Mortality Trends After a Voluntary Checklist-based Surgical Safety Collaborative

Alex B. Haynes, MD, MPH, Lizabeth Edmondson, BA,† Stuart R. Lipsitz, ScD,† George Molina, MD, MPH,* Bridget A. Neville, MPH,† Sara J. Singer, MBA, PhD,* Aunyika T. Moonan, PhD, CPHQ,§ Ashley Kay Childers, PhD, CPHQ,‡ Richard Foster, MD,§ Lorri R. Gibbons, MSHL, RN, CPHQ,§ Atul A. Gawande, MD, MPH,† and William R. Berry, MD, MPH†*

Objective: To determine whether completion of a voluntary, checklist-based surgical quality improvement program is associated with reduced 30-day postoperative mortality.

Background: Despite evidence of efficacy of team-based surgical safety checklists in improving perioperative outcomes in research trials, effective methods of population-based implementation have been lacking. The Safe Surgery 2015 South Carolina program was designed to foster state-wide engagement of hospitals in a voluntary, collaborative implementation of a checklist program.

Methods: We compared postoperative mortality rates after inpatient surgery in South Carolina utilizing state-wide all-payer discharge claims from 2008 to 2013, linked with state vital statistics, stratifying hospitals on the basis of completion of the checklist program. Changes in risk-adjusted 30-day mortality were compared between hospitals, using propensity score-adjusted difference-in-differences analysis.

Results: Fourteen hospitals completed the program by December 2013. Before program launch, there was no difference in mortality trends between the completion cohort and all others ($P = 0.33$), but postoperative mortality diverged thereafter ($P = 0.021$). Risk-adjusted 30-day mortality among completers was 3.38% in 2010 and 2.84% in 2013 ($P < 0.00001$), whereas mortality among other hospitals ($n = 44$) was 3.50% in 2010 and 3.71% in 2013 ($P = 0.3281$), reflecting a 22% difference between the groups on difference-in-differences analysis ($P = 0.0021$).

Conclusions: Despite similar pre-existing rates and trends of postoperative mortality, hospitals in South Carolina completing a voluntary checklist-based surgical quality improvement program had a reduction in deaths after inpatient surgery over the first 3 years of the collaborative compared with other hospitals in the state. This may indicate that effective large-scale implementation of a team-based surgical safety checklist is feasible.

Keywords: implementation, postoperative mortality, surgical safety checklists

(*Ann Surg* 2017;266:923–929)

In 2009, the results of an 8-hospital pilot of the World Health Organization Safe Surgery Saves Lives checklist were reported, describing a marked reduction in postoperative morbidity and mortality after checklist implementation in diverse hospitals around the world.[1] After that publication and the public launch of the checklist, multiple research trials have confirmed the efficacy of checklist-based quality-improvement initiatives using a variety of methodologies, including randomized trials.[2–6] However, larger, population-level implementation efforts, often in conjunction with a regulatory mandate, have demonstrated disappointing results, and the elements required for effective implementation are unclear.[7,8]

Evidence-based surgical safety checklists are designed to have a simple form, making it easier for teams to ensure that critical safety steps are consistently applied and foster an atmosphere of communication and information sharing that protects patient safety.[9,10] However, bringing surgical teams to integrate checklists into the complex environment of the operating room appears to often require a coordinated and sustained effort.[9,11] According to previous studies, effective adoption of the checklist is unlikely to be achieved without multidisciplinary participation in the implementation effort by clinical and executive leadership and adaptation of the checklist to the local perioperative workflow.[9] Mandated use of checklists without systematic implementation processes has produced limited adoption and no measureable mortality improvement.[7,12]

To facilitate meaningful introduction of a surgical safety checklist at a population-wide level, a group of stakeholders in South Carolina came together, beginning in October 2010, to engage and support hospitals to improve surgical safety through the integration of a customized version of the WHO Surgical Safety Checklist into their perioperative care processes. The checklist is designed to enable teamwork, communication, and a culture of safety; a voluntary, structured process was therefore employed to increase acceptance of change in these facets of perioperative care. Our group has previously reported improvements of staff perceptions of patient safety associated with this program.[13] We seek here to understand the relationship between completion of the program and mortality after inpatient surgery.

