

Analysis of surgical errors in closed malpractice claims at 4 liability insurers

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Background. *The relative importance of the different factors that cause surgical error is unknown. Malpractice claim file analysis may help to identify leading causes of surgical error and identify opportunities for prevention.*

Methods. *We retrospectively reviewed 444 closed malpractice claims, from 4 malpractice liability insurers, in which patients alleged a surgical error. Surgeon-reviewers examined the litigation file and medical record to determine whether an injury attributable to surgical error had occurred and, if so, what factors contributed. Detailed descriptive information concerning etiology and outcome was recorded.*

Results. *Reviewers identified surgical errors that resulted in patient injury in 258 of the 444 (58%) claims. Sixty-five percent of these cases involved significant or major injury; 23% involved death. In most cases (75%), errors occurred in intraoperative care; 25% in preoperative care; 35% in postoperative care. Thirty-one percent of the cases had errors occurring during multiple phases of care; in 62%, more than 1 clinician played a contributory role. Systems factors contributed to error in 82% of cases. The leading system factors were inexperience/lack of technical competence (41%) and communication breakdown (24%). Cases with technical errors (54%) were more likely than those without technical errors to involve errors in multiple phases of care (36% vs 24%, $P = .03$), multiple personnel (83% vs 63%, $P < .001$), lack of technical competence/knowledge (51% vs 29%, $P < .001$) and patient-related factors (54% vs 33%, $P = .001$).*

Conclusions. *Systems factors play a critical role in most surgical errors, including technical errors. Closed claims analysis can help to identify priority areas for intervening to reduce errors. (Surgery 2006;140:25-33.)*

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REDUCING THE INCIDENCE AND COST of medical injuries has become a national health care priority in the United States. Estimates from previous patient safety research suggest that one half to two thirds of inpatient adverse events are attributable to

surgical care,¹⁻³ and that more than half of these events may be preventable.^{3,4} However, prevention efforts depend on detailed knowledge of the etiology of errors in surgery, which remains meager.

Researchers have linked poor surgical outcomes to a wide variety of factors, including surgeon inexperience,⁵⁻⁷ low hospital volume for some operations,⁸⁻¹⁴ excessive workload,¹⁵ fatigue,^{16,17} lack of optimal technology,¹⁸ poor supervision of trainees,¹⁹ inadequate hospital systems,²⁰ poor staff communication,²¹ emergency circumstances,²² and time of day.²³ Many of these are "systems" factors—that is, they involve interrelationships between individuals, their tools, and the environment they work in, rather than single straightforward causes. However, determining the relative importance of these causal factors in surgical errors to target interventions has proved extremely difficult.

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Chart review and observational studies have not been able to collect sufficiently detailed information about a large enough number of events to discern the underlying patterns and recommend interventional strategies.^{3,23-25} Interview studies with surgeons have provided only suggestions for areas to explore.²⁶ Direct observation methods have been used to identify problems in specific operations,²⁷ and in-depth investigations have focused on “root causes” of error in individual cases,²⁸ but such approaches have proved too time- and labor-intensive to replicate on a large scale.

To date, little attention has been paid to medical malpractice claim files as a source of information on surgical error. Concerns about confidentiality, unfounded litigation, and potential biases have stifled interest in the study of malpractice claims.²⁹ Yet, this data source has several attractive features. First, because large malpractice insurers cover thousands of physicians and reflect on the care provided to hundreds of thousands of patients, they represent a powerful catchment point for information on errors. Second, the economics of the trial bar typically ensure that errors surfacing through claims have caused relatively severe injury. Third, by drawing together documentation from both formal legal documents, such as depositions and interrogatories, and confidential internal investigations, claim files present a substantially richer body of information about the antecedents of medical injury than the medical record alone.

Anesthesiology has made impressive use of malpractice claims file analysis.²⁹ Pulse oximetry monitoring, standardized protocols for intraoperative staffing, and a range of other evidence-based safety reforms owe much to the study of lawsuits against anesthesiologists.^{29,30} In this study, we sought to extend this analytic approach to surgical care by identifying the characteristics of operative errors and the underlying contributing factors. Our goals were to use analysis of closed claim files to improve understanding of surgical errors and to help identify priority areas for interventions that could increase the safety of surgical care.

