, and comorbidity score). To explore associations between other variables and surgical outcomes, we also conducted analyses with adjustment for all these factors as well as for the patient's neighborhood income quintile. Since generalized-estimating-equation models did not converge for some of the infrequent surgical outcomes, we used generalized linear models to estimate the effect of checklists on surgical outcomes in analyses of specific surgical complications.

For each hospital, we estimated the age-, sex-, and month-adjusted changes in operative mortality, risk of surgical complications, length of stay, and risk of readmission or emergency department visit and plotted these values with 95% confidence intervals. The effect of the checklist did not vary substantially according to the type of checklist used (Table S1 in the Supplementary Appendix). To determine whether enthusiasm for using checklists was associated with effect, we tested interactions between the date of checklist adoption and the effect on surgical outcomes, under the assumption that earlier adopters of checklists had greater enthusiasm for their use. A priori, we planned five subgroup analyses to explore the effect of the introduction of a surgical safety checklist in subgroups defined by age, sex, procedure status, admission category, and procedure type. To test whether the effect of the checklist varied according to subgroup, we fit a separate generalized linear model for each subgroup analysis, with an interaction term specifying the joint effect of the checklist and the subgroup categories, adjusting for all other subgroup variables except those defining the subgroup analysis. All reported P values are two-sided. P values lower than 0.05 were considered to indicate statistical significance.

RESULTS

HOSPITALS AND CHECKLISTS

We retrieved information on the use of surgical safety checklists from 130 of 133 hospitals listed by the Ministry of Health and Long-Term Care as providing surgical services. Some hospitals did not perform procedures during the study period, and some multisite hospitals introduced the checklist at the same time at all sites and had a single hospital identifier, which left 101 hospitals suitable for analysis. All hospitals introduced a surgical safety checklist between June 2008 and September 2010. More than a third of the hospitals (37) began using a checklist in April 2010. Ninety-two of the 101 hospitals provided copies of their checklist; 79 used a Canadian Patient Safety Institute version (see the Supplementary Appendix), 9 used customized checklists, and 4 used the WHO checklist. Ninety-seven hospitals used a special intervention or educational program for checklist implementation. Hospital-reported compliance with checklists was high. Almost all of the 97 large community hospitals reported compliance of 99% or 100% during the period from January through June 2013. The lowest reported compliance by a large community hospital during this period was 91.6%.[19]

The number of surgical procedures performed per hospital ranged from 9 to 4422 (median, 654) during the 3-month interval before the checklist was implemented and from 2 to 4522 (median, 633) during the 3-month interval after implementation. During both periods, nearly 90% of procedures were elective, and nearly 40% were performed during inpatient hospitalizations (Table 1, and Table S2 in the Supplementary Appendix).

EFFECT OF INTRODUCTION OF CHECKLISTS

The adjusted risk of death in the hospital or within 30 days after discharge was 0.71% (95% confidence interval [CI], 0.66 to 0.76) before and 0.65% (95% CI, 0.60 to 0.70) after implementation of a surgical safety checklist (P=0.07) (Table 2). There was a significant but small and clinically unimportant decrease in the adjusted length of stay, from 5.11 days (95% CI, 5.08 to 5.14) before checklist introduction to 5.07 days (95% CI, 5.04 to 5.10) afterward (P=0.003). There was no significant improvement in the adjusted risk of an emergency department visit within 30 days after discharge (10.44% [95% CI, 10.26 to 10.62] before implementation and 10.55% [95% CI, 10.37 to 10.73] afterward, P=0.37) or of readmission (3.11% [95% CI, 3.01 to 3.22] and 3.14% [95% CI, 3.03 to 3.24], respectively; P=0.76).

The adjusted risk of surgical complications within 30 days after the procedure was 3.86% (95% CI, 3.76 to 3.96) before implementation of a checklist and 3.82% (95% CI, 3.71 to 3.92) afterward (P=0.53). The risks of most complications did not differ significantly between the two periods. The only complication for which the risk significantly decreased was an unplanned return to the operating room (from 1.94% [95% CI, 1.87 to 2.00] to 1.78% [95% CI, 1.72 to 1.85], P=0.001). After introduction of a checklist, there were increases in the adjusted risk of deep venous thrombosis (from 0.03% [95% CI, 0.02 to 0.05] to 0.07% [95% CI, 0.05 to 0.08], P<0.001) and ventilator use (from 0.08% [95% CI, 0.06 to 0.10] to 0.12% [95% CI, 0.10 to 0.14], P=0.007).

In additional regression analyses of other determinants of surgical outcomes that also included adjustment for income quintile, the results of checklist introduction were similar. Introduction of a checklist was associated with an odds ratio of 0.91 (95% CI, 0.80 to 1.03) for operative mortality (P=0.13) and 0.97 (95% CI, 0.80 to 1.03) for surgical complications (P=0.29) (see Table S3 in the Supplementary Appendix).

EFFECT OF CHECKLISTS IN INDIVIDUAL HOSPITALS

Figure 1 shows the effect of introducing surgical safety checklists in individual hospitals. No hospital had a significant change in operative mortality after checklist introduction (Fig. 1A). Within-hospital changes in other surgical outcomes were mixed (Fig. 1B, and Fig. S1A, S1B, and S1C in the Supplementary Appendix). For example, six hospitals had significantly fewer complications after introduction of a checklist, whereas three had significantly more complications (Fig. 1B).

SUBGROUP ANALYSES

The effect of checklists did not vary substantially according to date of adoption (before, around, or after April 2010) (Table S1 in the Supplementary Appendix), which suggests that there was no benefit conferred by earlier versus later adoption. Stratified analyses did not reveal any subgroup with a significant reduction in operative mortality associated with introduction of a surgical safety checklist (Fig. 2A). There was no significant reduction in operative mortality associated with checklist introduction among subgroups at higher risk for operative death, such as persons undergoing emergency procedures (4.51% [95% CI, 4.16 to 4.86] before introduction and 4.12% [95% CI, 3.77 to 4.46] afterward, P=0.11) or inpatient procedures (1.71% [95% CI, 1.59 to 1.83] and 1.58% [95% CI, 1.46 to 1.69], respectively; P=0.11). For surgical complications (Fig. 2B), we found interactions between checklist introduction and both procedure type and admission category, with a significant increase in risk associated with checklist use for ambulatory procedures (odds ratio, 2.55; 95% CI, 1.61 to 4.03) but no significant effect for inpatient procedures (odds ratio, 0.97; 95% CI, 0.92 to 1.02; P<0.001 for interaction). The effect of the checklist on length of hospital stay differed for elective and emergency procedures and among some procedure types (Fig. S2A in the Supplementary Appendix). There were no differences among subgroups in the effect of surgical checklist introduction on the risk of readmission (Fig. S2B in the Supplementary Appendix). The results of sensitivity analyses testing longer and shorter intervals before and after checklist introduction were similar to the results of primary analyses.

DISCUSSION

In contrast to other studies, our population-based study of surgical safety checklists in Ontario hospitals showed no significant reduction in operative mortality after checklist implementation. Adjusted operative mortality was 0.71% before

Table 1. Characteristics of the Patients.*

Characteristic	Before Checklist Introduction (N=109,341)	After Checklist Introduction (N=106,370)
	number (percent)	
Procedure status		
Elective	97,040 (88.7)	93,699 (88.1)
Emergency	12,301 (11.3)	12,671 (11.9)
Admission category		
Ambulatory	66,660 (61.0)	64,718 (60.8)
Inpatient	42,681 (39.0)	41,652 (39.2)
Procedure type†		
Eye	21,578 (19.7)	21,471 (20.2)
Orocraniofacial	9,663 (8.8)	9,582 (9.0)
Digestive	12,867 (11.8)	13,206 (12.4)
Genitourinary	17,785 (16.3)	16,340 (15.4)
Musculoskeletal	31,381 (28.7)	30,554 (28.7)
Other	9,855 (9.0)	9,410 (8.8)
Age		
0–17 yr	7,689 (7.0)	7,806 (7.3)
18–39 yr	18,955 (17.3)	18,232 (17.1)
40–64 yr	43,669 (39.9)	42,023 (39.5)
≥65 yr	39,028 (35.7)	38,309 (36.0)
Sex		
Female	63,591 (58.2)	61,672 (58.0)
Male	45,750 (41.8)	44,698 (42.0)
Comorbidity score‡		
0–2	5,544 (5.1)	5,450 (5.1)
3	51,935 (47.5)	49,856 (46.9)
4	32,325 (29.6)	31,457 (29.6)
5	19,537 (17.9)	19,607 (18.4)
Neighborhood income quintile§		
Unknown	406 (0.4)	414 (0.4)
1	19,574 (17.9)	19,098 (18.0)
2	21,223 (19.4)	20,684 (19.4)
3	22,078 (20.2)	21,216 (19.9)
4	23,392 (21.4)	22,698 (21.3)
5	22,668 (20.7)	22,260 (20.9)
Hospital type¶		
Community	77,026 (70.4)	74,817 (70.3)
Pediatric	1,808 (1.7)	1,827 (1.7)
Small	1,713 (1.6)	1,690 (1.6)
Teaching	28,794 (26.3)	28,002 (26.3)