METHODS

Intervention

We established a surgical safety program built upon principles taken from prior initiatives that have successfully introduced team-based safety tools into complex clinical environments, particularly emphasizing multidisciplinary engagement, team alignment, and a culture of patient safety.[14–18] This program consisted of a 12-part hospital implementation process composed of activities to support checklist implementation and culture change over time, such as securing resources and multidisciplinary participation (including surgical and executive leaders); conducting formal assessment of patient safety culture; modifying the checklist based on local feedback; providing teams with training in checklist use; rollout with a pilot group before full launch; evaluating progress through direct observation; and pursuing continuous quality improvement (Table 1).

From the *Ariadne Labs, Massachusetts General Hospital, Harvard T.H. Chan School of Public Health, Boston, MA; †Ariadne Labs, Brigham and Women's Hospital, Boston, MA; ‡South Carolina Hospital Association, Clemson University; and §South Carolina Hospital Association, Columbia, SC.
Funding: Branta and Rx Foundations, AHRQ (R18:HS019631).
The authors declare no conflict of interests.
Reprints: Alex B. Haynes, MD, MPH, Ariadne Labs, 401 Park Drive, 3rd Floor East, Boston, MA 02115. E-mail: abhaynes@partners.org.

ISSN: 0003-4932/17/26606-0923
DOI: 10.1097/SLA.0000000000002249

TABLE 1. Checklist Implementation Process Recommended to Participating Hospitals

1. Recruitment of a multidisciplinary implementation team
2. Ensuring resources in place for the work to be done
3. Assessment of surgical culture, environment, and safe practice
4. Active decision to implement once prepared
5. Customization and small-scale testing of the modified checklist
6. Structured rollout, starting with a pilot group, then scaling to all on an explicit timeline
7. Engagement of all involved in surgical care delivery with 1-on-1 conversations before full launch
8. Promotion of the checklist in the perioperative environment
9. Training of OR team members and spread of checklist use
10. Observation of checklist performance
11. Coaching of individual OR teams
12. Continuous monitoring of checklist use with ongoing quality improvement

Ariadne Labs partnered with the South Carolina Hospital Association to establish a state-wide hospital collaborative to facilitate voluntary implementation of the surgical safety program. The design of the collaborative and its activities follows lessons from previous population-based quality improvement programs.[19–22] A state-level leadership team including clinical champions, administrators, representatives from insurance carriers, and researchers was convened to guide the effort. To support hospitals, the collaborative offered several activities to foster engagement, learning, and success in completing the implementation program; hospitals were encouraged to participate in as many activities as possible. Each hospital formed a leadership team with representatives from all perioperative disciplines. This work was conducted within the scope of existing positions (eg, quality officers and perioperative safety teams); hospitals did not hire additional staff or receive direct financial support for this work. The collaborative held semi-annual in-person meetings with implementation leaders from participating hospitals to provide training and to allow peer-to-peer sharing of experiences between hospitals. A webinar-based educational series was provided that walked the hospitals' implementation teams through the steps to put the checklist into clinical use. There were 3 opportunities for hospitals to participate in the educational series over the course of the program. Hospitals could participate in as many modules as fit their needs. All modules were also available online for asynchronous viewing.

Members of the collaborative leadership team also provided coaching in implementation strategy and checklist performance improvement, both through teleconferences and site visits. Implementation materials were collected from hospitals, including checklists and promotional materials throughout the program, to monitor progress, improve the educational program, and coach individual hospitals. Hospital executive leaders were continually engaged, including through engagement reports, newsletters, presentations at conferences, and one-on-one visits by the collaborative team.

As part of the implementation, surveys were administered to measure perceptions of safety of perioperative practice before implementation.[23] These surveys provided baseline data and frequently helped identify areas for improvement that checklist implementation could address. Once local teams reported that their implementation process was complete, repeat perioperative safety assessments were performed to measure progress.

Data Sources

We used all-payer discharge claims from South Carolina encompassing all inpatient admissions and emergency department (ED) visits from 2008 to 2013 to assess perioperative outcomes before and during the program period. These datasets were obtained from the state Revenue and Fiscal Affairs (RFA) Office. The inpatient dataset included all hospital admissions in South Carolina, whereas the ED dataset captured all ED use. Information from these datasets included patient demographics, primary diagnosis [International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic codes], primary procedure (ICD-9-CM procedure codes), primary payer, and discharge disposition, including death. Patients are assigned an encrypted unique identifier that provides linkage both within and across these datasets, allowing identification of subsequent episodes of care. Using this identifier, we linked the data to the state vital statistics registry, allowing identification of patient deaths at any point in the postoperative period.

