Safety of inpatient care in surgical settings: cohort study

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Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2024;387:e080480 http://dx.doi.org/10.1136/bmj-2024-080480

Accepted: 25 September 2024

ABSTRACT

OBJECTIVES

To estimate the frequency, severity, and preventability of adverse events associated with perioperative care, and to describe the setting and professions concerned.

DESIGN

Multicenter retrospective cohort study.

SETTING

11 US hospitals.

PARTICIPANTS

1009 patients from a randomly selected sample of 64 121 adults admitted for surgery during 2018.

MAIN OUTCOME MEASURES

Adverse events during inpatient perioperative care were assessed using a trigger method, identifying information previously associated with similar events, and from a comprehensive review of electronic health records. Trained nurses reviewed all records and flagged admissions with possible adverse events, which were then adjudicated by physicians, who confirmed the occurrence and characteristics of the events. Adverse events were classified as major if they resulted in serious harm requiring substantial intervention or prolonged recovery, involved a life threatening event, or led to a fatal outcome. Potentially preventable events included those definitively, probably, or possibly preventable.

RESULTS

Among 1009 patients reviewed, adverse events were identified in 38.0% (95% confidence interval 32.6 to 43.4), with major adverse events occurring in 15.9% (12.7 to 19.0). Of 593 identified adverse events, 353 (59.5%) were potentially preventable and 123 (20.7%) were definitely or probably preventable. The most common adverse events were related to surgical procedures (n=292, 49.3%), followed by adverse drug events (n=158, 26.6%), healthcare associated infections (n=74, 12.4%), patient care events (n=66, 11.2%), and blood transfusion reactions (n=3, 0.5%). Adverse events were most frequent in general care units (n=289, 48.8%), followed by operating rooms (n=155, 26.1%), intensive care units (n=77, 13.0%), recovery rooms (n=20, 3.3%), emergency departments (n=11, 1.8%), and other in-hospital locations (n=42, 7.0%). Professions most involved were attending physicians (n=531, 89.5%), followed by nurses (n=349, 58.9%), residents (n=294, 49.5%), advanced level practitioners (n=169, 28.5%), and fellows (n=68, 11.5%).

CONCLUSIONS

Adverse events were identified in more than one third of patients admitted to hospital for surgery, with nearly half of the events classified as major and most potentially preventable. These findings emphasize the critical need for ongoing improvement in patient safety, involving all health professionals, throughout perioperative care.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Adverse events during hospital admission represent a major cause of patient harm

Large available datasets lack the granularity needed to categorize adverse events by preventability, severity, setting, and professionals involved, through detailed analysis of electronic health records

An updated assessment is necessary to establish a reference point of the incidence rates and main characteristics of adverse events in surgery

WHAT THIS STUDY ADDS

Adverse events were identified in 38% of adults admitted to hospital for surgery, with major events occurring in 16% and potentially preventable events in 26%

These incidents were not solely a concern for surgeons in operating rooms but involved healthcare professions throughout the hospital

The findings of this study suggest that adverse events remain widespread in perioperative care, resulting in substantial and preventable patient harm

Introduction

The foundational tenet of medical practice, "First, do no harm," serves as a guiding principle for ensuring patient safety. However, adverse events during hospital admission are a major and widespread cause of harm in healthcare. The landmark Harvard Medical Practice Study, conducted in the 1980s, estimated the incidence and preventability of adverse events during hospital care, with nearly half associated with surgical procedures.[1] Revealing the extent of unintended injuries caused by medical care, this extensive study provided crucial support to the 2000 report of the US National Academy of Medicine titled "To Err is Human: Building a Safer Health System."[2] That report initiated a global effort to improve patient safety, with the goal of identifying and preventing errors associated with adverse events.

