

Surgical never events in the United States

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Background. Surgical never events are being used increasingly as quality metrics in health care in the United States. However, little is known about their costs to the health care system, the outcomes of patients, or the characteristics of the providers involved. We designed a study to describe the number and magnitude of paid malpractice claims for surgical never events, as well as associated patient and provider characteristics.

Methods. We used the National Practitioner Data Bank, a federal repository of medical malpractice claims, to identify malpractice settlements and judgments of surgical never events, including retained foreign bodies, wrong-site, wrong-patient, and wrong-procedure surgery. Payment amounts, patient outcomes, and provider characteristics were evaluated.

Results. We identified a total of 9,744 paid malpractice settlement and judgments for surgical never events occurring between 1990 and 2010. Malpractice payments for surgical never events totaled \$1.3 billion. Mortality occurred in 6.6% of patients, permanent injury in 32.9%, and temporary injury in 59.2%. Based on literature rates of surgical adverse events resulting in paid malpractice claims, we estimated that 4,082 surgical never event claims occur each year in the United States. Increased payments were associated with severe patient outcomes and claims involving a physician with multiple malpractice reports. Of physicians named in a surgical never event claim, 12.4% were later named in at least 1 future surgical never event claim.

Conclusion. Surgical never events are costly to the health care system and are associated with serious harm to patients. Patient and provider characteristics may help to guide prevention strategies. (Surgery 2013;■:■-■.)

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RETAINED FOREIGN BODY, wrong-site, wrong-patient, and wrong-procedure events persist in surgical care despite wide agreement that they are always avoidable.¹⁻⁸ In an effort to incentivize patient safety in surgery, payers are increasingly focusing on these events that should never take place (surgical never events) as metrics of quality care. Medicare and several states have already announced that hospitals will be penalized for such events in pay-for-performance programs.⁹ One state has even mandated that cameras be installed in the

operating rooms of the state's largest hospital after a string of such never events occurred there.¹⁰ The occurrence of a surgical never event can be catastrophic for a patient and can also be destructive to a surgeon's career and an institution's reputation.

On a local level, never events may also be a surrogate marker of unsafe hospital systems and poor safety culture.¹¹ Many hospital and national quality improvement efforts have been committed to reducing or eliminating surgical never events; however, there has been limited investigation into these events so as to inform such prevention strategies. Previous studies of the topic have been limited primarily to single-institution medical record reviews, self-reported data, and closed claims data.^{1-7,12} To address this knowledge gap and better guide prevention and policy efforts, we designed a study to describe surgical never events with respect to the financial burdens they place

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on the health care system, the outcomes of patients after these events, and the characteristics of providers involved their occurrence.

METHODS

Data source. The National Practitioner Data Bank (NPDB) was established by Congress as part of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101, et seq.). All malpractice payments made on behalf of a licensed health care provider must be reported to the NPDB within 30 days under the Health Care Quality Improvement Act of 1986.¹³ The NPDB Public Use Data File is administered by the U.S. Department of Health and Human Services and collects information on all paid liability claims, including out-of-court settlements and court judgments in which a physician has been named.¹³ The use of these data for research was covered under a data-use agreement between The Johns Hopkins University and the Department of Health and Human Services.

Patient population. We reviewed NPDB paid malpractice claim reports from September 1, 1990, through September 30, 2010, in which a surgical never event was alleged.¹³ These included events preclassified at the time of data entry as retained surgical or other foreign body, wrong body part, wrong patient, or wrong procedure or treatment. The event was included only if it was listed as the first or second allegation of the paid malpractice claim report. Data concerning the death of an American Society of Anesthesiology class I patient were not available from these reports. We excluded payments that were linked to dentists, pharmacists, social workers, or nurses. For each malpractice report, we extracted year of occurrence, patient age, clinical outcome, payment amount, physician's age, year of physician's medical school graduation, and disciplinary action taken against the physician. The number of years between a physician's medical school graduation and the year of the occurrence was used as a proxy measure of a physician's duration of practice. The event classification of wrong patient as well as patient age and severity of injury were available only after January 31, 2004.