Cohort Definition

All hospitals in the state of South Carolina performing adult inpatient surgery were included in the analysis, unless they did not bill insurance or generate standardized discharge claims for all patients (eg, Veteran's Administration, military, and exclusively charitable hospitals). Hospitals were included in the program completion cohort if they had completed the longitudinal program, culminating in the postimplementation assessment of safe surgical practice and culture, by December 31, 2013. All other hospitals were included in the comparison cohort, regardless of the degree of participation in activities of the collaborative.

Patient Inclusion and Exclusion Criteria

We identified patients undergoing inpatient surgical procedures in 1 of the above-mentioned hospitals from inpatient claims data. We excluded from analysis patients under the age of 18, undergoing obstetric procedures, or spending less than 2 midnights in the hospital after their index procedure. Outcome data were only available through the end of 2013; therefore we removed patients with index operations in December 2013 due to less than 30 days of available follow-up. We classified procedures according to the clinical classification software for ICD-9-CM single-level procedure categories.[24]

Comparing Cohort Characteristics

We used generalized estimating equations, clustering by hospital, for categorical and continuous outcomes when testing for differences in patient characteristics between hospital cohorts.[25] We used Fisher exact tests to analyze differences in hospital characteristics, which are all categorical.

Analysis of 30-Day Postoperative Mortality Trends, 2008 to 2013

To understand any pre-existing trends, we modeled 30-day postoperative mortality over time (monthly from January 2008 through November 2013) using a logistic regression model for the probability of death within the first 30-day period as a function of time of covariates, clustering by hospital to estimate the standard error.[26] We defined the period January 2008 through December 2010 as the "baseline period," because it was before the beginning of the implementation, and then defined the period January 2011 through November 2013 as the "postimplementation period." In the logistic regression, instead of fitting a highly parametric function in time, we modeled time as a quadratic spline of month, with different quadratic splines in the pre and post period.[27] An interaction term between group (completers vs comparison) and time was included to determine if the trends over time were similar in the 2 groups during both the pre and post periods. In these repeated-measures models, we also adjusted for 143 available patient and hospital characteristics using a machine learning technique—supervised principal components regression.[28] We employed generalized estimating equations to estimate the parameters of the repeated-measures models, clustering by hospital. The Akaike information criterion was used to determine the best fitting logistic regression model as a function of time trends and principal components.

Preprogram Versus Postprogram Implementation Comparison (2010 vs 2013)

For the main analysis, the primary outcome of interest was the difference in changes in 30-day postoperative mortality between hospitals that completed the program and all others. Secondary outcomes were differences in rates of reoperation and unplanned readmissions. We aimed to determine if outcomes (30-day postoperative mortality, rates of reoperation, and unplanned readmissions) changed over time and selected the years 2010 and 2013 for comparison in relation to the Safe Surgery 2015 program: 2010 was before implementation and 2013 was the most recent data available. To estimate the effect size, we used propensity score methods to estimate the differences in outcomes between these years. The propensity score, defined as the probability of having surgery in 1 of 4 groups (either in 2010 or 2013 and in a completion or comparison hospital was estimated using multinomial logistic regression). Propensity score weighting was used to account for possible differences in the 143 possible correlated confounders. Supervised principal components logistic regression was used to incorporate the large number of possibly highly correlated predictors in the propensity score to minimize confounding bias.[28] The Akaike information criterion was used to determine the best fitting propensity score logistic regression model. In the propensity-weighted approach, each patient was weighted by the inverse propensity of having surgery in 2010 versus 2013 within the 2 cohorts. The effect of time period (2010 vs 2013) within group (completers vs others) on any of the outcomes was estimated using the simple difference in propensity-weighted proportions or means between the 2 hospital groups. To account for clustering within hospital, generalized estimating equations were used to test for differences in outcomes between the cohorts, and also to calculate 95% confidence intervals (CIs) for adjusted proportions and means.

A *P* value less than 0.05 was considered statistically significant. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC). This study was approved by the Harvard T.H. Chan School of Public Health Institutional Review Board.