* Percentages may not sum to 100 because of rounding. Table S2 in the Supplementary Appendix provides a complete description of patient characteristics. Each study period was 3 months long, extending from 6 months to 3 months before checklist introduction and from 3 months to 6 months after checklist introduction.

† Categories are from the Canadian Classification of Interventions. The "other" category includes procedures involving the nervous system, respiratory system, cardiovascular system, lymphatic system, and ear.

‡ Comorbidity was assessed as the resource utilization band, a component of a six-level simplified morbidity categorization in the Adjusted Clinical Groups system[21]; it is defined by health resource use, with 0 indicating nonusers and 5 indicating users with very high morbidity.

§ Neighborhood income quintiles were calculated for the median household income in the neighborhood of a patient's residence; 1 denotes the lowest income category, and 5 the highest.

¶ Small hospitals, as defined by the Joint Policy and Planning Commission of the Ontario Ministry of Health and Long-Term Care, are hospitals with fewer than 50 inpatient beds and a referral population of fewer than 20,000 residents. Community hospitals are nonteaching hospitals.

Table 2. Surgical Outcomes before and after Introduction of a Surgical Safety Checklist.*

Outcome	Before Checklist Introduction	After Checklist Introduction	P Value†
Rate of death in the hospital or within 30 days after discharge — % (95% CI)			
Unadjusted	0.70 (0.65–0.75)	0.66 (0.61–0.71)	0.27
Adjusted	0.71 (0.66–0.76)	0.65 (0.60–0.70)	0.07
Length of hospital stay — days (95% CI)‡			
Unadjusted	5.07 (5.01–5.13)	5.11 (5.05–5.17)	0.02
Adjusted	5.11 (5.08–5.14)	5.07 (5.04–5.10)	0.003
Rate of emergency department visit within 30 days after discharge — % (95% CI)			
Unadjusted	10.28 (10.10–10.46)	10.71 (10.52–10.90)	0.001
Adjusted	10.44 (10.26–10.62)	10.55 (10.37–10.73)	0.37
Rate of readmission within 30 days after discharge — % (95% CI)			
Unadjusted	3.08 (3.00–3.18)	3.17 (3.07–3.28)	0.21
Adjusted	3.11 (3.01–3.22)	3.14 (3.03–3.24)	0.76
Rate of complications — % (95% CI)			
Unadjusted	3.80 (3.69–3.92)	3.87 (3.76–3.99)	0.41
Adjusted	3.86 (3.76–3.96)	3.82 (3.71–3.92)	0.53
Adjusted rate of specific complications — % (95% CI)			
Acute renal failure	0.10 (0.08–0.12)	0.13 (0.11–0.15)	0.08
Bleeding	0.64 (0.59–0.68)	0.63 (0.58–0.67)	0.76
Cardiac arrest	0.10 (0.08–0.12)	0.12 (0.10–0.14)	0.20
Coma	0.00 (0.00–0.01)	0.01 (0.00–0.01)	0.46
Deep venous thrombosis	0.03 (0.02–0.05)	0.07 (0.05–0.08)	<0.001
Acute myocardial infarction	0.29 (0.26–0.32)	0.29 (0.26–0.32)	0.91
Ventilator use	0.08 (0.06–0.10)	0.12 (0.10–0.14)	0.007
Pneumonia	0.31 (0.27–0.34)	0.31 (0.28–0.34)	0.80
Pulmonary embolism	0.03 (0.02–0.04)	0.03 (0.02–0.04)	0.58
Stroke	0.15 (0.12–0.17)	0.16 (0.14–0.18)	0.35
Major disruption of wound	0.14 (0.12–0.16)	0.13 (0.11–0.16)	0.61
Infection of surgical site	0.61 (0.56–0.65)	0.64 (0.59–0.69)	0.30
Sepsis	0.10 (0.08–0.11)	0.09 (0.07–0.11)	0.73
Septic shock	0.05 (0.03–0.06)	0.05 (0.04–0.06)	0.83
Unplanned return to operating room‡	1.94 (1.87–2.00)	1.78 (1.72–1.85)	0.001
Vascular graft failure	0.01 (0.00–0.02)	0.02 (0.01–0.02)	0.15
Shock	0.07 (0.06–0.09)	0.09 (0.07–0.10)	0.26

* Rates were adjusted with the use of generalized linear models for age, sex, procedure type, procedure status (emergency vs. elective), admission category (inpatient vs. ambulatory), rural or urban residence, month of surgery, and comorbidity score (assessed as the resource utilization band).

† P values are for the comparison of values before and after introduction of the checklist.

‡ The model included only inpatient hospitalizations.

and 0.65% after checklist introduction. Checklist use did not result in reductions in risks of surgical complications, emergency department visits, or hospital readmissions within 30 days after discharge. There was a significant but small and not clinically relevant reduction in adjusted length of hospital stay (5.11 days before checklist introduction and 5.07 days afterward). Surgical checklists did not reduce the risk of operative death in any subgroup we studied, including high-risk groups such as elderly patients, patients who underwent emergency procedures, and patients who underwent inpatient procedures.

The absence of meaningful improvements in outcomes after surgical checklist implementation was unexpected in light of the findings of studies evaluating the effects of such checklists.[1,6,11,14] In a meta-analysis of three before-and-after studies evaluating the effect of surgical safety checklists,[5] the pooled relative risk of operative death was 0.57 (95% CI, 0.42 to 0.76), and the relative risk of complications was 0.63 (95% CI, 0.58 to 0.67). Our inability to replicate these large effects cannot be explained by inadequate power; our study included more than 200,000 surgical procedures in 101 hospitals.

Ontario hospitals implemented surgical checklists between June 2008 and September 2010 in response to the plan of the Ontario Ministry of Health and Long-Term Care to publicly report compliance with use of the checklist. Self-reported compliance by all hospitals in the province is high: 92% from April through June 2010 and never less than 98% after June 2010.[19] Although materials were available to assist in the implementation of surgical safety checklists in hospitals,[23] no formal team training was required before public reporting, and implementation was not standardized. Real-world compliance with checklists varies.[24] In one hospital in the Netherlands, surgical safety checklists were fully completed for only 39% of surgical procedures after mandatory implementation.[6] In that study, the odds ratio for death in the period after implementation, as compared with the period before implementation, was reduced only among patients who underwent procedures with full checklist compliance (0.23; 95% CI, 0.16 to 0.33). There was no reduction in the odds ratio for death among patients for whom the checklist was partially completed (1.16; 95% CI, 0.95 to 1.41) or not completed (1.57; 95% CI, 1.31 to 1.89). Although selection bias probably explains much of the negative effect of noncompliance in hospitals where checklists are used, this study highlighted the fact that checklists are not always applied in a uniform manner. The absence of an effect of checklist implementation in our study may therefore reflect inadequate adherence to the checklist in Ontario. The approach to implementation in Ontario was consistent with WHO recommendations[25] and was similar to that used in many other jurisdictions.[3,26-28] It is possible that published evidence regarding the efficacy of implementing checklists within hos-