Since the Harvard Medical Practice Study was performed, patient safety and various aspects of surgical care have undergone substantial transformations. In modern surgery, minimally invasive procedures have become increasingly prominent.[3] The implementation of surgical safety checklists, globally disseminated and utilized in operating rooms,[4] has been complemented by enhanced recovery after surgery protocols.[5] Together, these initiatives have introduced a systematic approach to improve perioperative care. Concurrently, a substantial portion of surgery has transitioned from the inpatient to outpatient setting, and the widespread adoption of electronic health records has become the norm. In 2001, the American College of Surgeons launched the national surgical quality improvement

programme, drawing inspiration from Codman's pioneering surgical registry a century ago and building upon a previous programme initiated by the Veterans Health Administration in the 1990s.[6]

Given the transformative changes in delivery of surgical care over the past decades, an updated assessment is crucial to establish a precise reference point for patient safety. Understanding the frequency, type, and location of adverse events is essential for continuous quality improvement. Aligned with the comprehensive approach of the Harvard Medical Practice Study, the SafeCare study identified adverse events in nearly one in four admissions during overall inpatient healthcare in 2018.[7] Based on a subset of this original study, here we specifically focused on surgery and other interventional procedures. The worldwide volume of surgeries is large and poses substantial risks to patients.[8] Our goal was to provide a current and precise assessment of surgical safety by presenting important data on adverse events within the hospital setting. We primarily described the incidence, severity, and preventability of adverse events during perioperative care for patients undergoing surgery. Additionally, we identified the settings where adverse events occurred and professions concerned, both inside and outside the operating room.

Methods

Study design and population

We conducted a retrospective cohort study. The study sample was designed to include hospitals that could provide reliable safety estimates for patients aged 18 years and older at each location. We selected the 11 participating hospitals to represent a mix of both large and small facilities, and they were also part of three different healthcare systems. Among these hospitals, two had fewer than 100 beds, four had 100-200 beds, two had 201-500 beds, and three had more than 700 beds.

Our sampling strategy, along with additional details on its representativeness, is outlined in a previous publication focusing on the overall study population.[7] At each participating hospital, a random sample of admissions records was obtained, with oversampling in the smaller hospitals. The target sample from the participating hospitals in Massachusetts included all inpatient admissions with discharges in 2018, excluding those for admissions for hospice or rehabilitation care, psychiatric or addiction treatment, and observation only under the two-midnight rule, which categorises a hospital stay that does not cross two midnights as an observation only encounter. If patients were admitted to hospital from a day procedure owing to an adverse event that occurred in the outpatient setting, these patients were not included in our inpatient surgery sample. A total sample of 2750 admissions (averaging 250 per hospital) was initially calculated. Owing to oversampling of four smaller hospitals, the final sample size increased to 2836 admissions. Of 2809 inpatient admissions with usable charts, we ultimately selected those that involved a surgical procedure. Surgical admissions were primarily identified using surgical discharge diagnosis related groups, which categorize and reimburse hospital inpatient services associated with procedures performed in an operating room setting and carry substantial risk for patients. In addition to surgical procedures, these groups included major interventional cardiovascular and endoscopic procedures. To ensure comprehensive sampling, we subsequently included admissions not initially classified under surgical diagnosis related groups but that involved an adverse event related to a surgical procedure and directly involved surgical specialties during the inpatient stay.

To accurately estimate adverse event rates based on a sufficient sample size, we opted a priori to categorize by single specialty for orthopedic and gastrointestinal surgery, group closely related specialties by organs and surgical outcomes for cardiovascular and thoracic procedures and for urology and gynecology procedures, and combine all other remaining specialties with limited samples.

Record review

Nine trained nurses reviewed the records for adults admitted to hospital to identify possible adverse events, using a detailed manual that outlined the chart review process and specified the data to be collected. In this study, we defined adverse events as unintended physical injury resulting from or contributed to by medical care that required additional monitoring, treatment, or hospital admission, or that resulted in death.[9] Medical care encompassed the actions of individual hospital staff as well as the broader systems and care processes, including both acts of omission (such as failure to diagnose or treat) and acts of commission (such as incorrect diagnosis or treatment, or substandard performance). We excluded adverse events that occurred during previous inpatient admissions or outpatient visits, as our focus was on assessing the incidence of adverse events during hospital admissions.