RESULTS

Fifty-eight hospitals performing inpatient surgery in South Carolina were included in the analysis; 14 had completed the Safe Surgery 2015 program by December 2013, representing nearly 40% of the inpatient operative volume in the state. There were no significant differences between the 2 cohorts in terms of rurality, teaching status, or licensed bed size (Table 2). Completion hospitals were more likely to have participated in the complete webinar series (78.6% vs 38.6%; $P = 0.022$), administer the baseline safety of surgical practice survey (100% vs 40.9%; $P < 0.001$), formally designate a physician champion (78.6% vs 15.9%; $P < 0.001$), and attend 1 of the team training sessions (92.9% vs 47.7%; $P = 0.008$). In hospitals that completed the Safe Surgery 2015 program, 22,514 adult patients underwent nonobstetric, inpatient procedures in 2010, whereas 18,112 did so in the first 11 months of 2013. Within comparison hospitals, 38,876 and 30,218 patients underwent procedures in 2010 and 2013, respectively. After propensity score adjustment, there were no significant patient-level differences between years in either group of hospitals (Table 3).

Figure 1 presents the trends in mortality rate from 2008, 2 years before formation of the collaborative, through 2013, in the 2 cohorts of hospitals. Using difference-in-difference analysis, there was no significant difference in mortality trends between the groups in the period before collaborative formation, 2008 to 2010 ($P = 0.72$). From 2011 to 2013, there was a statistically significant trend of decreasing postoperative mortality among the completion cohort ($P = 0.024$), whereas there was no such trend within the comparison cohort ($P = 0.27$). The difference between these 2 cohorts' mortality trends was significantly different in the postintervention period ($P = 0.016$).

TABLE 2. Characteristics of Hospitals in South Carolina*

Characteristics	Completing Hospitals (n = 14 hospitals)	All Other Hospitals (n = 44 hospitals)	*P*†
	(N, %)	(N, %)	
Location			0.76
Rural	7 (50.0)	18 (40.9)	
Urban	7 (50.0)	26 (59.1)	
Teaching status			0.09
No	10 (71.4)	40 (90.9)	
Yes	4 (28.6)	4 (9.1)	
Number of beds‡			0.19
0 to 269	8 (57.1)	34 (77.3)	
270 to 453	3 (21.4)	7 (15.9)	
≥454	3 (21.4)	3 (6.8)	

*Excludes hospitals that do not generate a standard discharge claim (eg, Veteran's Administration, military, and exclusively charitable hospitals).
†Chi-square statistic test used to compare categorical groups.
‡Number of licensed hospital beds based on data from 2012.

Among hospitals that completed the program, the 30-day postoperative mortality rate was 3.38% in 2010 and 2.84% in 2013 ($P < 0.001$). There was no difference between the 2010 and 2013 rates in comparison hospitals: 3.50% and 3.71%, respectively ($P = 0.33$). Difference in differences analysis identified a significant change of 0.74% between the 2 cohorts [95% confidence interval (CI) 0.27%, 1.22%, $P = 0.0021$], reflecting a relative reduction in postoperative mortality of 21.9%. The overall state-wide 30-day postoperative mortality rate was not significantly changed from 2010 to 2013 (3.43% vs 3.40%; $P = 0.84$) There were no significant differences in unplanned readmissions or reoperations over the period of the program (Table 4).

DISCUSSION

In South Carolina hospitals completing a voluntary, structured introduction of a team-based surgical safety checklist through a statewide collaborative, clinical outcomes of patients undergoing inpatient surgery were improved with significantly lower 30-day postoperative mortality than those hospitals that had not completed the program by the end of 2013. Whereas there are likely differences between these groups of hospitals in their ability to execute on large-scale quality-improvement projects, those differences had not been sufficient to produce a significant difference in postoperative mortality trends before the intervention period. They only diverged following introduction of the checklist program.

In 2 population-level introductions of surgical safety checklists that have been evaluated—in Ontario, Canada, and in England—government regulators made surgical checklist adoption mandatory for hospitals, but provided limited training and support for their implementation teams.[7,11] In Ontario, researchers found no overall mortality reduction 3 months after self-reported compliance with the mandate.[7,11] This finding has been interpreted to mean that although surgical safety checklists have shown efficacy in research trials, they

TABLE 3. Weighted Propensity-adjusted* Counts and Proportions of Patient Characteristics