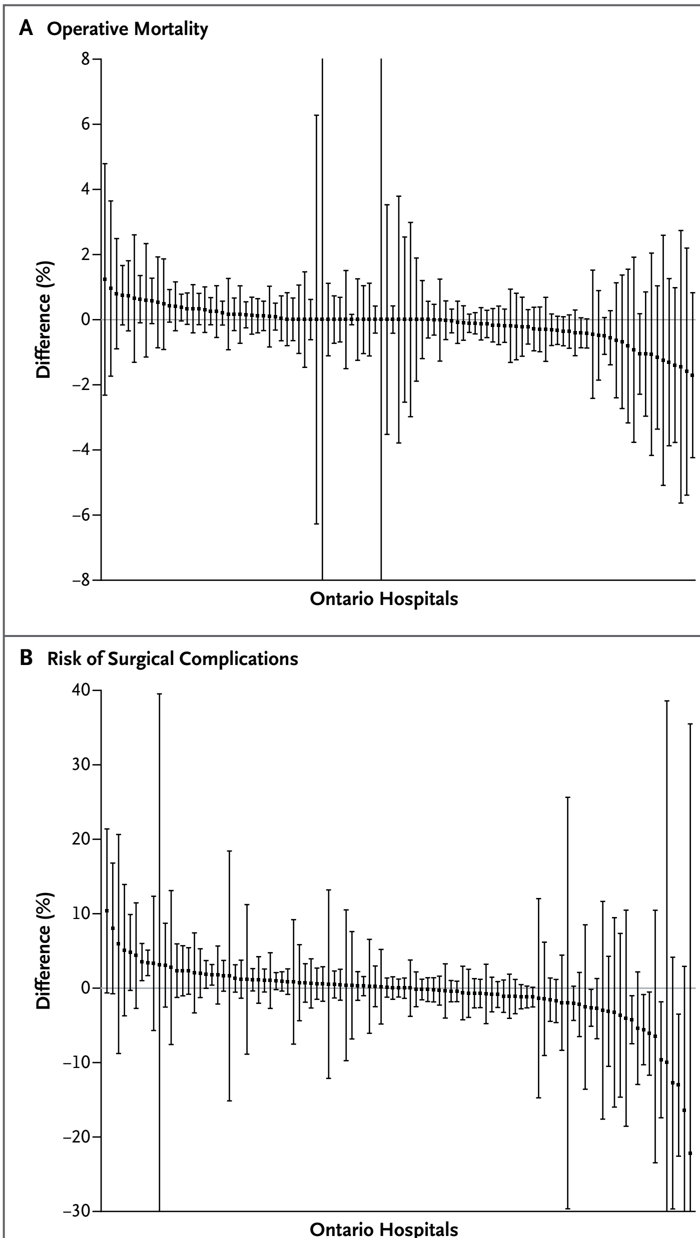

Figure 1. Within-Hospital Changes in Operative Mortality and Risk of Surgical Complications.

Each data point represents the difference in operative mortality (Panel A) and the risk of surgical complications (Panel B) before and after the implementation of a surgical safety checklist in one hospital, adjusted for age, sex, and month of surgery. Negative values indicate improvement. Hospitals are ordered from those with the highest values (least improvement) to those with the lowest values (most improvement). I bars denote 95% confidence intervals.

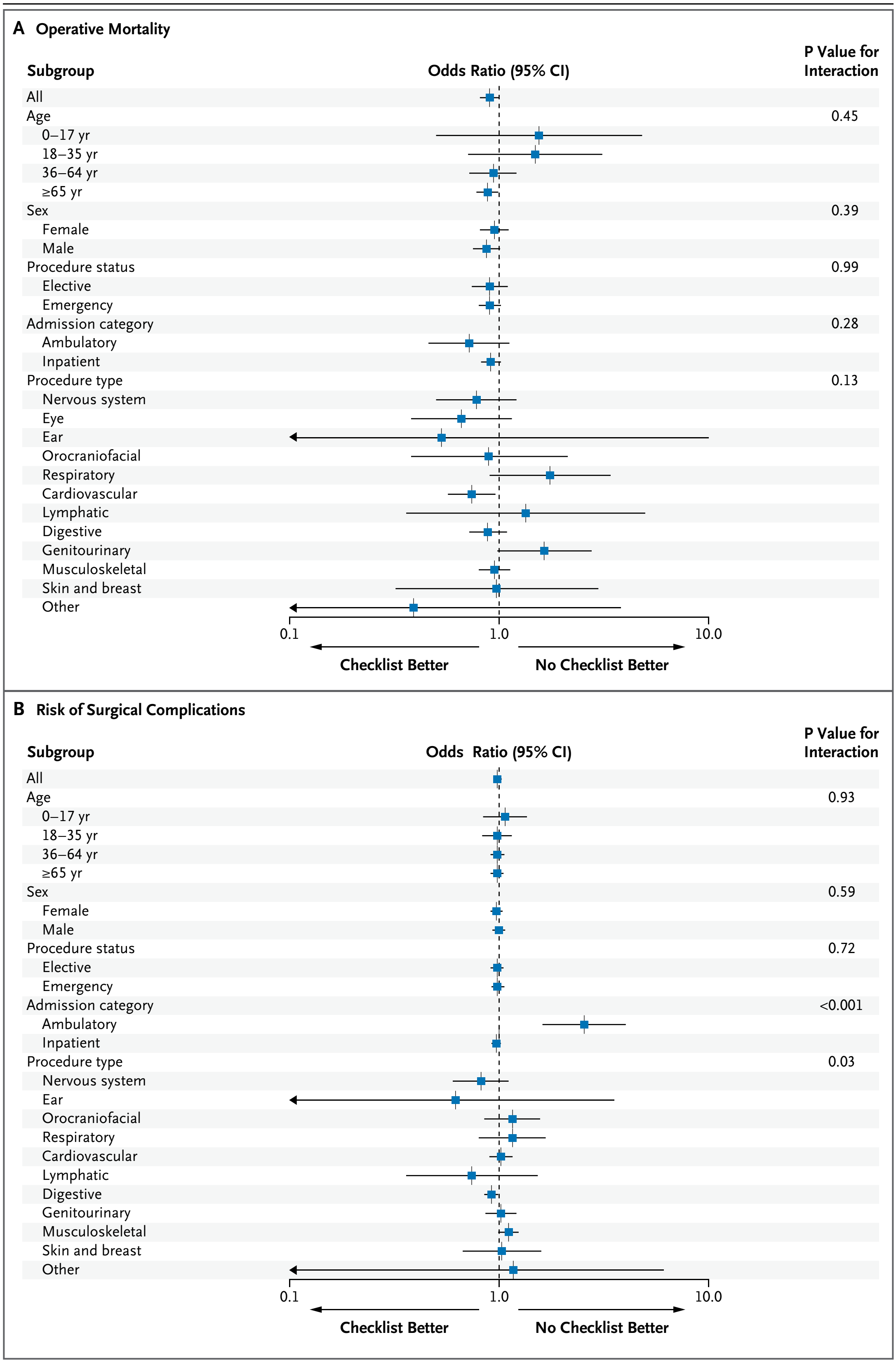
A Operative Mortality
Subgroup
Odds Ratio (95% CI)
P Value for Interaction
All
Age
0.45
0–17 yr
18–35 yr
36–64 yr
≥65 yr
Sex
0.39
Female
Male
Procedure status
0.99
Elective
Emergency
Admission category
0.28
Ambulatory
Inpatient
Procedure type
0.13
Nervous system
Eye
Ear
Orocraniofacial
Respiratory
Cardiovascular
Lymphatic
Digestive
Genitourinary
Musculoskeletal
Skin and breast
Other
0.1
1.0
10.0
Checklist Better
No Checklist Better
B Risk of Surgical Complications
Subgroup
Odds Ratio (95% CI)
P Value for Interaction
All
Age
0.93
0–17 yr
18–35 yr
36–64 yr
≥65 yr
Sex
0.59
Female
Male
Procedure status
0.72
Elective
Emergency
Admission category
<0.001
Ambulatory
Inpatient
Procedure type
0.03
Nervous system
Ear
Orocraniofacial
Respiratory
Cardiovascular
Lymphatic
Digestive
Genitourinary
Musculoskeletal
Skin and breast
Other
0.1
1.0
10.0
Checklist Better
No Checklist Better

Figure 2 (facing page). Odds Ratios for Operative Mortality and Surgical Complications, Stratified According to Age, Sex, Procedure Status, Admission Category, and Type of Procedure.