Statistical analysis. Our primary outcome measures were multiple surgical never events and malpractice payments. Descriptive analyses were performed to identify the providers' and patients' characteristics associated with these measures. For the first outcome, we identified providers with single surgical never events versus those with multiple surgical never events and restricted the analysis to the description of the index event. Bivariate analyses were performed using chi-squared statistics

and simple logistic regression. Variables associated with an increased likelihood of multiple surgical never events in simple logistic regression ($P < .20$) were included in a multivariable logistic regression model along with variables previously identified in the literature. Based on a prior study estimate that only 12% of surgical adverse events result in indemnity payments, we estimated the incidence of surgical event claims in the United States.¹⁴

For the second outcome of malpractice payments for surgical never events, malpractice payments were inflation-adjusted to the 2010 U.S. dollar, using the consumer price index. Because of the skewed nature of our data, we created a dichotomous outcome variable for payments above versus at or below the mean (\$133,055) for our logistic regression analysis. Variables associated with an increased likelihood of payment above the mean in simple logistic regression ($P < .20$) were included in a multivariate logistic regression model along with variables previously identified in the literature. A full cohort analysis was performed to identify the events and physician characteristics associated with increased payments. A subgroup analysis of events after January 31, 2004, was performed to identify patient characteristics associated with increased payments. For both logistic regression analyses, the Huber-White robust standard errors were estimated to correct for clustering at the physician level (eg, multiple claims per physician). As a sensitivity analysis, multivariable linear regression modeling of log-transformed payments also was performed. All analyses were performed using STATA 11 Software (STATA, College Station, TX).

RESULTS

We identified 9,744 paid malpractice reports with surgical never events between September 1990 and September 2010. The most common type of event was retained foreign body ($n = 4,857$; 49.8%), followed by wrong-procedure ($n = 2,447$; 25.1%); wrong-site ($n = 2,413$; 24.8%); and wrong-patient surgery ($n = 27$, 0.3%). Of the reports, 17 identified included 2 never events; the first event listed was used for categorization. Annual frequencies of surgical never events ranged from 410 to 708. Between 1990 and 2010, malpractice payments for surgical never events reported to the NPDB totaled \$1.3 billion. Table I displays the malpractice payment per surgical never event. The mean payment was \$133,055. The highest median payment was associated with wrong-procedure events (\$106,777), and the lowest median payment (\$33,953) was for surgical retained foreign body.

Table I. Malpractice payments per surgical never event

<i>Surgical never event</i>	<i>Mean</i>	<i>Median</i>	<i>Range</i>
All never events (<i>N</i> = 9,744)*	\$133,055	\$46,172	\$51–\$7,082, 528
Wrong procedure (<i>n</i> = 2,447)	\$232,035	\$106,777	\$71–\$4,340,521
Wrong site (<i>n</i> = 2,413)	\$127,159	\$43,197	\$923–\$7,082,528
Wrong patient (<i>n</i> = 27)	\$109,648	\$18,928	\$4,040–\$1,110,936
Surgical retained foreign body (<i>n</i> = 4,857)	\$86,247	\$33,953	\$51–\$3,988,829

*Malpractice payouts for all surgical never events (*N* = 9,744) totaled \$1.3 billion.