	Completing Hospitals (N = 40,626 Patients)					All Other Hospitals (N = 69,094 Patients)				
	2010 (n = 22,514)		2013 (n = 18,112)			2010 (n = 38,876)		2013 (n = 30,218)		
Characteristics	Normalized n	% (SE)	Normalized n	% (SE)	*P*	Normalized n	% (SE)	Normalized n	% (SE)	*P*
Patient level										
Mean age	58.1	(1.1)	58.1	(1.3)	0.82	60.2	(0.6)	60.2	(0.6)	0.95
Age					0.60					0.98
<60	11052	49.1	8968	49.5		17446	44.9	13556	44.9	
≥60	11462	50.9	9144	50.5		21429	55.1	16662	55.1	
Sex					0.90					0.97
Female	12352	54.9	9926	54.8		21308	54.8	16556	54.8	
Male	10162	45.1	8186	45.2		17566	45.2	13661	45.2	
Race					0.06					0.82
White	15254	67.8	12095	66.8		28774	74.0	22458	74.3	
African-American	6440	28.6	5390	29.8		8958	23.0	6927	22.9	
Other	820	3.6	627	3.5		1142	2.9	833	2.8	
Insurance type					0.28					0.99
Self-pay	1460	6.5	1321	7.3		2512	6.5	1954	6.5	
Government†	12580	55.9	10183	56.2		23395	60.2	18201	60.2	
Commercial/HMO	8474	37.6	6607	36.5		12967	33.4	10062	33.3	
Charlson score					0.21					0.20
None	14577	64.8	12142	67.0		24897	64.0	19482	64.5	
1	2860	12.7	2293	12.7		5050	13.0	3875	12.8	
2	1805	8.0	1331	7.4		3264	8.4	2402	8.0	
≥3	3272	14.5	2345	13.0		5663	14.6	4459	14.8	
Case-mix					0.61					0.27
Neurosurgical	2462	12.2	2125	13.2		3190	9.2	2694	10.0	
Head and neck	1020	5.1	847	5.2		912	2.6	756	2.8	
Thoracic	537	2.7	531	3.3		948	2.7	783	2.9	
Cardiac	1322	6.5	1107	6.9		2909	8.4	2196	8.1	
GI/abdominal	4665	23.1	3670	22.7		7825	22.5	6218	23.0	
Urologic	1062	5.3	735	4.6		1903	5.5	1475	5.5	
Gynecologic	1754	8.7	1362	8.4		3476	10.0	2345	8.7	
Orthopedic	4145	20.5	3306	20.5		7573	21.8	5860	21.7	
Vascular	2347	11.6	1814	11.2		4696	13.5	3628	13.4	
Skin/soft tissue	891	4.4	664	4.1		1301	3.8	1061	3.9	
Hospital level										
Location					0.95					0.38
Rural	2473	11.0	1977	10.9		6925	17.8	5222	17.3	
Urban	20041	89.0	16134	89.1		31949	82.2	24996	82.7	
Teaching status					0.58					0.89
No	8895	39.5	7282	40.2		27094	69.7	21019	69.6	
Yes	13619	60.5	10830	59.8		11781	30.3	9198	30.4	
Number of beds					0.44					0.42
0 to 269	2896	12.9	2208	12.2		16401	42.2	13005	43.0	
270 to 453	9333	41.5	7767	42.9		12404	31.9	9314	30.8	
≥454	10285	45.7	8136	44.9		10070	25.9	7899	26.1	

*Variables adjusted for in the propensity score analysis (using the 30 most significant principal components remaining in the model if $P < 0.10$, plus age, sex and insurance payor, race, Charlson score, taking into account the year before the index surgery, hospital location (urban vs rural), hospital teaching status, number of licensed hospital beds, and case-mix (using Clinical Classification System grouper).

†Government insurance includes Medicare, Medicaid, Worker's Compensation, and Indigent Care.

may not be effective outside such trials.[29] In England, however, researchers examined checklist adoption after the mandate, and found wide discrepancies between self-reported and observed compliance.[8] A study of 5 hospitals found that surgical inpatients for whom the checklist was actually completed (only 62% of cases) had significantly (34%) lower rates of major complications compared with other patients. Mortality trended similarly lower as well, but the sample size was too small to establish significance. The findings suggested that, with an implementation process to strengthen actual use, the surgical safety checklist program could be effective in improving outcomes in the real world, as opposed to a research setting.[11] It has been unknown, however, what the features of such a process are and whether it could be feasible. This current study establishes features of an effective process, feasibility, and substantial impact. Whereas overall state-wide postoperative mortality rates did not deviate from pre-existing trends, there was a significant, 22% mortality reduction in those hospitals that completed the checklist-based safety program.