Adjusted effect sizes for operative mortality (Panel A) and risk of surgical complications (Panel B) in each stratum were estimated with the use of generalized linear models, with adjustment for all variables shown except the stratification variable. For surgical complications, an odds ratio for the Eye procedure type could not be estimated because of the small number of events. P values are for the interaction between the stratification variable and the effect of checklist use on the outcome.

pitals participating in safety research is not generalizable; the effectiveness of surgical checklists in typical practice settings — as in this study — may be more limited.

It is also possible that the surgical safety checklist is less effective in practice than suggested by the existing literature. A Hawthorne effect — the tendency for some people to perform better when they perceive that their work is under scrutiny — may explain the strong effect of surgical checklists in studies in which hospitals were aware of the intervention under study. Before-and-after comparisons[1] are uncontrolled observational designs with inherent limitations, and inferences of causality should be made with caution.[29] The effectiveness of a surgical safety checklist has never been shown in a controlled trial with randomization, despite the feasibility of using cluster-randomized designs to test context-dependent interventions such as strategies for ensuring patient safety. Studies showing a substantial effect of a checklist, apart from the WHO study,[1] either coupled the checklist with extensive team training[11-13] or used an expansive checklist that covered care from the preoperative period to discharge from the hospital.[14]

In some of the 101 hospitals in this study, outcomes did change significantly — for better or worse — after implementation of a checklist. Because thousands of hospitals around the world have implemented surgical safety checklists, many will have improvements in the outcomes by chance alone. Hospital-based studies showing improvements in outcomes after checklist implementation are more likely to be published than are negative studies (publication bias[30]). The population-based nature of our study, which included virtually all hospitals providing surgical care for the population of Ontario, allowed us to obtain an estimate of the effectiveness of surgical safety checklists that is less susceptible to biases from selective reporting of institutional experience.

Our study has a number of limitations. First, secular trends and major cointerventions during the period when checklists were introduced may have confounded our results. However, we used an analytic approach similar to that used in the studies that showed a significant effect of checklists.[1,14] No other Ontario-wide interventions to improve surgical quality were implemented during the study period. Since surgical outcomes tend to improve over time,[31] it is highly unlikely that confounding due to time-dependent factors prevented us from identifying a significant improvement after implementation of a surgical checklist. Second, we used administrative data to assess surgical complications. Although this method is commonly used,[32-34] it is inferior to prospective measurement or chart review[35-37] and may have obscured changes in surgical complications after checklist implementation. However, the other outcomes studied, including operative mortality, length of stay, emergency department visits, and readmission, are less susceptible to misclassification in administrative data.

In conclusion, our study of the implementation of surgical safety checklists in Ontario did not show the striking improvement in patient outcomes identified in previous studies. We did not identify any subgroup that particularly benefited from checklists. Although a greater effect of surgical safety checklists might occur with more intensive team training or better monitoring of compliance, surgical safety checklists, as implemented during the study period, did not result in improved patient outcomes at the population level. There may be value in the use of surgical safety checklists, such as enhanced communication and teamwork and the promotion of a hospital culture in which safety is a high priority; however, these potential benefits did not translate into meaningful improvements in the outcomes we analyzed.

The opinions, results, and conclusions reported in this article are those of the authors and are independent from the funding sources. No endorsement by the Institute for Clinical Evaluative Sciences (ICES) or the Ontario Ministry of Health and Long-Term Care is intended or should be inferred.

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REFERENCES

1. 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.

2. Safe surgery saves lives. Geneva: World Health Organization (http://www.who.int/patientsafety/safesurgery/en).

3. Patient safety alert: WHO Surgical Safety Checklist. Geneva: World Health Association, 2009 (http://www.nrls.npsa.nhs.uk/resources/clinical-specialty/surgery/?entryid45=59860&p=3).

4. Patient safety: surgical safety Web map. Geneva: World Health Organization (http://maps.cga.harvard.edu:8080/Hospital/#).

5. Borchard A, Schwappach DL, Barbir A, Bezzola P. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. Ann Surg 2012;256:925-33.

6. van Klei WA, Hoff RG, van Aarnhem EE, et al. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. Ann Surg 2012;255:44-9.

7. Sewell M, Adebibe M, Jayakumar P, et al. Use of the WHO Surgical Safety Checklist in trauma and orthopaedic patients. Int Orthop 2011;35:897-901.

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

9. Takala RS, Pauniaho SL, Kotkansalo A, et al. A pilot study of the implementation of WHO surgical checklist in Finland: improvements in activities and communication. Acta Anaesthesiol Scand 2011;55:1206-14.

10. Nilsson L, Lindberget O, Gupta A, Vegfors M. Implementing a pre-operative checklist to increase patient safety: a 1-year follow-up of personnel attitudes. Acta Anaesthesiol Scand 2010;54:176-82.

11. Bliss LA, Ross-Richardson CB, Sanzari LJ, et al. Thirty-day outcomes support implementation of a surgical safety checklist. J Am Coll Surg 2012;215:766-76.

12. Young-Xu Y, Neily J, Mills PD, et al. Association between implementation of a medical team training program and surgical morbidity. Arch Surg 2011;146:1368-73.

13. Neily J, Mills PD, Young-Xu Y, et al. Association between implementation of a medical team training program and surgical mortality. JAMA 2010;304:1693-700.

14. de Vries EN, Prins HA, Crolla RM, et al. Effect of a comprehensive surgical safety system on patient outcomes. N Engl J Med 2010;363:1928-37.

15. Conley DM, Singer SJ, Edmondson L, Berry WR, Gawande AA. Effective surgical safety checklist implementation. J Am Coll Surg 2011;212:873-9.

16. Vogts N, Hannam JA, Merry AF, Mitchell SJ. Compliance and quality in administration of a Surgical Safety Checklist in a tertiary New Zealand hospital. N Z Med J 2011;124:48-58.

17. Patient Safety. Toronto: Ontario Ministry of Health and Long Term Care (http://www.health.gov.on.ca/en/public/programs/patient_safety).

18. Surgical Safety Checklist. Toronto: Ontario Hospital Association (http://www.oha.com/CurrentIssues/keyinitiatives/PatientSafety/Pages/SurgicalSafetyChecklist.aspx).

19. Public reporting — patient safety: percent of surgeries in which a surgical safety checklist was performed, April 2010–June 2013. Toronto: Health Quality Ontario (http://www.hqontario.ca/public-reporting/patient-safety).

20. Canadian classification of health interventions. Vol. 3: tabular list. Ottawa: Canadian Institute of Health Information, 2003.

21. The Johns Hopkins ACG Case-Mix System, version 8.2. Baltimore: Johns Hopkins Bloomberg School of Public Health, 2008.

22. Zeger SL, Liang KY, Albert PS. Models for longitudinal data: a generalized estimating equation approach. Biometrics 1988;44:1049-60. [Erratum, Biometrics 1989;45:347.]

23. Surgical Safety Checklist "how-to" implementation guide. Toronto: Ontario Hospital Association (https://www.oha.com/CurrentIssues/keyinitiatives/PatientSafety/Documents/SSC_Toolkit_PartB_Feb04.pdf).

24. Levy SM, Senter CE, Hawkins RB, et al. Implementing a surgical checklist: more than checking a box. Surgery 2012;152:331-6.

25. World Alliance for Patient Safety. Implementation manual: Surgical Safety Checklist. Geneva: World Health Organization (http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf).

26. North Carolina Quality Center. WHO Surgical Safety Checklist. Cary, NC: NCQC (http://www.ncqualitycenter.org/?s=WHO+surgical+safety+checklist).

27. Safe Surgery 2015: South Carolina (http://www.safesurgery2015.org/safe-surgery-2015-south-carolina.html).

28. Oregon Association of Hospitals and Health Systems. Sprint for surgical safety (http://www.oahhs.org/quality/initiatives/sprint-to-surgical-safety.html).

29. Auerbach AD, Landefeld CS, Shojania KG. The tension between needing to improve care and knowing how to do it. N Engl J Med 2007;357:608-13.