Table II. Characteristics of physicians reported for surgical never events by frequency*

<i>Covariates</i>		<i>All surgical never events (n = 9,562)</i>	<i>Single surgical never event (n = 8,363)</i>	<i>Multiple surgical never events (n = 1,199)</i>	<i>P value†</i>
Physician age‡	20–39	2,135 (22.4)	1,920 (23.0)	215 (18.0)	<.001
	40–49	3,413 (35.8)	2,967 (35.6)	446 (37.4)	
	50–59	2,603 (27.3)	2,222 (26.7)	381 (31.9)	
	60–69	1,190 (12.5)	1,051 (12.6)	139 (11.6)	
	≥70	185 (1.94)	172 (2.1)	13 (1.1)	
Years since graduation from medical school§	≤20	3,341 (35.0)	2,976 (35.7)	329 (30.5)	<.001
	21–30	3,099 (32.5)	2,653 (31.8)	446 (27.3)	
	31–40	2,157 (22.6)	1,880 (22.5)	277 (23.2)	
	≥41	941 (9.9)	834 (10.0)	107 (9.0)	
Additional malpractice reports	0	3,659 (38.3)	3,659 (43.8)	0 (0.0)	<.001
	≥1	5,903 (61.7)	4,704 (56.2)	1,199 (100.0)	
State licensure disciplinary reports	0	8,635 (90.3)	7,609 (91.0)	1,026 (85.6)	<.001
	≥1	927 (9.7)	754 (9.0)	173 (14.4)	
Clinical privilege disciplinary reports	0	9,038 (94.5)	7,958 (95.2)	1,080 (90.1)	<.001
	≥1	524 (5.5)	405 (4.8)	119 (9.9)	

*Unadjusted descriptive statistics.

†*P* values were determined using chi-squared statistics in reports of single and multiple events.

‡0.37% of all physicians missing age (0.37% in single-event group, 0.41% in multiple-event group).

§0.25% of all physicians missing date of graduation from medical school (0.24% single-event group, 3.3% multiple-event group).

Table II displays the characteristics of the 9,562 unique physicians named in surgical never-event reports. Physicians between 40 and 49 years of age accounted for 35.8% of all reports as compared to physicians 60 years of age or older, which represented 14.4%. Of the physicians, 62% (5,903/9,562) were also named in other separate malpractice reports, and 12.4% (1,199/9,562) were also named in other separate surgical never event malpractice reports. Of physicians involved in a surgical never event, 10% (927/9,562) were disciplined at least once by their state licensing boards. The logistic regression models for multiple versus single never event claims are shown in Table III. The final model included physician years in practice, practitioner age, presence or absence of physician state licensure action reports, presence or absence of physician clinical privilege disciplinary reports, and presence or absence of multiple malpractice reports as covariates. Physicians with clinical privilege or state licensure disciplinary action reports had an increased adjusted odds ratio

(aOR = 1.73; 95% CI, 1.47–2.03) of being named in multiple surgical never event claims compared to physicians who did not have clinical privilege or state licensure disciplinary action reports. Based on the number of paid claims we identified in the NPDB and the literature estimates of surgical adverse events resulting in paid claims, we estimated that 4,082 surgical never claims occur each year in the United States (retained foreign body = 2,024/year; wrong-procedure surgery = 1,020/year; wrong-site surgery = 1,005/year; wrong-patient surgery = 33/year).

A subgroup analysis was performed for those records having complete patient data since 2004 (*n* = 2,355). Surgical never events occurred most commonly in patients 40 to 49 years of age (35.7%, 511/2,355). Mortality was reported in 6.6% (155/2,355) of patients, permanent injury in 32.9% (774/2,355), and temporary injury in 59.2% (1,395/2,355) (Table IV). Patients 60 years of age and older had a mortality of 14.8% compared to 4% for those younger than 60 years.

Table III. Multivariable logistic regression of multiple surgical never events by providers' characteristics

Physicians' characteristics		Adjusted* odds ratio	95% confidence interval	P value
Years since graduation from medical school	≤20		Reference	
	21–30	1.16	0.96–1.40	.13
	31–40	0.95	0.73–1.24	.71
	>41	0.99	0.67–1.45	.95
Clinical privilege or state licensure report	0		Reference	
	≥1	1.73	1.47–2.03	<.001
Age of physician	<40		Reference	
	40–49	1.22	0.99–1.50	.06
	50–59	1.47	1.13–1.93	.01
	≥60	1.14	0.78–1.65	.5

*Multivariable logistic regression, number of observations: 9,562 unique provider claims for surgical never events.