The findings indicate that the institutional engagement necessary to create the requisite behavioral changes among teams of surgical professionals is unlikely to occur without broad, sustained participation of both frontline clinicians and hospital leadership. The checklist was specifically designed to better enable team communication and a culture of safety; implementation is unlikely to affect patient outcomes without fostering acceptance of change in attitudes toward patient safety and team behaviors in the operating room. Participants in the program moved at different paces, and implementation efforts continue beyond the timeframe reported here in

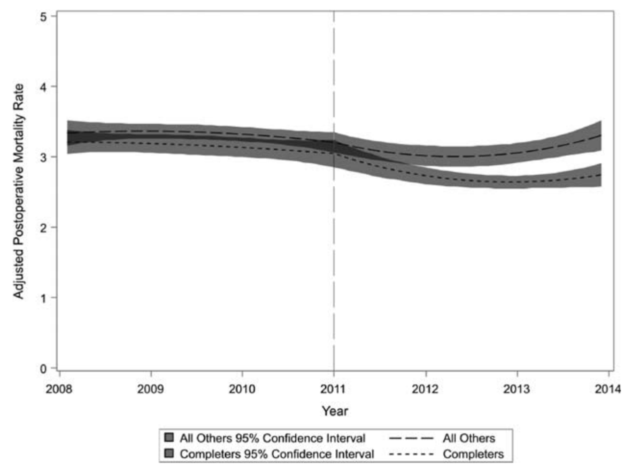

FIGURE 1. Trends in postoperative mortality after inpatient surgery in South Carolina, 2008 to 2013. The 2 lines illustrate trends in adjusted mortality rates among hospitals that completed the program (dashed line) and all others (solid line) with 95% confidence intervals. Difference-in-difference analysis of the trends from 2008 to 2010 shows no difference between the 2 groups ($P = 0.72$), whereas the difference in trends from 2011 to 2013 is significant ($P = 0.016$).

many hospitals within the state. The specific attributes leading to completion of the program within this group are important to understand to inform other hospitals and large-scale initiatives. There were no significant structural differences identified; hospitals completing the program included large and small, rural and urban, and also teaching and nonteaching hospitals, but there are likely unmeasured differences that led the completion group to be primed for improvement.

A limitation of this evaluation is that it involved a large-scale quality improvement initiative instead of a research trial, and no formal control group was established, as all hospitals in the state were exposed to at least some portion of the intervention. However, this partial involvement would have introduced a conservative bias into this analysis. It is also important to recognize that the intervention extended beyond simple presence of checklists in the operating room. It is likely and has been established in other settings that checklists may be present in the perioperative process without effective utilization.[7,8,12] The Safe Surgery program stressed stepwise implementation paired with targeted education around team communication and consistency of care, the fundamental principles around which surgical safety checklists are formed. It is not possible from this study to know which elements of the intervention were key to the changes in perioperative practice and outcomes.

It is conceivable that differences seen between the 2 groups of hospitals could be due to factors other than implementation of the checklist. There is a slight trend toward decreasing mortality before the intervention in both cohorts of hospitals. However, the 2 groups of hospitals had statistically similar rates of postoperative mortality before commencement of the collaborative program, with the trends in mortality only diverging significantly as the program progressed. This suggests that pre-existing improvement trends were not responsible for the differences between the 2 groups after the initiative. However, it is possible that other factors between the 2 groups changed during this time period and may serve as potential confounders. We adjusted for case-mix and differences in patient population in the analysis to mitigate potential differences between

TABLE 4. Adjusted Outcomes of Interest in Completing Hospitals Versus All Others in 2010 and 2013

	Adjusted Completers					Adjusted All Others					Difference Between Completers and All Others	
	2010 Rate (%)	2013 Rate (%)	Absolute Percentage Point Difference	Relative % Difference (95% CI)	P^*	2010 Rate (%)	2013 Rate (%)	Absolute Percentage Point Difference	Relative % Difference (95% CI)	P^*	Absolute Percentage Point Difference (95% CI)	P
30-day postoperative mortality†	3.38	2.84	0.54	16.06 (9.93 to 21.77)	<0.0001	3.50	3.71	−0.20	−5.75 (−18.17 to 5.37)	0.33	0.74 (0.27 to 1.22)	0.002
Unplanned readmission‡	9.35	7.87	1.48	15.81 (−1.18 to 29.95)	0.08	8.27	8.42	−0.14	−1.75 (−11.09 to 6.82)	0.70	1.62 (−0.17 to 3.42)	0.08
Reoperation	2.59	2.50	0.09	3.41 (−2.78 to 9.23)	0.26	2.72	2.59	0.13	4.89 (−6.81 to 15.30)	0.40	−0.04 (−0.39 to 0.30)	0.80
Death during index admission	1.95	1.55	0.40	20.53 (8.47 to 31.01)	0.01	2.09	2.21	−0.13	−6.00 (−22.87 to 8.56)	0.45	0.52 (0.08 to 0.97)	0.02