The reviewers were randomly assigned admitted patients across the hospitals. If they discovered information in a chart that warranted further investigation to identify adverse events related to the index admission, they were allowed to review data recorded up to 30 days after the patient's discharge. To determine if harm was associated with the index admission, we applied no restrictions to reviewing chart information recorded before the index admission. The reviewers adhered to a protocol outlining the sequence of reviewing an admitted patient in Epic, the widely used electronic health records system used by the hospitals. For hospitals using other electronic health records systems, we randomly assigned admissions to reviewers trained in those systems, following a protocol similar to that used for Epic. Eight hospitals used Epic, two used Meditech, and one used a custom made electronic health records system. All data were entered into a data collection tool developed with Microsoft Access, which allowed for live data validation.

doi: 10.1136/bmj-2024-080480 | *BMJ* 2024;387:e080480 | the bmj

As previously detailed and presented in supplementary method S1,[7] in addition to reviewing all relevant information documented in the electronic health records to identify adverse events for each patient, the reviewers looked for triggers of potential adverse events related to patient care, drugs, surgical procedures, intensive care, and emergency care. For each patient, the reviewers were allowed to document up to eight possible adverse events. When the reviewers identified an adverse event, they classified it into specific types, such as an event related to a surgical procedure, an adverse drug event, a patient care event related to nursing care (eg, fall or pressure ulcer), a healthcare associated infection, or a blood transfusion reaction. The reviewers also identified the inpatient setting where the medical management leading to the adverse event occurred, along with the most directly involved specialties and professions. Subsequently, the reviewers performed a comprehensive search to identify any signs of errors during care, such as mistakes in diagnosis or failures to follow procedures. Finally, they compiled a narrative summary of the admission, accompanied by a description of each related adverse event.

Eight physicians reviewed the randomly assigned summaries of adverse events and either agreed or disagreed with the classification of adverse event type. If these adjudicators disagreed, the event type was revised. When the adjudicators had questions or thought one adverse event should be counted as several, they sent their queries or comments back to the nurse for further review. In addition, the adjudicators assessed the severity of each event using a general severity scale,[10] which categorized events as clinically significant (causing unnecessary harm but leading to a quick recovery), serious (resulting in substantial intervention or prolonged recovery), life threatening (posing a potentially fatal situation that required immediate intervention), or fatal (resulting in death). A major adverse event was defined as serious, life threatening, or fatal (supplementary table S1). The adjudicators also provided assessments of whether the harm was preventable.[11] A potentially preventable adverse event encompassed those assessed as definitively, probably, or possibly preventable. A preventable adverse event only included those assessed as definitively or probably preventable (supplementary table S2). Finally, the adjudicators

Table 1 | Characteristics of weighted random sample of patients admitted to hospital for surgery and corresponding cohort of 11 US hospitals in Massachusetts, USA. Values are number (percentage) unless stated otherwise

	Surgical admissions			
	Weighted random sample (n=1009)		Hospital cohort (n=64 121)	
Characteristics	No*	Estimate (95% CI)†	No*	Estimate (95% CI)†
Mean age (years)		60.9 (60.0 to 61.7)		60.9 (59.8 to 62.0)
Age group:				
18-44	175	17.3 (14.6 to 20.1)	11 103	17.3 (16.0 to 18.7)
45-64	368	36.5 (32.2 to 40.8)	23 718	37.0 (35.4 to 38.6)
65-84	414	41.0 (36.9 to 45.1)	25 838	40.3 (38.6 to 42.0)
≥85	52	5.2 (3.9 to 6.5)	3462	5.4 (4.2 to 6.6)
Sex:				
Female	519	51.4 (48.7 to 54.2)	33 065	51.6 (48.0 to 55.1)
Male	488	48.4 (45.6 to 51.2)	31 048	48.4 (44.9 to 52.0)
Unknown	1	0.1 (0.0 to 0.5)	8	0.0 (0.0 to 0.0)
Race:				
White	806	79.9 (74.1 to 85.7)	52 216	81.4 (75.8 to 87.1)
Black	81	8.0 (5.1 to 11.0)	4366	6.8 (4.4 to 9.2)
Asian§	24	2.4 (1.1 to 3.7)	1783	2.8 (2.2 to 3.3)
Other or unknown	97	9.6 (7.1 to 12.1)	5756	9.0 (5.3 to 12.7)
Type of insurance:				
Private	523	51.8 (47.5 to 56.3)	33 730	52.6 (48.4 to 56.8)
Medicare	403	39.9 (36.5 to 43.3)	24 982	39.0 (36.5 to 41.4)
Medicaid	75	7.4 (4.8 to 10.0)	4653	7.3 (4.7 to 9.8)
Uninsured	5	0.5 (0.0 to 1.0)	362	0.6 (0.3 to 0.8)
Other or unknown	3	0.3 (0.0 to 0.8)	394	0.6 (0.1 to 1.1)
Surgical specialty:				
Orthopedic	315	31.2 (22.6 to 39.8)	20 354	31.7 (25.7 to 37.8)
Cardiovascular and thoracic	223	22.1 (15.9 to 28.2)	14 848	23.2 (18.8 to 27.5)
Gastrointestinal	155	15.4 (12.5 to 18.2)	9744	15.2 (13.7 to 16.7)
Urology and gynecology	119	11.8 (10.8 to 12.7)	7154	11.2 (9.8 to 12.5)
Other‡ or unknown	198	19.6 (15.6 to 23.7)	12 021	18.7 (15.6 to 21.9)
Mean length of hospital stay (days)		6.4 (5.4 to 7.4)		6.4 (5.3 to 7.4)