30. Song F, Parekh S, Hooper L, et al. Dissemination and publication of research findings: an updated review of related biases. Health Technol Assess 2010;14:1-193.

31. Tu JV, Wu K. The improving outcomes of coronary artery bypass graft surgery in Ontario, 1981 to 1995. CMAJ 1998;159:221-7.

32. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. JAMA 2010;303:1259-65.

33. Hu JC, Gu X, Lipsitz SR, et al. Comparative effectiveness of minimally invasive vs open radical prostatectomy. JAMA 2009;302:1557-64.

34. Schermerhorn ML, O'Malley AJ, Jhaveri A, Cotterill P, Pomposelli F, Landon BE. Endovascular vs. open repair of abdominal aortic aneurysms in the Medicare population. N Engl J Med 2008;358:464-74.

35. Cima RR, Lackore KA, Nehring SA, et al. How best to measure surgical quality? Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicators (AHRQ-PSI) and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) postoperative adverse events at a single institution. Surgery 2011;150:943-9.

36. Best WR, Khuri SF, Phelan M, et al. Identifying patient preoperative risk factors and postoperative adverse events in administrative databases: results from the Department of Veterans Affairs National Surgical Quality Improvement Program. J Am Coll Surg 2002;194:257-66.

37. Kaafarani HM, Rosen AK. Using administrative data to identify surgical adverse events: an introduction to the Patient Safety Indicators. Am J Surg 2009;198:Suppl:S63-S68.

SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

Alex B. Haynes, M.D., M.P.H., Thomas G. Weiser, M.D., M.P.H., William R. Berry, M.D., M.P.H., Stuart R. Lipsitz, Sc.D., Abdel-Hadi S. Breizat, M.D., Ph.D., E. Patchen Dellinger, M.D., Teodoro Herbosa, M.D., Sudhir Joseph, M.S., Pascience L. Kibatala, M.D., Marie Carmela M. Lapitan, M.D., Alan F. Merry, M.B., Ch.B., F.A.N.Z.C.A., F.R.C.A., Krishna Moorthy, M.D., F.R.C.S., Richard K. Reznick, M.D., M.Ed., Bryce Taylor, M.D., and Atul A. Gawande, M.D., M.P.H., for the Safe Surgery Saves Lives Study Group*

ABSTRACT

BACKGROUND

Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Surgical complications are common and often preventable. We hypothesized that a program to implement a 19-item surgical safety checklist designed to improve team communication and consistency of care would reduce complications and deaths associated with surgery.

METHODS

Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients participated in the World Health Organization's Safe Surgery Saves Lives program. We prospectively collected data on clinical processes and outcomes from 3733 consecutively enrolled patients 16 years of age or older who were undergoing noncardiac surgery. We subsequently collected data on 3955 consecutively enrolled patients after the introduction of the Surgical Safety Checklist. The primary end point was the rate of complications, including death, during hospitalization within the first 30 days after the operation.

RESULTS

The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward (P=0.003). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist (P<0.001).

CONCLUSIONS

Implementation of the checklist was associated with concomitant reductions in the rates of death and complications among patients at least 16 years of age who were undergoing noncardiac surgery in a diverse group of hospitals.

From the Harvard School of Public Health (A.B.H., T.G.W., W.R.B., A.A.G.), Massachusetts General Hospital (A.B.H.), and Brigham and Women's Hospital (S.R.L., A.A.G.) — all in Boston; University of California–Davis, Sacramento (T.G.W.); Prince Hamzah Hospital, Ministry of Health, Amman, Jordan (A.-H.S.B.); University of Washington, Seattle (E.P.D.); College of Medicine, University of the Philippines, Manila (T.H.); St. Stephen's Hospital, New Delhi, India (S.J.); St. Francis Designated District Hospital, Ifakara, Tanzania (P.L.K.); National Institute of Health–University of the Philippines, Manila (M.C.M.L.); University of Auckland and Auckland City Hospital, Auckland, New Zealand (A.F.M.); Imperial College Healthcare National Health Service Trust, London (K.M.); and University Health Network, University of Toronto, Toronto (R.K.R., B.T.). Address reprint requests to Dr. Gawande at the Department of Surgery, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, or at safesurgery@hsph.harvard.edu.

*Members of the Safe Surgery Saves Lives Study Group are listed in the Appendix.

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Surgical care is an integral part of health care throughout the world, with an estimated 234 million operations performed annually.[1] This yearly volume now exceeds that of childbirth.[2] Surgery is performed in every community: wealthy and poor, rural and urban, and in all regions. The World Bank reported that in 2002, an estimated 164 million disability-adjusted life-years, representing 11% of the entire disease burden, were attributable to surgically treatable conditions.[3] Although surgical care can prevent loss of life or limb, it is also associated with a considerable risk of complications and death. The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17%.[4,5] These rates are likely to be much higher in developing countries.[6-9] Thus, surgical care and its attendant complications represent a substantial burden of disease worthy of attention from the public health community worldwide.

Data suggest that at least half of all surgical complications are avoidable.[4,5] Previous efforts to implement practices designed to reduce surgical-site infections or anesthesia-related mishaps have been shown to reduce complications significantly.[10-12] A growing body of evidence also links teamwork in surgery to improved outcomes, with high-functioning teams achieving significantly reduced rates of adverse events.[13,14]

In 2008, the World Health Organization (WHO) published guidelines identifying multiple recommended practices to ensure the safety of surgical patients worldwide.[15] On the basis of

Table 1. Elements of the Surgical Safety Checklist.*

Sign in
Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that:
The patient has verified his or her identity, the surgical site and procedure, and consent
The surgical site is marked or site marking is not applicable
The pulse oximeter is on the patient and functioning
All members of the team are aware of whether the patient has a known allergy
The patient's airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available
If there is a risk of blood loss of at least 500 ml (or 7 ml/kg of body weight, in children), appropriate access and fluids are available
Time out
Before skin incision, the entire team (nurses, surgeons, anesthesia professionals, and any others participating in the care of the patient) orally:
Confirms that all team members have been introduced by name and role
Confirms the patient's identity, surgical site, and procedure
Reviews the anticipated critical events
Surgeon reviews critical and unexpected steps, operative duration, and anticipated blood loss
Anesthesia staff review concerns specific to the patient
Nursing staff review confirmation of sterility, equipment availability, and other concerns
Confirms that prophylactic antibiotics have been administered ≤60 min before incision is made or that antibiotics are not indicated
Confirms that all essential imaging results for the correct patient are displayed in the operating room
Sign out
Before the patient leaves the operating room:
Nurse reviews items aloud with the team
Name of the procedure as recorded
That the needle, sponge, and instrument counts are complete (or not applicable)
That the specimen (if any) is correctly labeled, including with the patient's name
Whether there are any issues with equipment to be addressed
The surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery.[15] For the complete checklist, see the Supplementary Appendix.

these guidelines, we designed a 19-item checklist intended to be globally applicable and to reduce the rate of major surgical complications (Table 1). (For the formatted checklist, see the Supplementary Appendix, available with the full text of this article at NEJM.org.) We hypothesized that implementation of this checklist and the associated culture changes it signified would reduce the rates of death and major complications after surgery in diverse settings.

METHODS

STUDY DESIGN

We conducted a prospective study of preintervention and postintervention periods at the eight hospitals participating as pilot sites in the Safe Surgery Saves Lives program (Table 2). These institutions were selected on the basis of their geographic distribution within WHO regions, with the goal of representing a diverse set of socioeconomic environments in which surgery is performed. Table 3 lists surgical safety policies in place at each institution before the study. We required that a coinvestigator at each site lead the project locally and that the hospital administration support the intervention. A local data collector was chosen at each site and trained by the four primary investigators in the identification and reporting of process measures and complications. This person worked on the study full-time and did not have clinical responsibilities at the study site. Each hospital identified between one and four operating rooms to serve as study rooms. Patients who were 16 years of age or older and were undergoing noncardiac surgery in those rooms were consecutively enrolled in the study. The human subjects committees of the Harvard School of Public Health, the WHO, and each participating hospital approved the study and waived the requirement for written informed consent from patients.