*P value from propensity-adjusted chi-square test. Variables adjusted for in the propensity score analysis (using the 30 most significant principal components remaining in the model if $P < 0.10$, plus age, sex and insurance payor, race, Charlson score, taking into account the year before the index surgery, hospital location (urban vs rural), hospital teaching status, number of licensed hospital beds, and case-mix (using Clinical Classification System grouper).

†Death during the index admission or during a 30-day readmission or ED visit. This also includes all deaths that were registered with the state-wide vital statistics database that occurred within 30 days of the index surgical procedure.

‡Unplanned readmission within 30 days, as defined by Centers for Medicare and Medicaid Services (CMS).

the groups and changes over time. However, it is likely that there are unmeasured differences between the 2 cohorts of hospitals. The classification of hospitals according to completion of the program was made after we encountered significant variation in follow through with the program, providing a natural experiment, but it remains unclear what factors led to successful completion in these sites. The hospitals that completed the program are potentially more capable of executing quality improvement initiatives. Nonetheless, these facilities require an intervention to execute. The findings here demonstrate that when given such a tool, clinically and statistically meaningful changes in postoperative mortality rates occur. For future interventions, it will be important to understand what factors within the completion cohort may have contributed to the ability to execute on this change initiative. Facilities may have differed in the focus that leadership put on quality and safety initiatives, and in management capacity. Work is underway to assess these factors to identify best practices and opportunities for augmenting the capacity of all hospitals to successfully complete quality-improvement programs such as this.

Like many population-based quality-improvement studies, there were limitations to the information available about the actual use of the checklist in participating hospitals. Whereas collaborative tracking data indicated that the hospitals completing the program participated in more elements of the implementation, it was not feasible to measure actual checklist use in the operating room due to inability of our program to place observers in operating rooms across the state. However, it was unlikely that a hospital not actively engaged in using the checklist would expend the considerable effort necessary to complete the program. This is especially true as the introduction of checklists was not mandated by any governmental or regulatory agency in South Carolina, and thus there was no threat of penalty for noncompliance present in environments where checklist use had been mandated.

The analysis presented here focused solely on inpatient surgery, which was defined according to the Medicare standard of having spent at least 2 midnights in the hospital after the procedure. This was chosen to study the population at highest risk of mortality after surgery and to avoid diluting the effect of the checklist on exceedingly low mortality outpatient procedures constituting a significant portion of the overall operative volume in the state. Since we were unable to assess causes of mortality in a meaningful fashion, we utilized all-cause 30-day postoperative mortality as our primary measure of outcome. Deaths within 30 days after minor outpatient procedures are more likely to be unrelated to the surgery itself and thus unlikely to be reduced by perioperative quality improvement. Additionally, it was not possible to reliably assess other important perioperative outcomes, such as complications, patient quality of life, or healthcare costs due to the limitations of available administrative data. No significant changes were observed in rates of readmission and reoperation. This may be due to attenuation by other competing trends, such as overall emphasis on readmission reduction.[30]

In summary, the findings from the Safe Surgery 2015 South Carolina collaborative for producing quality improvement through checklist use within the context of a surgical safety collaborative contrast with the disappointing effects observed with a regulatory mandate alone. Completion of a structured, voluntary implementation process appears capable of facilitating change in hospital-level surgical outcomes, paralleled with changes in patient safety culture, as have been previously reported.[13] Our research suggests that the checklist serves as a catalyst for these changes, but that leaders and frontline clinicians, including surgeons, must engage in implementation to produce a meaningful clinical change. Further work in implementation science must focus on identifying factors and interventions that can support or inhibit hospitals' ability to meaningfully employ patient safety innovations.