CI=confidence interval.
*Weighting of admission records allowed adjustment for oversampling of smaller hospitals. Numbers of admissions may not sum to 1009 because of weighting and rounding. Percentages may not total 100 because of rounding.
†CIs were not adjusted for multiplicity and should not be used in place of hypothesis testing.
‡Includes neurosurgery, plastic and reconstructive surgery, endocrine surgery, otolaryngology, head and neck surgery, oral surgery, and eye surgery.
§Inclusive of individuals from East, South, and South East Asia.

Table 2 | Weighted incidence, severity, and preventability of at least one adverse event for each hospital admission, overall and according to population characteristics, insurance type, and the surgical specialty associated with the admission.* Values are number (percentage) unless stated otherwise

			Type of adverse event								
Variables	No of patients	≥1 adverse event	Potentially preventable†	Preventable‡	Clinically significant	Serious	Life threat-ening	Fatal	Major	Potentially preventable major†	Preventable major‡
Overall rate, No of patients, % (95% CI)	1009	383, 38.0 (32.6 to 43.4)	258, 25.6 (19.6 to 31.5)	103, 10.2 (7.2 to 13.3)	292, 28.9 (23.4 to 34.5)	143, 14.2 (10.9 to 17.5)	25, 2.5 (1.0 to 3.8)	6, 0.6 (0.0 to 1.3)	160, 15.9 (12.7 to 19.0)	85, 8.4 (6.0 to 11.0)	31, 3.1 (1.3 to 4.8)
Age group (years):											
18-44	175	50 (28.6)	30 (17.1)	13 (7.4)	39 (22.3)	18 (10.3)	2 (1.1)	0	20 (11.4)	10 (5.7)	6 (3.4)
45-64	368	124 (33.7)	83 (22.6)	40 (10.9)	100 (27.2)	46 (12.5)	7 (1.9)	2 (0.5)	51 (13.9)	27 (7.3)	11 (3.0)
65-84	414	186 (44.9)	128 (30.9)	44 (10.6)	139 (33.6)	71 (17.1)	13 (3.1)	3 (0.7)	79 (19.1)	42 (10.1)	12 (2.9)
≥85	52	23 (44.2)	16 (30.8)	7 (13.5)	15 (28.8)	8 (15.4)	2 (3.8)	1 (1.9)	10 (19.2)	6 (11.5)	2 (3.8)
Sex:											
Female	519	173 (33.3)	118 (22.7)	46 (8.9)	131 (25.2)	66 (12.7)	11 (2.1)	1 (0.2)	73 (14.1)	41 (7.9)	13 (2.5)
Male	488	211 (43.2)	140 (28.7)	58 (11.9)	161 (33.0)	77 (15.8)	13 (2.7)	5 (1.0)	87 (17.8)	45 (9.2)	18 (3.7)
Race:											
White	806	313 (38.8)	215 (26.7)	87 (10.8)	238 (29.5)	115 (14.3)	20 (2.5)	4 (0.5)	130 (16.1)	70 (8.7)	22 (2.7)
Black	81	31 (38.3)	19 (23.5)	9 (11.1)	26 (32.1)	11 (13.6)	1 (1.2)	1 (1.2)	12 (14.8)	7 (8.6)	6 (7.4)
Asian§	24	9 (37.5)	6 (25.0)	1 (4.2)	7 (29.2)	3 (12.5)	1 (4.2)	0 (0.0)	4 (16.7)	2 (8.3)	1 (4.2)
Other	49	9 (18.4)	4 (8.2)	2 (4.1)	5 (10.2)	5 (10.2)	0 (0.0)	0 (0.0)	5 (10.2)	2 (4.1)	1 (2.0)
Unknown	49	22 (44.9)	15 (30.6)	5 (10.2)	17 (34.7)	9 (18.4)	2 (4.1)	1 (2.0)	9 (18.4)	5 (10.2)	1 (2.0)
Type of insurance:											
Private	523	185 (35.4)	118 (22.6)	44 (8.4)	144 (27.5)	70 (13.4)	10 (1.9)	2 (0.4)	77 (14.7)	36 (6.9)	15 (2.9)
Medicare	403	172 (42.7)	125 (31.0)	51 (12.7)	128 (31.8)	64 (15.9)	13 (3.2)	4 (1.0)	72 (17.9)	44 (10.9)	13 (3.2)
Medicaid	75	24 (32.0)	14 (18.7)	8 (10.7)	19 (25.3)	9 (12.0)	1 (1.3)	0 (0.0)	10 (13.3)	5 (6.7)	3 (4.0)
Uninsured	5	2 (40.0)	1 (20.0)	1 (20.0)	2 (40.0)	1 (20.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)
Surgical specialty:											
Orthopedics	315	102 (32.4)	69 (21.9)	29 (9.2)	86 (27.3)	36 (11.4)	3 (1.0)	0 (0.0)	37 (11.7)	21 (6.7)	7 (2.2)
Cardiovascular and thoracic	223	105 (47.1)	69 (30.9)	29 (13.0)	74 (33.2)	46 (20.6)	14 (6.3)	3 (1.3)	55 (24.7)	29 (13.0)	10 (4.5)
Gastrointestinal	155	61 (39.4)	39 (25.2)	15 (9.7)	45 (29.0)	24 (15.5)	2 (1.3)	0 (0.0)	26 (16.8)	10 (6.5)	3 (1.9)
Urology and gynecology	119	29 (24.4)	19 (16.0)	8 (6.7)	24 (20.2)	10 (8.4)	0 (0.0)	0 (0.0)	10 (8.4)	5 (4.2)	2 (1.7)
Other¶	169	58 (34.3)	45 (26.6)	17 (10.1)	46 (27.2)	20 (11.8)	4 (2.4)	2 (1.2)	23 (13.6)	17 (10.1)	7 (4.1)
Unknown	29	29 (100)	16 (55.2)	6 (20.7)	19 (65.5)	8 (27.6)	1 (3.4)	1 (3.4)	10 (34.5)	4 (13.8)	2 (6.9)