METHODS

Study sites. Four malpractice insurance companies based in 3 regions (Northeast, Southwest, West) contributed surgical claims to the study. In aggregate, the participating insurers covered approximately 21,000 physicians, 46 acute care hospitals (20 academic and 26 nonacademic), and 390 outpatient facilities. The study was approved by ethics review boards at the Harvard School of Pub-

lic Health, the Brigham & Women’s Hospital, and each of the review sites.

Claims sample. The insurers contributed to the study sample in proportion to their annual claims volume. We established a target number of reviews at each site on the basis of the insurer’s average annual caseload. Next, beginning with the most recently closed claim, we retrieved the file and medical records, confirmed it met our study definition of a surgical claim, and then proceeded with the review. This process was repeated until the target number of reviews at each site was reached.

The claim file is the repository of information accumulated by the insurer during the life of a claim. It captures a wide variety of data, including the statement of claim, depositions, interrogatories, and other litigation documents; reports of internal investigations, such as preclaim reports of the event, risk management evaluations, and sometimes root cause analyses; expert opinions from both sides; medical reports and records detailing the plaintiff’s pre- and postevent condition; and, while the claim is open, medical records pertaining to the episode of care at issue. We reacquired the relevant medical records from insured institutions for sampled claims.

Following previous studies, we defined a claim as a written demand for compensation for medical injury.^{31,32} A surgical claim was defined as one involving an operation, care related to an operation, or an alleged failure to provide a timely and appropriate operation. We excluded injuries attributable to medical treatment or procedures (eg, cardiac catheterizations, endoscopy, and interventional radiology procedures); anesthesia-related claims (unless they overlapped with a surgical claim); claims in which the main allegation was defective equipment or devices; and claims related to abortions or dilation and curettage.

Insurers contributed to the study sample in proportion to their annual claims volume. Working with staff at the insurers, we used administrative databases to generate lists of candidate claims and reviewed narrative summaries to confirm they met the study definition of a surgical claim.

Claims file review. The reviews were conducted at insurer’s offices or insured facilities by senior surgical residents, surgical fellows, and board-certified surgeons. Two surgeon-investigators (S.O.R., A.A.G.) trained the reviewers in the content of claim files, use of the study instruments, and confidentiality issues in a 1-day session conducted at each site. The reviewers also were assisted by a detailed manual. Reviews took 1.9 hours per file on average. To assess the reliability of the review pro-

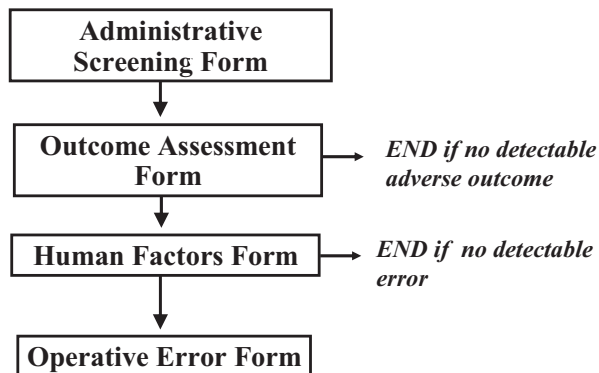


Figure. Claim review process for detection of injuries attributable to surgical error.

cess, 10% ($n = 44$) of the sampled claims were re-reviewed by a second reviewer who was unaware of the first review.

Four instruments were used in sequence to conduct the review (Figure). For all claims, insurance staff recorded administrative details of the case (Administrative Screening Data Form) and clinical reviewers recorded details of the injury, if any (Outcome Assessment Form). Reviewers scored injuries according to the National Association of Insurance Commissioners' 9-point severity scale, which ranges from emotional injury only to death.³³

For claims with identifiable injuries, reviewers then considered the potential contributory role of 17 "human factors" (Human Factors Form), which were selected on the basis of a review of the safety literature and covered cognitive-, system-, and patient-related factors. The candidate human factors were error in judgment; failure of vigilance or memory; lack of technical competence or knowledge; some other failing of an individual clinician; inadequate hand-off; failure to establish clear lines of responsibility; conflict; some other failure of communication; failure to follow/break protocol; lack of supervision; interruptions; technology problems; fatigue; workload; ergonomic problems; patient-related clinical factors; and patient-related behavioral factors.