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: 491–499.
2. Haugen AS, Søfteland E, Almeland SK, et al. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. *Ann Surg*. 2015;261:821–828.
3. Chaudhary N, Varma V, Kapoor S, et al. Implementation of a surgical safety checklist and postoperative outcomes: a prospective randomized controlled study. *J Gastrointest Surg*. 2015;19:935–942.
4. 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;255:44–49.
5. de Vries EN, Prins HA, Crolla RM, et al. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med*. 2010;363:1928–1937.
6. 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: 766–776.
7. Urbach DR, Govindarajan A, Saskin R, et al. Introduction of surgical safety checklists in Ontario, Canada. *N Engl J Med*. 2014;370:1029–1038.
8. Mayer EK, Sevdalis N, Rout S, et al. Surgical Checklist Implementation Project: the impact of variable WHO Checklist compliance on risk-adjusted clinical outcomes after national implementation: a longitudinal study. *Ann Surg*. 2016;263:58–63.
9. Conley DM, Singer SJ, Edmondson L, et al. Effective surgical safety checklist implementation. *J Am Coll Surg*. 2011;212:873–879.
10. Weiser TG, Haynes AB, Lashoher A, et al. Perspectives in quality: designing the WHO Surgical Safety Checklist. *Int J Qual Health Care*. 2010;22: 365–370.
11. Russ SJ, Sevdalis N, Moorthy K, et al. A qualitative evaluation of the barriers and facilitators toward implementation of the WHO surgical safety checklist across hospitals in England: lessons from the "Surgical Checklist Implementation Project". *Ann Surg*. 2015;261:81–91.
12. Russ S, Rout S, Caris J, et al. Measuring variation in use of the WHO surgical safety checklist in the operating room: a multicenter prospective cross-sectional study. *J Am Coll Surg*. 2015;220. 1-11.e14.
13. Molina G, Jiang W, Edmondson L, et al. Implementation of the Surgical Safety Checklist in South Carolina hospitals is associated with improvement in perceived patient safety. *J Am Coll Surg*. 2016;222:725–736.
14. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82:581–629.
15. Kaplan HC, Brady PW, Dritz MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. *Milbank Q*. 2010;88:500–559.
16. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50.
17. Reinertsen J, Rupp W, Whittington J. *Engaging Physicians in a Shared Quality Agenda.* Cambridge, MA: Institute for Healthcare Improvement; 2007
18. Hackman J, Wageman R. A theory of team coaching. *Acad Med Rev*. 2005;30: 269–287.
19. Kilo CM. A framework for collaborative improvement: lessons from the Institute for Healthcare Improvement's Breakthrough Series. *Qual Manag Health Care*. 1998;6:1–13.
20. Dixon-Woods M, Bosk CL, Aveling EL, et al. Explaining Michigan: developing an ex post theory of a quality improvement program. *Milbank Q*. 2011;89:167–205.
21. McCannon CJ, Hackbarth AD, Griffin FA. Miles to go: an introduction to the 5 Million Lives Campaign. *Jt Comm J Qual Patient Saf*. 2007;33: 477–484.
22. Krumholz HM, Bradley EH, Nallamothu BK, et al. A campaign to improve the timeliness of primary percutaneous coronary intervention: door-to-balloon: an alliance for quality. *JACC Cardiovasc Interv*. 2008;1:97–104.
23. Singer SJ, Jiang W, Huang LC, et al. Surgical team member assessment of the safety of surgery practice in 38 South Carolina hospitals. *Med Care Res Rev*. 2015;72:298–323.
24. HCUP-US Tools & Software Page. 2015. Available at: https://www.hcupus.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp. Accessed November 28, 2015.

25. Liang K-Y, Zeger S. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986;73:13–22.
26. Prentice RL, Gloeckler LA. Regression analysis of grouped survival data with application to breast cancer data. *Biometrics*. 1978;34: 57–67.
27. Smith P. Splines as a useful and convenient statistical tool. *Am Stat*. 1979;33:57–62.
28. Bair E, Hastie T, Paul D, et al. Prediction by supervised principal components. *J Am Stat Assoc*. 2006;101:119–137.
29. Anthes E. Hospital checklists are meant to save lives: so why do they often fail? *Nature*. 2015;523:516–518.
30. Gerhardt G, Yemane A, Hickman P, et al. Medicare readmission rates showed meaningful decline in 2012. *Medicare Medicaid Res Rev*. 2013;3. doi: 10.5600/mmrr.003.02.b01. eCollection 2013.