# SPECIAL ARTICLE

# Introduction of Surgical Safety Checklists in Ontario, Canada

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#### 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.)

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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,<sup>5-11</sup> have been limited to a small number of centers,<sup>6-11</sup> have not evaluated patient outcomes,<sup>8-10</sup> or have not shown the magnitude of effectiveness found in the WHO study.<sup>6,7</sup> Only studies including team training<sup>11-13</sup> or a more comprehensive safety system that includes multiple checklists<sup>14</sup> have shown effectiveness similar to that seen in the WHO study.

Implementation of surgical safety checklists is not uniform, <sup>15,16</sup> 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. <sup>17</sup> 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.<sup>20</sup> 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),<sup>21</sup> 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 generalizedestimating-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 hos-

pital had a significant change in operative mortality after checklist introduction (Fig. 1A). Withinhospital 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 populationbased 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

| 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)                            |  |

<sup>\*</sup> 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.

<sup>†</sup> 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<sup>21</sup>; 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.

<sup>¶</sup> 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.

| Outcome                                                                        | Before Checklist<br>Introduction | After Checklist<br>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    |
| ength 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    |

<sup>\*</sup> 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).

use did not result in reductions in risks of surgical complications, emergency department visits,

and 0.65% after checklist introduction. Checklist discharge. There was a significant but small and not clinically relevant reduction in adjusted length of hospital stay (5.11 days before checklist introor hospital readmissions within 30 days after duction and 5.07 days afterward). Surgical check-

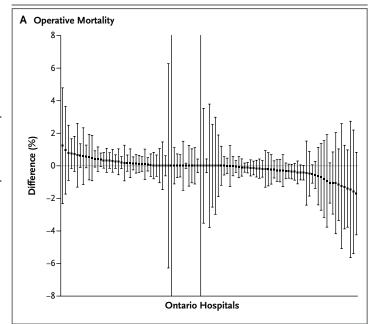
<sup>†</sup> P values are for the comparison of values before and after introduction of the checklist.

<sup>†</sup>The model included only inpatient hospitalizations.

lists 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



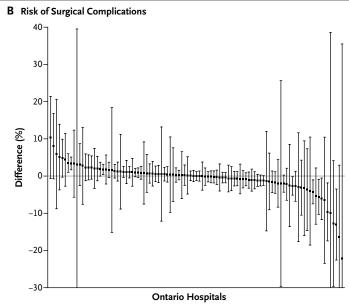


Figure 1. Within-Hospital Changes in Operative Mortality and Risk of Surgical Complications.

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.

WHO recommendations<sup>25</sup> and was similar to that used in many other jurisdictions.<sup>3,26-28</sup> It is possible that published evidence regarding the efficacy of implementing checklists within hos-

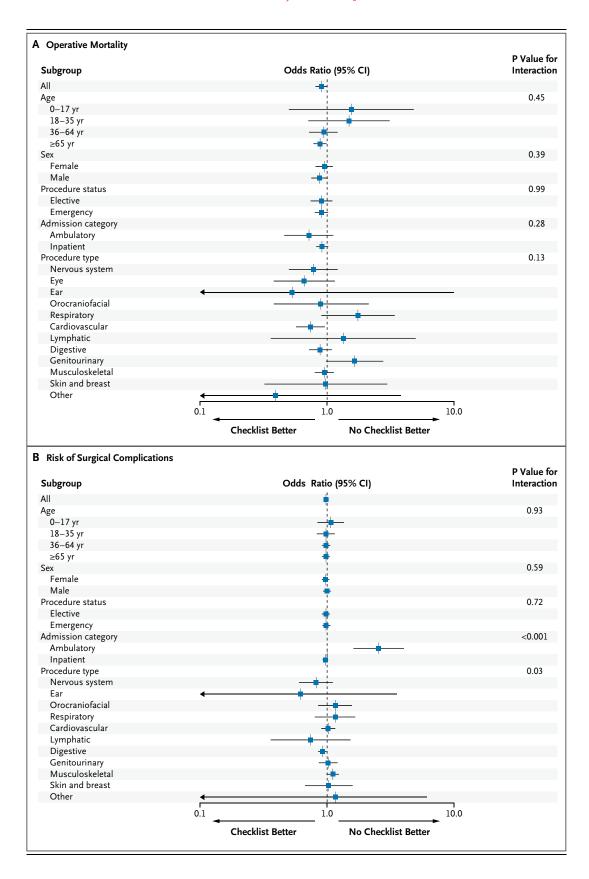


Figure 2 (facing page). Odds Ratios for Operative Mortality and Surgical Complications, Stratified According to Age, Sex, Procedure Status, Admission Category, and Type of Procedure.

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<sup>1</sup> 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 training11-13 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<sup>30</sup>). 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 review35-37 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.

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