After completing the Human Factors Form, reviewers judged, in light of all available information and the decisions they had made about various contributing factors, whether the injury was attributable to one or more medical errors. We used the Institute of Medicine's definition of error: "the failure of a planned action to be completed as intended (ie, error of execution) or the use of a wrong plan to achieve an aim (ie, error of planning)."²⁵ The judgment was made on a 6-point confidence scale ranging from "1" (little or no

evidence that adverse outcome resulted from error/errors) to "6" (virtually certain evidence that adverse outcome resulted from error/errors). Reviewers were not blinded to the litigation outcomes but were instructed to ignore them in rendering error judgments.

Finally, claims that scored "4" (more likely than not that adverse outcome resulted from error/errors; more than 50-50 but a close call) or higher were classified as involving error, and reviewers completed the review by collecting specific clinical information about the nature and circumstances of the error (Operative Error Form).

Analysis. The hand-filled data forms were entered electronically and verified by a professional data entry vendor and sent to the Harvard School of Public Health for analysis. Additional validity checks and data cleaning were performed by study programmers.

Our analyses are descriptive. We examined the characteristics of the claims, patients, injuries, and errors. We also examined the frequency with which various human factors were identified as a cause of the error. The human factors were grouped into 5 general categories: (1) cognitive factors, (2) lack of technical competence/knowledge, (3) communication breakdowns, (4) patient-related factors, and (5) other system factors.

The primary unit of analysis is the episode of care that resulted in injury to the patient in claims judged to involve both error and injury. For ease of exposition, we refer hereafter to such episodes as "cases." We compared characteristics across subgroups of cases (technical vs nontechnical errors; trainee vs nontrainee) using Pearson chi-square tests. Data analyses were performed with the use of SAS 8.2 (SAS Institute, Cary, NC) and Stata/SE 8.0 (Stata Corp, College Station, Tex) statistical software packages.

RESULTS

Characteristics of surgical claims and cases. We reviewed 444 surgical claims, which covered claims closed between 1986 and 2004, and alleged injuries sustained between 1980 and 2002. Eighty-eight percent of the claims were closed in 1994 or later, and 80% of the injuries occurred in 1990 or later.

Sixteen (4%) claims did not have an identifiable injury attributable to medical care, and 6 (1%) alleged a breach of informed consent but no physical harm; the remaining 422 (95%) involved injuries. Reviewers attributed 258 of these injuries to surgical error; these constituted the "cases" for purposes of subsequent analyses. The sample of re-reviewed claims demonstrated excellent inter-

Table I. Characteristics of patients and injuries attributable to surgical errors identified in malpractice claims

	Frequency (n = 258)	%		Frequency (n = 258)	%
Female	134	52	Nature of procedure		
Age (y; median)	43	—	Elective	195	76
Infant	5	2	Urgent/emergent	62	24
1-17	20	8	Type of operation*		
18-34	57	22	Gastrointestinal	57	22
35-49	74	29	Laparoscopic cholecystectomy	17	7
50-64	59	23	Spine (laminectomy, lumbar fusion)	36	14
>64	43	17	Orthopedic (non-spine)	26	10
Severity of injury†			Cardiothoracic	22	9
Minor Injury	32	13	Gynecologic (hysterectomy)	18	7
Significant	141	55	Vascular	16	6
Major	26	10	Genitourinary	12	5
Death	59	23	Head and neck	11	4
Type of injury			Breast/soft tissue	9	3
Unnecessary advancement of disease	25	10	Hernia	9	3
Operative injury	192	74	Neurosurgery (nonspine)	8	3
Visceral/nerve injury	68	26	Plastic surgery	7	3
Unexpected bleeding	30	12	Hand	6	2
Foreign body left in patient	26	10	Ophthalmology	5	2
Failure to relieve (ineffective operation)	18	7	Transplant	3	1
Musculoskeletal injury (fracture, burn)	12	5	Other	6	2
CVA/MI	9	3			
Other	36	14			
Unnecessary/inappropriate operation	39	15			
Wrong site/wrong patient	20	8			

CVA, Cerebrovascular accident; MI, myocardial infarction.

*Types of operation sum to 251, because 7 errors did not involve an operation.