†Dependent variable = log odds of a physician's having multiple surgical never events versus a single surgical never event.

‡Adjusted for above-listed covariates as well as type of surgical never event.

Table IV. Patient outcome by type of surgical never event*

Patient outcomes	All surgical never events n = 2,355 (%)	Surgical retained foreign body n = 1,126 (%)	Wrong procedure n = 620 (%)	Wrong site n = 583 (%)	Wrong patient n = 26 (%)
Mortality	155 (6.6)	51 (4.5)	86 (13.9)	16 (2.7)	2 (7.7)
Permanent injury	774 (32.9)	184 (16.3)	341 (55.0)	242 (41.5)	7 (26.9)
Temporary injury	1,395 (59.2)	879 (78.1)	186 (30.0)	318 (54.6)	12 (46.2)
Emotional injury	31 (1.3)	12 (1.1)	7 (1.1)	7 (1.2)	5 (19.2)

*Descriptive statistics, number of observations: 2,355 paid malpractice claims for surgical never events with patient outcomes.

Analysis of physician and patient predictors of increased payments were carried out in the full cohort and in subgroup analysis. Of surgical never events, 96% were settled out of court in the full cohort. Claims that resulted in court judgments had an increased adjusted odds of payments above the mean [aOR = 2.75; 95% CI, 2.18–3.47] compared to out-of-court settlements (Table V). The odds of a payment above the mean were increased in events in which physicians had multiple malpractice claims compared to those involving physicians not having any other malpractice claims [aOR = 1.19; 95% CI, 1.08–1.32]. In the subgroup analysis, adjusted odds of payments above the mean were greater for surgical never events resulting in death [aOR = 5.88; 95% CI, 4.07–8.50] and permanent injury [aOR = 4.66; 95% CI, 3.74–5.79] compared to those resulting in temporary injury (Table V). Multivariable linear regression modeling of log-transformed payments yielded similar patient and provider characteristics associated with increased payments.

DISCUSSION

Surgical never events continue to compromise high-quality patient care. Despite the contention about other patient safety metrics,¹⁵ there is

unanimous consensus that surgical never events are preventable.¹⁻⁸ Our study describes national malpractice payments for surgical never events, furthering our understanding of their overall financial burden, the outcomes for patients following these events, and the characteristics of physicians involved in these events.

The financial burden of surgical never events. We estimated that malpractice payments for surgical never events amounted to over \$1.3 billion between 1990 and 2010. These payments do not capture the even greater financial burdens of legal fees, additional inpatient and disability care, lost work days, and harm to provider and hospital reputation. They do, however, identify part of the significant financial incentive to reduce surgical never events already being leveraged by Centers for Medicare and Medicaid Services (CMS) and other third-party payers. The nonpayment for never events policy by CMS and third-party payers may reduce an individual payment by as much as 40%.¹⁶ Applied nationally, this policy alone would result in a 2.4% reduction in CMS payments and total more than \$88 million over 4 years.⁹

Patient outcomes following surgical never events. Beyond the financial implications, eliminating surgical never events is necessary to limit

Table V. Multivariable logistic regression for malpractice payouts above the mean (\$113,055)*

Characteristic	Categoric definitions	Full cohort analysis (n = 9,744)†			Subgroup analysis with Patient data (n = 2,355)‡		
		Full cohort analysis (n = 9,744)	(95% CI)	P value	Adjusted OR	(95% CI)	P value
Type of surgical never event	Surgical retained foreign body		Reference			Reference	
	Wrong site, wrong procedure, and wrong patient	2.82	2.55–3.12	<.001	1.49	1.20–1.85	<.001
Multiple malpractice sclaims	1 claim		Reference			Reference	
	>1 claim	1.19	1.08–1.32	<.001	1.29	1.06–1.59	.01
Clinical privilege or state disciplinary report	0 reports		Reference			Reference	
	≥1 report	1.18	1.02–1.36	.03	1.05	0.78–1.43	.76
Method of settlement	Out-of-court settlement		Reference			Reference	
	Court judgment	2.75	2.18–3.47	<.001	2.54	1.55–4.14	<.001
Time period	1990–1999		Reference			—§	
	2000–2010	1.34	1.22–1.48	<.001			
Patient outcome	Temporary injury		—¶			Reference	
	Permanent injury				4.66	3.74–5.79	<.001
	Death				5.88	4.07–8.50	<.001
	Emotional injury				0.17	0.02–1.27	.08