INTERVENTION

The intervention involved a two-step checklist-implementation program. After collecting baseline data, each local investigator was given information about areas of identified deficiencies and was then asked to implement the 19-item WHO safe-surgery checklist (Table 1) to improve practices within the institution. The checklist consists of an oral confirmation by surgical teams of the completion of the basic steps for ensuring safe delivery of anesthesia, prophylaxis against infection, effective teamwork, and other essential practices in surgery. It is used at three critical junctures in care: before anesthesia is administered, immediately before incision, and before the patient is taken out of the operating room. The checklist was translated into local language when appropriate and was adjusted to fit into the flow of care at each institution. The local study team introduced the checklist to operating-room staff, using lectures, written materials, or direct guidance. The primary investigators also participated in the training by distributing a recorded video to the study sites, participating in a teleconference with each local study team, and making a visit to each site. The checklist was introduced to the study rooms over a period of 1 week to 1 month. Data collection resumed during the first week of checklist use.

Table 2. Characteristics of Participating Hospitals.

Site	Location	No. of Beds	No. of Operating Rooms	Type
Prince Hamzah Hospital	Amman, Jordan	500	13	Public, urban
St. Stephen's Hospital	New Delhi, India	733	15	Charity, urban
University of Washington Medical Center	Seattle, Washington	410	24	Public, urban
St. Francis Designated District Hospital	Ifakara, Tanzania	371	3	District, rural
Philippine General Hospital	Manila, Philippines	1800	39	Public, urban
Toronto General Hospital	Toronto, Canada	744	19	Public, urban
St. Mary's Hospital*	London, England	541	16	Public, urban
Auckland City Hospital	Auckland, New Zealand	710	31	Public, urban

* St. Mary's Hospital has since been renamed St. Mary's Hospital–Imperial College National Health Service Trust.

DATA COLLECTION

We obtained data on each operation from standardized data sheets completed by the local data collectors or the clinical teams involved in surgical care. The data collectors received training and supervision from the primary investigators in the identification and classification of complications and process measures. Perioperative data included the demographic characteristics of patients, procedural data, type of anesthetic used, and safety data. Data collectors followed patients prospectively until discharge or for 30 days, whichever came first, for death and complications. Outcomes were identified through chart monitoring and communication with clinical staff. Completed data forms were stripped of direct identifiers of patients and transmitted to the primary investigators. We aimed to collect data on 500 consecutively enrolled patients at each site within a period of less than 3 months for each of the two phases of the study. At the three sites at which this goal could not be achieved, the period of data collection was extended for up to 3 additional months to allow for accrual of a sufficient number of patients. The sample size was calculated to detect a 20% reduction in complications after the checklist was implemented, with a statistical power of 80% and an alpha value of 0.05.

OUTCOMES

The primary end point was the occurrence of any major complication, including death, during the period of postoperative hospitalization, up to 30 days. Complications were defined as they are in the American College of Surgeons' National Surgical Quality Improvement Program[17]: acute renal failure, bleeding requiring the transfusion of 4 or more units of red cells within the first 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma of 24 hours' duration or more, deep-vein thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours or more, pneumonia, pulmonary embolism, stroke, major disruption of wound, infection of surgical site, sepsis, septic shock, the systemic inflammatory response syndrome, unplanned return to the operating room, vascular graft failure, and death. Urinary tract infection was not considered a major complication. A group of physician reviewers determined, by consensus, whether postoperative events reported as "other complications" qualified as major complications, using the Clavien classification for guidance.[18]

We assessed adherence to a subgroup of six safety measures as an indicator of process adherence. The six measures were the objective evaluation and documentation of the status of the patient's airway before administration of the anesthetic; the use of pulse oximetry at the time of initiation of anesthesia; the presence of at least two peripheral intravenous catheters or a central venous catheter before incision in cases involving an estimated blood loss of 500 ml or more; the administration of prophylactic antibiotics within 60 minutes before incision except in the case of preexisting infection, a procedure not involving incision, or a contaminated operative field; oral confirmation, immediately before incision, of the

Table 3. Surgical Safety Policies in Place at Participating Hospitals before the Study.

Site No.*	Routine Intraoperative Monitoring with Pulse Oximetry	Oral Confirmation of Patient's Identity and Surgical Site in Operating Room	Routine Administration of Prophylactic Antibiotics in Operating Room	Standard Plan for Intravenous Access for Cases of High Blood Loss	Formal Team Briefing: Preoperative	Formal Team Briefing: Postoperative
1	Yes	Yes	Yes	No	No	No
2	Yes	No	Yes	No	No	No
3	Yes	No	Yes	No	No	No
4	Yes	Yes	Yes	No	No	No
5	No	No	No	No	No	No
6	No	No	Yes	No	No	No
7	Yes	No	No	No	No	No
8	Yes	No	No	No	No	No

* Sites 1 through 4 are located in high-income countries; sites 5 through 8 are located in low- or middle-income countries.[16]

identity of the patient, the operative site, and the procedure to be performed; and completion of a sponge count at the end of the procedure, if an incision was made. We recorded whether all six of these safety measures were taken for each patient.

STATISTICAL ANALYSIS

Statistical analyses were performed with the use of the SAS statistical software package, version 9.1 (SAS Institute). To minimize the effect of differences in the numbers of patients at each site, we standardized the rates of various end points to reflect the proportion of patients from each site. These standardized rates were used to compute the frequencies of performance of specified safety measures, major complications, and death at each site before and after implementation of the checklist.[19] We used logistic-regression analysis to calculate two-sided P values for each comparison, with site as a fixed effect. We used generalized-estimating-equation methods to test for any effect of clustering according to site.

We performed additional analyses to test the robustness of our findings, including logistic-regression analyses in which the presence or absence of a data collector in the operating room and the case mix were added as variables. We classified cases as orthopedic, thoracic, nonobstetric abdominopelvic, obstetric, vascular, endoscopic, or other. To determine whether the effect of the checklist at any one site dominated the results, we performed cross-validation by sequentially removing each site from the analysis. Finally, we disaggregated the sites on the basis of whether they were located in high-income or low- or middle-income countries and repeated our analysis of primary end points. All reported P values are two-sided, and no adjustments were made for multiple comparisons.

RESULTS

We enrolled 3733 patients during the baseline period and 3955 patients after implementation of the checklist. Table 4 lists characteristics of the patients and their distribution among the sites; there were no significant differences between the patients in the two phases of the study.

The rate of any complication at all sites dropped from 11.0% at baseline to 7.0% after introduction of the checklist (P<0.001); the total in-hospital rate of death dropped from 1.5% to 0.8% (P=0.003) (Table 5). The overall rates of surgical-site infection and unplanned reoperation also declined significantly (P<0.001 and P=0.047, respectively). Operative data were collected by the local data collector through direct observation for 37.5% of patients and by unobserved clinical teams for the remainder. Neither the presence nor

Table 4. Characteristics of the Patients and Procedures before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Age		Female Sex		Urgent Case		Outpatient Procedure		General Anesthetic	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
			years		*percent*							
1	524	598	51.9±15.3	51.4±14.7	58.2	62.7	7.4	8.0	31.7	31.8	95.0	95.2
2	357	351	53.5±18.4	54.0±18.3	54.1	56.7	18.8	14.5	23.5	20.5	92.7	93.5
3	497	486	51.9±21.5	53.0±20.3	44.3	49.8	17.9	22.4	6.4	9.3	91.2	94.0
4	520	545	57.0±14.9	56.1±15.0	48.1	49.6	6.9	1.8	14.4	11.0	96.9	97.8
5	370	330	34.3±15.0	31.5±14.2	78.3	78.4	46.1	65.4	0.0	0.0	17.0	10.0
6	496	476	44.6±15.9	46.0±15.5	45.0	46.6	28.4	22.5	1.4	1.1	61.7	59.9
7	525	585	37.4±14.0	39.6±14.9	69.1	68.6	45.7	41.0	0.0	0.0	49.1	55.9
8	444	584	41.9±15.8	39.7±16.2	57.0	52.7	13.5	21.9	0.9	0.2	97.5	94.7
Total	3733	3955	46.8±18.1	46.7±17.9	56.2	57.6	22.3	23.3	9.9	9.4	77.0	77.3
P value			0.63		0.21		0.26		0.40		0.68	

* Plus–minus values are means ±SD. Urgent cases were those in which surgery within 24 hours was deemed necessary by the clinical team. Outpatient procedures were those for which discharge from the hospital occurred on the same day as the operation. P values are shown for the comparison of the total value after checklist implementation with the total value before implementation.