†These severity categories collapse the National Association of Insurance Commissioners' 9-point scale as follows: "Minor injury" consists of emotional, temporary insignificant, and temporary minor injuries; "significant injury" consists of temporary major, permanent minor, and permanent significant injuries; "major injury" consists of major permanent and permanent grave injuries; the "deaths" category was the same.

reviewer reliability for the error judgment (91% agreement; kappa = 0.80, 95% confidence interval, 0.24-0.92).

Table I shows characteristics of the cases. The injuries were serious: 23% involved patient death and 65% involved significant or major disability. In a quarter of cases, the injuries stemmed from an inappropriate operation (15%) or a delay in diagnosis or therapeutic measures that allowed unnecessary advancement of disease (10%). Examples of delayed diagnoses were late recognition of hemorrhage after cholecystectomy, of esophageal perforation after gastric surgery, and of mesenteric ischemia in a patient with extensive vascular disease. Inappropriate operations included hemilaminectomy at the wrong spinal level and an attempted repair of a complete common bile duct transection with an end-to-end anastomosis.

Three quarters of cases involved injuries that occurred in connection with an indicated operative procedure. Visceral and/or nerve injuries (26%), unexpected bleeding (12%), and foreign bodies left in patients (10%) were the leading types. Examples of visceral and nerve injuries were common bile duct injury during a laparoscopic cholecystectomy and femoral nerve injury during a sigmoid colectomy. There was wide variation in the types of operations; the 4 most common types were gastrointestinal (22%), spinal (14%), nonspine orthopedic (10%), and cardiothoracic (9%).

Errors occurred most frequently during the intraoperative phase of care (75% of cases; Table II). However, 1 in 4 occurred preoperatively, 1 in 3 postoperatively, and 31% crossed multiple phases of care. In 38% of the cases, a single clinician

Table II. Circumstances of injuries attributable to surgical errors

	Frequency (n = 258)	%
Phase of care in which an error occurred		
Preoperative	65	25
Intraoperative	193	75
Postoperative	89	35
Errors spanning >1 phase of care	79	31
No. of clinicians contributing to error		
1	99	38
2	91	35
≥3	68	26
Type of personnel contributing to error		
Attending physicians	237	92
Intern, resident, or fellow	118	46
Nurse	45	17
Other	19	7

contributed to the error; however, the majority (62%), involved more than 1 clinician. Attending surgeons played a role in error in virtually all cases (92%), but trainees (interns, residents, or fellows) were contributors in 46%, and nurses in 17%.

Factors contributing to surgical error. Judgment errors (66%) and vigilance or memory failures (63%) were the most common contributory factors (Table III). However, these factors rarely occurred alone: Judgment was the sole contributing factor in 7% of cases. Eighty-two percent of cases involved human factors other than judgment and/or failure of vigilance/memory (“systems factors”). Communication breakdowns, patient-related factors, and other systems factors were implicated in 69% of cases. Overall, the median number of contributing factors per case was 3.

Lack of technical competence or knowledge was identified as a contributing factor in 41% of cases. A surgical trainee’s lack of competence was implicated in 40% of these cases (42/106), and several cases involved an attending surgeon who was practicing outside his specialty. However, the dominant scenario, which accounted for 58% (61/106) of cases involving lack of technical competence or knowledge, was a surgeon practicing within his or her specialty but lacking experience or skill with the task at hand. For example, in 1 case, a surgeon qualified in general surgery but not highly experienced in adrenalectomy mistakenly ligated the renal artery instead of the adrenal artery during an

Table III. Factors contributing to injuries attributable to surgical errors

	Frequency (n = 258)	%
Cognitive factors		
Error in judgment	169	66
Failure of vigilance/memory	162	63
Lack of technical competence or knowledge	106	41
Communication breakdown	61	24
Hand-off error	28	11
Lack of clear lines of responsibility	24	9
Conflict among personnel	7	3
Other	29	11
Patient-related factors	114	44
Anatomic/physiologic	91	35
Complicating prior medical/surgical history	41	16
Abnormal or difficult anatomy	34	13
Morbid obesity	9	3
Behavioral	23	9
Noncompliance	10	4
Substance abuse	4	2
Psychiatric illness (eg, depression)	4	2
Other systems factors		
Lack of supervision	47	18
Technology failure	38	15
Workload/inadequate staffing	9	3
Interruptions/distraction	7	3
Ergonomic failure (lighting, setup, etc)	5	2
Fatigue	3	1

adrenalectomy, resulting in the need for a nephrectomy.