*Dependent variable, log odds of malpractice payout above the mean versus below the mean.

†Adjusted for types of surgical never events, multiple malpractice claims, multiple physician disciplinary action reports, methods of settlement, and time periods.

‡Adjusted for types of surgical never events, multiple malpractice claims, multiple physician disciplinary action reports, methods of settlement, patient outcomes, and patient ages.

§Time period was not included in the subgroup analysis because data were collected only after January 31, 2004.

¶Patient outcomes were available only for the subgroup analysis.

harm to patients. We found that 6.6% of surgical never events result in the death of the patient. Previous studies using claims and single-institution data to examine surgical never events have reported lower rates of mortality. Gawande et al conducted a 15-year retrospective case-control study of retained foreign bodies using a Massachusetts malpractice database and found that mortality was identified in 1 of 61 cases (1.6%).⁵ Another study by Lincourt et al found no mortality in 30 cases of retained foreign body in a retrospective institutional risk-management incident report of cases occurring between 1996 and 2005.⁶ Unlike prior studies that were limited to state and institutional malpractice data, our study utilized a national database and highlighted that the consequences of surgical never events for patients may have been previously underestimated.

Understanding the problem: Reporting of surgical never events. To realize the total eradication of surgical never events, we need a better and more accurate mechanism for reporting them. Although the data we utilized captured surgical never events resulting in malpractice claims, many do not reach legal process and are then only voluntarily

disclosed, with little coordination among reporting bodies. Between 2004 and 2010, 666 voluntary self-reports of wrong-patient, wrong-site, and wrong-procedure events were recorded by the Joint Commission.¹⁷ Over the same period, for the same events, we identified 1,187 paid malpractice claims. A more granular observational study by the Joint Commission Center for Transforming Healthcare extrapolated data from 8 hospitals and ambulatory surgery centers and concluded wrong-site surgery alone may occur as often as 40 times a week nationwide.¹⁸

In a 5-year retrospective review of admissions to multiple surgical patient care centers, Morris et al identified 130 patients injured by a surgical adverse event. Only 12% (15/130) of patients injured by these adverse events received indemnity payments. The average number of failures resulting in injury was 4.7 contributing failures per case.¹⁴ Extrapolating this rate, we estimate that 4,082 surgical never event claims occur each year in the United States. This figure probably underestimates the true incidence of surgical never events because many events are not filed as claims; 69% (90/130) of patients with adverse events identified by Morris

et al did not file claims.¹⁴ Another report found that as little as 4% of serious, preventable adverse events resulted in complaints.¹⁹ It is clear that we need a mandatory reporting system of surgical never events that is not reliant on risk management or voluntary reporting. We also need reporting systems that provide more root-cause information about each event so that safer hospital systems can be developed. A centralized mandatory reporting mechanism that would require uniform reporting criteria across states would minimize the surveillance bias inherent in current estimates.

Physicians' errors in the context of hospital safety culture. Anecdotally, surgical never events are thought to be rare and random occurrences, with some hospitals never experiencing them.²⁰ Our study found that 12.4% of physicians had malpractice claims for more than 1 surgical never event, which suggest that there may be underlying individual-provider factors at play. Prior work suggests that this finding is not unique to surgical never events and that any medical error is associated with an increased risk for being repeated by the same provider. In 1 report, 20% of physicians involved in any unprofessional conduct and negligent care were repeat offenders.²¹ Bovberg et al also found that physicians with at least 1 malpractice claim had approximately twice the odds of subsequent claims compared to physicians with no claim history.²² Our data support these prior reports and suggest that future interventions aimed at providers involved in repeat never events are warranted. To comprehensively understand the mechanism of surgical never events, we recognize that individual errors must be examined in the context of the system-level institutional safety culture.