Table 5. Outcomes before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Surgical-Site Infection		Unplanned Return to the Operating Room		Pneumonia		Death		Any Complication	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
			percent									
1	524	598	**4.0**	**2.0**	**4.6**	**1.8**	0.8	1.2	**1.0**	**0.0**	**11.6**	**7.0**
2	357	351	2.0	1.7	0.6	1.1	3.6	3.7	1.1	0.3	7.8	6.3
3	497	486	5.8	4.3	4.6	2.7	1.6	1.7	0.8	1.4	13.5	9.7
4	520	545	3.1	2.6	2.5	2.2	0.6	0.9	1.0	0.6	7.5	5.5
5	370	330	**20.5**	**3.6**	1.4	1.8	0.3	0.0	**1.4**	**0.0**	**21.4**	**5.5**
6	496	476	4.0	4.0	3.0	3.2	2.0	1.9	3.6	1.7	10.1	9.7
7	525	585	**9.5**	**5.8**	**1.3**	**0.2**	1.0	1.7	2.1	1.7	**12.4**	**8.0**
8	444	584	4.1	2.4	0.5	1.2	0.0	0.0	1.4	0.3	6.1	3.6
Total	3733	3955	**6.2**	**3.4**	**2.4**	**1.8**	1.1	1.3	**1.5**	**0.8**	**11.0**	**7.0**
P value			<0.001		0.047		0.46		0.003		<0.001	

* The most common complications occurring during the first 30 days of hospitalization after the operation are listed. Bold type indicates values that were significantly different (at P<0.05) before and after checklist implementation, on the basis of P values calculated by means of the chi-square test or Fisher's exact test. P values are shown for the comparison of the total value after checklist implementation as compared with the total value before implementation.

absence of a direct observer nor changes in case mix affected the significance of the changes in the rate of complications (P<0.001 for both alternative models) or the rate of death (P=0.003 with the presence or absence of direct observation included and P=0.002 with case-mix variables included). Rates of complication fell from 10.3% before the introduction of the checklist to 7.1% after its introduction among high-income sites (P<0.001) and from 11.7% to 6.8% among lower-income sites (P<0.001). The rate of death was reduced from 0.9% before checklist introduction to 0.6% afterward at high-income sites (P=0.18) and from 2.1% to 1.0% at lower-income sites (P=0.006), although only the latter difference was significant. In the cross-validation analysis, the effect of the checklist intervention on the rate of death or complications remained significant after the removal of any site from the model (P<0.05). We also found no change in the significance of the effect on the basis of clustering (P=0.003 for the rate of death and P=0.001 for the rate of complications).

Table 6 shows the changes in six measured processes at each site after introduction of the checklist. During the baseline period, all six measured safety indicators were performed for 34.2% of the patients, with an increase to 56.7% of patients after implementation of the checklist (P<0.001). At each site, implementation of the checklist also required routine performance of team introductions, briefings, and debriefings, but adherence rates could not be measured.

DISCUSSION

Introduction of the WHO Surgical Safety Checklist into operating rooms in eight diverse hospitals was associated with marked improvements in surgical outcomes. Postoperative complication rates fell by 36% on average, and death rates fell by a similar amount. All sites had a reduction in the rate of major postoperative complications, with a significant reduction at three sites, one in a high-income location and two in lower-income locations. The reduction in complications was maintained when the analysis was adjusted for case-mix variables. In addition, although the effect of the intervention was stronger at some sites than at others, no single site was responsible for the overall effect, nor was the effect confined to high-income or low-income sites exclusively. The reduction in the rates of death and complications suggests that the checklist program can improve the safety of surgical patients in diverse clinical and economic environments.

Whereas the evidence of improvement in surgical outcomes is substantial and robust, the exact mechanism of improvement is less clear and most likely multifactorial. Use of the checklist involved both changes in systems and changes in the behavior of individual surgical teams. To implement the checklist, all sites had to introduce a formal pause in care during surgery for preoperative team introductions and briefings and postoperative debriefings, team practices that have previously been shown to be associated with improved safety processes and attitudes[14,20,21] and with a rate of complications and death reduced by as much as 80%.[13] The philosophy of ensuring the correct identity of the patient and site through preoperative site marking, oral confirmation in the operating room, and other measures proved to be new to most of the study hospitals.

In addition, institution of the checklist required changes in systems at three institutions, in order to change the location of administration of antibiotics. Checklist implementation encouraged the administration of antibiotics in the operating room rather than in the preoperative wards, where delays are frequent. The checklist provided additional oral confirmation of appropriate antibiotic use, increasing the adherence rate from 56 to 83%; this intervention alone has been shown to reduce the rate of surgical-site infection by 33 to 88%.[22-28] Other potentially lifesaving measures were also more likely to be instituted, including an objective airway evaluation and use of pulse oximetry, though the change in these measures was less dramatic.[15] Although the omission of individual steps was still frequent, overall adherence to the subgroup of six safety indicators increased by two thirds. The sum of these individual systemic and behavioral changes could account for the improvements observed.

Another mechanism, however, could be the Hawthorne effect, an improvement in performance due to subjects' knowledge of being observed.[29] The contribution of the Hawthorne effect is difficult to disentangle in this study. The checklist is orally performed by peers and is intentionally designed to create a collective awareness among surgical teams about whether safety processes are being completed. However, our analysis does show that the presence of study personnel in the operating room was not responsible for the change in the rate of complications.

This study has several limitations. The design, involving a comparison of preintervention data

Table 6. Selected Process Measures before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Objective Airway Evaluation Performed (N=7688)		Pulse Oximeter Used (N=7688)		Two Peripheral or One Central IV Catheter Present at Incision When EBL ≥500 ml (N=953)		Prophylactic Antibiotics Given Appropriately (N=6802)		Oral Confirmation of Patient's Identity and Operative Site (N=7688)		Sponge Count Completed (N=7572)		All Six Safety Indicators Performed (N=7688)	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
			percent													
1	524	598	97.0	98.5	100.0	100.0	95.7	83.6	98.1	96.9	100.0	100.0	98.9	100.0	94.1	94.2
2	357	351	72.0	75.8	97.5	98.6	78.8	61.3	56.9	76.9	9.5	97.2	100.0	100.0	3.6	55.3
3	497	486	74.7	66.3	98.6	100.0	83.8	82.5	83.8	87.7	47.1	90.1	97.8	96.8	30.8	51.0
4	520	545	94.6	95.8	100.0	100.0	66.7	48.6	80.0	81.8	98.9	97.6	97.3	99.1	67.1	63.7
5	370	330	6.2	0.0	68.9	91.2	7.6	2.7	29.8	96.2	0.0	86.1	0.0	92.4	0.0	0.0
6	496	476	46.2	56.3	76.4	83.0	49.2	57.9	25.4	50.6	21.8	64.9	99.4	99.4	1.4	18.1
7	525	585	97.5	99.7	99.4	100.0	32.0	100.0	42.5	91.7	98.9	100.0	100.0	100.0	46.7	92.1
8	444	584	0.5	94.0	99.3	99.5	68.8	57.1	18.2	77.6	16.4	98.8	61.3	70.0	0.0	51.7
Total	3733	3955	64.0	77.2	93.6	96.8	58.1	63.2	56.1	82.6	54.4	92.3	84.6	94.6	34.2	56.7
P value			<0.001		<0.001		0.32		<0.001		<0.001		<0.001		<0.001	

* Prophylactic antibiotics were considered to be indicated for all cases in which an incision was made through an uncontaminated field and appropriately administered when given within 60 minutes before an incision was made. Sponge counts were considered to be indicated in all cases in which an incision was made. P values are shown for the comparison of the total values before and after checklist implementation, calculated by means of the chi-square test. EBL denotes estimated blood loss, and IV intravenous.

with postintervention data and the consecutive recruitment of the two groups of patients from the same operating rooms at the same hospitals, was chosen because it was not possible to randomly assign the use of the checklist to specific operating rooms without significant cross-contamination. One danger of this design is confounding by secular trends. We therefore confined the duration of the study to less than 1 year, since a change in outcomes of the observed magnitude is unlikely to occur in such a short period as a result of secular trends alone. In addition, an evaluation of the American College of Surgeons' National Surgical Quality Improvement Program cohort in the United States during 2007 did not reveal a substantial change in the rate of death and complications (Ashley S. personal communication, http://acsnsqip.org). We also found no change in our study groups with regard to the rates of urgent cases, outpatient surgery, or use of general anesthetic, and we found that changes in the case mix had no effect on the significance of the outcomes. Other temporal effects, such as seasonal variation and the timing of surgical training periods, were mitigated, since the study sites are geographically mixed and have different cycles of surgical training. Therefore, it is unlikely that a temporal trend was responsible for the difference we observed between the two groups in this study.