Communication breakdowns contributed to error in one quarter of cases. The leading types of breakdowns were inadequate hand-offs or personnel changes (11%) and failures to establish clear lines of responsibility (9%). Eleven percent of cases were tied to a miscellaneous group of communication problems, including inadequate communication between physicians and nurses, and an inability to reach attending surgeons.

Patient-related factors played a contributory role in 44% of cases. These were predominantly anatomic factors (35%), such as morbid obesity, difficult anatomy, or complexities attributable to reoperation. One in 10 cases involved patient behavioral factors, such as noncompliance or substance abuse. Lack of supervision (18%) and technology failures (15%) were the most common types of breakdowns among other system factors identified in the claims file review.

Nature of technical errors. Fifty-four percent of cases involved errors of manual technique that oc-

Table IV. Characteristics of cases with and without technical errors

	<i>Errors in operative technique (n = 140)</i>	<i>%</i>	<i>No errors in operative technique (n = 118)</i>	<i>%</i>	<i>P value</i>
Nature of procedure					
Elective surgery	115	82	80	68	.008
Reoperation	39	28	10	19*	.20
Unexpected change in procedure	35	25	8	15*	.14
Personnel contributing to error					
Attending surgeon	132	94	105	89	.12
Trainee	61	44	57	48	.45
Errors involved in >1 phase of care	51	36	28	24	.03
Errors involving >1 personnel Contributing factors	116	83	74	63	<.001
Error in judgment	82	59	87	74	.01
Failure of vigilance/memory	88	63	74	63	.98
Patient-related factors	75	54	39	33	.001
Lack of technical competence/ knowledge	72	51	34	29	<.001
Lack of supervision	24	17	23	19	.62
Communication breakdown	22	16	39	33	.001
Technologic failure	23	16	15	13	.40
Ergonomic failure	5	4	0	0	.04
Workload/inadequate staffing	2	1	7	6	.05
Interruptions/distraction	1	1	6	5	.03
Fatigue	1	1	2	2	.46

*The denominator for these percentage calculations is the 53 cases unrelated to operative technique that involved intraoperative error.

curred during the course of an operation (“technical errors”). There were a number of significant differences in the pattern of contributing factors between cases that did and did not involve technical errors (Table IV).

Cases involving technical errors were more likely than those without technical errors to involve elective surgery (82% vs 68%, $P = .008$), contributions to error from multiple personnel (83% vs 63%, $P < .001$), and errors in multiple phases of care (36% vs 24%, $P = 0.03$). In addition, technical error cases were more likely than their nontechnical counterparts to have been caused by lack of technical competence/knowledge (51% vs 29%, $P < .001$) and by patient-related factors (54% vs 33%, $P = .001$). On the other hand, they were less likely to have been caused by judgment errors (59% vs 74%, $P = 0.01$) and communication breakdowns (16% vs 33%, $P = .001$). There were no significant differences between the 2 types of errors with respect to supervision problems or trainee involvement.

Role of trainees. Trainees contributed to error in 46% of cases (Table V). In 53% of the cases involving trainees, the trainee had the highest or equally highest contributory rating of any personnel involved. Cases with trainee involvement dif-

fered significantly from other cases across 3 main measures: They were significantly more likely to involve lack of supervision (36% vs 3%, $P < .001$), communication breakdowns (30% vs 19%, $P = .04$), and emergency care (20% vs 10%, $P = .01$; Table V).

DISCUSSION

We found that analysis of surgical malpractice claims could identify underlying patterns and causes of surgical errors. The errors identified in malpractice claims are of particular concern, because, unlike those identified by institutional reporting systems or observational studies, the vast majority results in serious injury. One quarter of errors detected in our study led to death.