Human-factors engineers have said that medical errors are often the result of a faulty system within the context of a weak culture of safety at an institutional level.^{23,24} In a root-cause analysis of sentinel event reports submitted to The Joint Commission between 2004 and 2010, lack of leadership and communication were identified as the most common root causes of wrong-site surgical procedures and surgical-retained foreign bodies.²⁵ Recognizing that patient safety is a function of a larger institutional culture, the Agency for Healthcare Research and Quality encourages hospitals to measure their culture annually using a validated survey instrument.²⁶ In the surgical setting, safety attitudes can be used to evaluate patient safety interventions and benchmark safety attitudes to those at other hospitals.²⁷ Safety training programs

aimed to improve communication and coordination of care have also been shown to improve safety attitudes^{28,29} and, if implemented systematically across hospitals, may lead to a reduction in surgical never events.²⁹ Additional, more detailed studies of larger surgical populations are needed to guide safety strategies directly so as to reduce surgical never events.

Limitations. Important limitations of our study should be considered. Our study included only events that resulted in paid malpractice claims. Many surgical never events do not result in paid claims or settlements and are therefore not captured in the NPDB. Furthermore, the NPDB may underestimate malpractice claims because, through the corporate shield, payments and settlements made on behalf of corporate entities instead of physicians are exempt from reporting. In a study comparing the RAND Jury Verdict Database to the NPDB, Chandra et al estimated that the NPDB underestimated the number malpractice claims by about 20%.³⁰ These 2 reporting limitations together suggest that our findings probably underestimated the true incidence of surgical never events. In addition, this study was subject to selection bias because severe cases may be more likely to result in paid claims, which may lead to an overestimation of the severity of these events. Prior NPDB and paid claims-based studies share a similar bias, underscoring the need for more robust reporting systems unrelated to claims. Hospital-level data were not available, which limited our ability to make inferences at the institutional level. Therefore, some errors may be attributed to an individual physician in the database when, in fact, they reflect larger institutional deficiencies not identifiable in this database. Finally, we did not have detailed information about physician specialties or the types of surgeries or patients involved in these events, which limited our ability to draw more specific inferences.

Moving forward to eliminate surgical never events. Several national and local programs have been launched to eliminate surgical never events. The Joint Commission has created a national patient safety goal to prevent these events³¹; the CMS denies payment for the marginal costs associated with these events⁹; and the National Quality Forum has developed safe practice recommendations to prevent these events.³² Additionally, many hospitals have implemented briefings,^{2,33,34} checklists,^{35,36} root-cause analysis of adverse events,²⁵ and the addition of institutional safety training programs for hospital staff.³⁷ Beyond responding to never events, attention and resources

should be directed to “near misses,” where harm to a patient was avoided but a systems deficiency was identified.³⁸

Despite our advances in the delivery of health care, surgical never events continue to occur, with serious implications for patients, providers, and health care costs. We trail behind other high-risk industries that have used systematic approaches to successfully identify and reduce sentinel errors. Strategies used in other complex systems such as aviation may help provide a blueprint to examine both the individual and the institutional factors that contribute to these preventable and costly events. For a fraction of the costs associated with surgical never events, we can monitor patterns of these errors better and ultimately discover effective approaches to eliminating them. Investment is needed to create more robust, mandatory data-collection systems concerning surgical never events, including subsequent thorough investigations by surgical health service researchers. Transparency in these fair and accurate reporting systems can help to facilitate improvement. Surgical societies can build on previous consensus statements to focus our attention on patient safety and the elimination of surgical never events.

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