CI=confidence interval.
Clinically significant adverse event=caused unnecessary harm but resulted in rapid recovery; serious adverse event=caused harm that resulted in substantial intervention or prolonged recovery; life threatening adverse event=caused a potentially fatal situation that required immediate intervention; fatal adverse event=caused the death of the patient; major adverse event=a serious, life threatening, or fatal occurrence.
*Multiple adverse events with different severity levels could have occurred during a single admission. Percentages may not total 100 because of rounding, and the numbers of admissions may not sum to 1009 because of weighting and rounding.
†Includes adverse events assessed as definitely, probably, or possibly preventable.
‡Includes adverse events assessed as definitely or probably preventable.
§Inclusive of individuals from East, South, and South East Asia.
¶Includes neurosurgery, plastic and reconstructive surgery, endocrine surgery, head and neck surgery, oral and eye surgery.

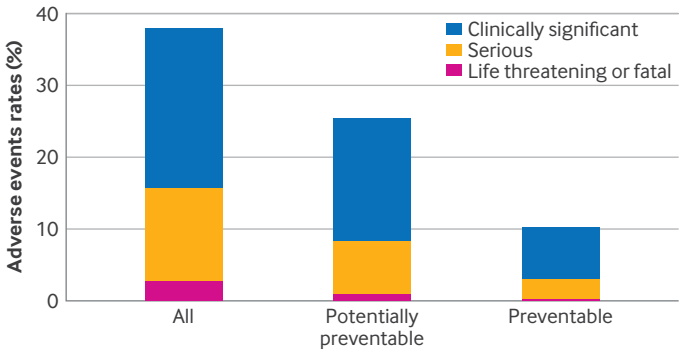

Fig 1 | Severity of adverse events weighted rates for each admitted patient according to preventability. Severity was determined using an ascending ordinal classification. Adverse events were defined as clinically significant (caused unnecessary harm but resulted in rapid recovery), serious (caused harm that resulted in substantial intervention or prolonged recovery), life threatening (caused a potentially fatal situation that required immediate intervention), and fatal (resulted in death). Potentially preventable adverse events included adverse events that were assessed as definitely, probably, or possibly preventable. Preventable adverse events included adverse events that were assessed as definitely or probably preventable