Patient safety experts have alleged that systems failure—not single individual error—is the predominant cause of error in medicine,²⁵ but whether this is accurate for surgery has never been demonstrated clearly. Our study reveals that, although patient harm from isolated individual errors occurs, the vast majority of surgical error cases involve multiple layers of failure. Of 258 cases analyzed, most involved more than 1 clinician, and nearly one third involved chains of

Table V. Trainee involvement in surgical injuries attributable to error

Contributing factors	Cases with errors involving trainees (n = 118)		Cases with errors not involving trainees (n = 140)		P value
		%		%	
Lack of supervision	43	36	4	3	<.001
Communication breakdown	35	30	26	19	.04
Emergency surgery	20	17	10	7	.01

events crossing multiple phases of care. In 68%, 1 or more of the following 4 systems factors contributed to error: communication breakdowns, lack of supervision, technology failures, and patient-related factors. In addition, a surgeon's lack of experience or technical competence (which can be understood as having both individual and systems components) was a contributing factor in 41% of cases.

Individual errors in judgment, vigilance, or memory were certainly not irrelevant. On the contrary, 9 of 10 cases involved at least 1 of these cognitive errors. In more than 80% of cases, however, they acted in concert with other factors in producing harm. This finding was true even among those surgical errors, which, at a superficial level, appeared to be purely technical in nature.

To have a major impact, strategies to reduce patient harm from surgical error must address the most common types of failures. Our findings highlight 2 priority areas: increasing the ability of surgeons to safely perform operations with which they have limited experience and reducing communication errors, especially when complicating patient factors are involved. Technical errors in particular were more likely to involve lack of experience/technical competence and patient-related factors. Nontechnical errors, on the other hand, were more likely to involve communication breakdowns, along with judgment error, excessive workload, and interruptions.

To reduce technical errors, we recommend directing research efforts toward devising and testing interventions to improve outcomes in settings in which teams have low experience and/or have patients with complicating preoperative factors (such as morbid obesity, previous surgery, or a complex medical history). Such cases may warrant more routine consultation and collaboration with experienced colleagues, additional preparation or certification, or increased willingness to refer to a higher-volume surgeon or hospital. Team training may help to promote these connections.

Innovations to reduce communication breakdowns should have the greatest potential impact

in reducing nontechnical errors. One third of nontechnical errors included a communication breakdown—twice the rate at which such breakdowns occurred in the realm of technical errors. These types of failures are of particular concern after the advent of the 80-hour workweek for surgical trainees and larger surgical coverage teams, developments that postdate our study. The increased handoffs they entail increase the risk of inadequate “sign-outs” and other communication failures. Researchers in general medicine have found that institution of a “night float” coverage team increased hand-offs and errors,³⁴ but that such errors could be reduced by implementation of a formal, computerized sign-out tool.³⁵ Anesthesiologists similarly have recognized the need for a more fail-safe hand-off process.³⁶ A more detailed and standardized surgical handoff for both residents and attending surgeons may be an important next step.

Increased use of electronic medical records is another strategy for guarding against communication breakdowns. This approach would improve the care team's access to necessary information across all settings, from preoperative to postoperative. A number of cases involved the failure of teams to contact the responsible attending physician in a timely manner. Predefined triggers stipulating specific circumstances in which the attending *must* be called—for example, prolonged hypotension or marked change in respiratory status—may help to combat this problem.

Our study has a number of limitations. Unlike prospective observational studies or root cause analysis based on discussions with relevant staff immediately after an event has occurred, retrospective review of records, even detailed records like those in malpractice claim files, will not capture effectively certain relevant human factors, such as fatigue, workload, or staffing. The bias means that prevalence estimates for such factors are lower bounds. For example, Landrigan and colleagues¹⁷ recently reported a reduction in serious medical errors in intensive care units by reducing intern's work hours. Our study did not identify fatigue as a common systems factor.

Malpractice claims data generally, and our sample in particular, have several other biases and limitations. Severe injuries and younger patients are overrepresented in the subset of medical injuries that proceed to litigation.³² Factors that lead to error in litigated cases may differ systematically from the factors that lead to error in nonlitigated cases, although we know of no reason why they would. Generalizability issues also arise: Teaching hospitals and the physicians that staff them are overrepresented in our sample. In addition, while closed claims may be useful in etiologic analyses of error, other data sources will be needed to support careful evaluations of error-reduction initiatives.

Nonetheless, we found that closed malpractice claims alleging surgical injuries yielded a rich source of data about errors in surgery and the factors that caused them. We found that systems factors played a critical role in surgical error, including technical error. Further analyses of this type may facilitate the design of targeted interventions to reduce surgical errors and improve the overall quality of surgical care.

Drs Rogers, Gawande, and Studdert had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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