Another limitation of the study is that data collection was restricted to inpatient complications. The effect of the intervention on outpatient complications is not known. This limitation is particularly relevant to patients undergoing outpatient procedures, for whom the collection of outcome data ceased on their discharge from the hospital on the day of the procedure, resulting in an underestimation of the rates of complications. In addition, data collectors were trained in the identification of complications and collection of complications data at the beginning of the study. There may have been a learning curve in the process of collecting the data. However, if this were the case, it is likely that increasing numbers of complications would be identified as the study progressed, which would bias the results in the direction of an underestimation of the effect.

One additional concern is how feasible the checklist intervention might be for other hospitals. Implementation proved neither costly nor lengthy. All sites were able to introduce the checklist over a period of 1 week to 1 month. Only two of the safety measures in the checklist entail the commitment of significant resources: use of pulse oximetry and use of prophylactic antibiotics. Both were available at all the sites, including the low-income sites, before the intervention, although their use was inconsistent.

Surgical complications are a considerable cause of death and disability around the world.[3] They are devastating to patients, costly to health care systems, and often preventable, though their prevention typically requires a change in systems and individual behavior. In this study, a checklist-based program was associated with a significant decline in the rate of complications and death from surgery in a diverse group of institutions around the world. Applied on a global basis, this checklist program has the potential to prevent large numbers of deaths and disabling complications, although further study is needed to determine the precise mechanism and durability of the effect in specific settings.

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APPENDIX

The members of the Safe Surgery Saves Lives Study Group were as follows: **Amman, Jordan:** A.S. Breizat, A.F. Awamleh, O.G. Sadieh; **Auckland, New Zealand:** A.F. Merry, S.J. Mitchell, V. Cochrane, A.-M. Wilkinson, J. Windsor, N. Robertson, N. Smith, W. Guthrie, V. Beavis; **Ifakara, Tanzania:** P. Kibatala, B. Jullu, R. Mayoka, M. Kasuga, W. Sawaki, N. Pak; **London, England:** A. Darzi, K. Moorthy, A. Vats, R. Davies, K. Nagpal, M. Sacks; **Manila, Philippines:** T. Herbosa, M.C.M. Lapitan, G. Herbosa, C. Meghrajani; **New Delhi, India:** S. Joseph, A. Kumar, H. Singh Chauhan; **Seattle, Washington:** E.P. Dellinger, K. Gerber; **Toronto, Canada:** R.K. Reznick, B. Taylor, A. Slater; **Boston, Massachusetts:** W.R. Berry, A.A. Gawande, A.B. Haynes, S.R. Lipsitz, T.G. Weiser; **Geneva, Switzerland:** L. Donaldson, G. Dziekan, P. Philip; **Baltimore, Maryland:** M. Makary; **Ankara, Turkey:** I. Sayek; **Sydney, Australia:** B. Barraclough.

REFERENCES

1. Weiser TG, Regenbogen SE, Thompson KD, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. Lancet 2008;372:139-44.
2. Ronsmans C, Graham WJ. Maternal mortality: who, when, where, and why. Lancet 2006;368:1189-200.
3. Debas HT, Gosselin R, McCord C,

Thind A. Surgery. In: Jamison DT, Breman JG, Measham AR, et al., eds. Disease control priorities in developing countries. 2nd ed. Disease Control Priorities Project. Washington, DC: International Bank for Reconstruction and Development/World Bank, 2006:1245-60.
4. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery 1999;126:66-75.
5. Kable AK, Gibberd RW, Spigelman AD. Adverse events in surgical patients in Australia. Int J Qual Health Care 2002;14:269-76.
6. Bickler SW, Sanno-Duanda B. Epidemiology of paediatric surgical admissions to a government referral hospital in the Gambia. Bull World Health Organ 2000;78:1330-6.
7. Yii MK, Ng KJ. Risk-adjusted surgical audit with the POSSUM scoring system in a developing country. Br J Surg 2002;89:110-3.
8. McConkey SJ. Case series of acute abdominal surgery in rural Sierra Leone. World J Surg 2002;26:509-13.
9. Ouro-Bang'na Maman AF, Tomta K, Ahouangbévi S, Chobli M. Deaths associated with anaesthesia in Togo, West Africa. Trop Doct 2005;35:220-2.
10. Dellinger EP, Hausmann SM, Bratzler DW, et al. Hospitals collaborate to decrease surgical site infections. Am J Surg 2005;190:9-15.
11. Classen DC, Evans RS, Pestotnik SL, Horn SD, Menlove RL, Burke JP. The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection. N Engl J Med 1992;326:281-6.
12. Runciman WB. Iatrogenic harm and anaesthesia in Australia. Anaesth Intensive Care 2005;33:297-300.
13. Mazzocco K, Petitti DB, Fong KT, et al. Surgical team behaviors and patient outcomes. Am J Surg 2008 September 11 (Epub ahead of print).
14. 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;143:12-8.
15. World Alliance for Patient Safety. WHO guidelines for safe surgery. Geneva: World Health Organization, 2008.
16. World Bank. Data & statistics: country classification. (Accessed January 5, 2009, at http://go.worldbank.org/K2CKM78CC0.)
17. Khuri SF, Daley J, Henderson W, et al. The National Veterans Administration Surgical Risk Study: risk adjustment for the comparative assessment of the quality of surgical care. J Am Coll Surg 1995;180:519-31.
18. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205-13.
19. Fleiss JL, Levin B, Paik MC. Statistical methods for rates and proportions. 3rd ed. Hoboken, NJ: John Wiley, 2003.
20. Sexton JB, Makary MA, Tersigni AR, et al. Teamwork in the operating room: frontline perspectives among hospitals and operating room personnel. Anesthesiology 2006;105:877-84.
21. Makary MA, Sexton JB, Freischlag JA, et al. Operating room teamwork among physicians and nurses: teamwork in the eye of the beholder. J Am Coll Surg 2006;202:746-52.
22. Platt R, Zaleznik DF, Hopkins CC, et al. Perioperative antibiotic prophylaxis for herniorrhaphy and breast surgery. N Engl J Med 1990;322:153-60.
23. Austin TW, Coles JC, Burnett R, Goldbach M. Aortocoronary bypass procedures and sternotomy infections: a study of antistaphylococcal prophylaxis. Can J Surg 1980;23:483-5.
24. Baum ML, Anish DS, Chalmers TC, Sacks HS, Smith H Jr, Fagerstrom RM. A survey of clinical trials of antibiotic prophylaxis in colon surgery: evidence against further use of no-treatment controls. N Engl J Med 1981;305:795-9.
25. Bernard HR, Cole WR. The prophylaxis of surgical infection: the effect of prophylactic antimicrobial drugs on the incidence of infection following potentially contaminated operations. Surgery 1964;56:151-7.
26. Hasselgren PO, Ivarsson L, Risberg B, Seeman T. Effects of prophylactic antibiotics in vascular surgery: a prospective, randomized, double-blind study. Ann Surg 1984;200:86-92.
27. Barker FG II. Efficacy of prophylactic antibiotics for craniotomy: a meta-analysis. Neurosurgery 1994;35:484-92.
28. Norden CW. Antibiotic prophylaxis in orthopedic surgery. Rev Infect Dis 1991;13:Suppl 10:S842-S846.
29. Mayo E. The human problems of an industrial civilization. New York: Macmillan, 1933.