graded their confidence (with the use of a six point ordinal scale) about whether the event was due to healthcare management.[12] A confidence score of 4 or higher indicated an adverse event had occurred, aligning with the confidence threshold used in the Harvard Medical Practice Study (supplementary table S3).[13] Supplementary method S2 provides additional information about the record review.

Statistical analysis

We employed a sampling design in which some of the smaller hospitals were oversampled. Each sampled patient's admission record was assigned a weight for the analyses. The weight for each patient sampled was the inverse of the probability that the patient was sampled, which is estimated as the inverse of the proportion of admission records sampled from that hospital. Intuitively, a sampled individual's weight can be interpreted as the number of patients in each hospital that the sampled individual represents. Applying these weights in all the analyses enabled us to derive estimates of characteristics and outcomes for the population of interest. Along with weighting, all 95% confidence intervals accounted for clustering within a hospital. A generalized estimating equations approach with an exchangeable correlation matrix was used to calculate the marginal probability of an adverse event.[14 15] We did not adjust confidence intervals for multiplicity, so they should not be used in place of hypothesis testing.

Patient characteristics associated with admissions were reported as numbers and percentages for categorical variables and as means for continuous variables. Weighted adverse event rates were described based on corresponding severity and preventability, stratified by population characteristics, insurance type, and surgical specialty associated with the admission. Additionally, weighted severity and preventability of adverse events were described according to the type of event, setting, and profession involved. Data manipulation and analyses were performed using SAS software version 9.4 (SAS Institute, Cary, NC). Supplementary method S3 provides the SAS code for data preparation and analysis.

Patient and public involvement

No patients directly participated in this retrospective review of electronic health records. Although the study was initiated before patient and public involvement became common practice, we did speak to patients about the study, and we asked a member of the public to read our manuscript after submission.

Results

Study sample

From 64 121 surgical admissions across 11 hospitals, we analyzed a weighted random sample of 1009 patients admitted to hospital where adverse events related to perioperative care may have occurred (supplementary figure S1). This sample was reasonably

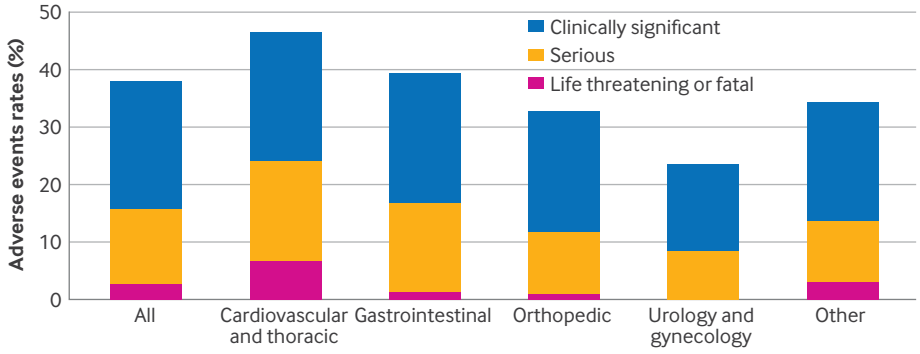

Fig 2 | Severity of adverse events weighted rates for each admitted patient according to surgical specialty. Severity was determined using an ascending ordinal classification. Adverse events were defined as clinically significant (caused unnecessary harm but resulted in rapid recovery), serious (caused harm that resulted in substantial intervention or prolonged recovery), life threatening (caused a potentially fatal situation that required immediate intervention), and fatal (resulted in death). The category for other included neurosurgery, plastic and reconstructive surgery, endocrine surgery, head and neck surgery, oral surgery, and eye surgery

representative of all inpatient surgical admissions in the corresponding Massachusetts hospitals during the study period (table 1). The specialties associated with the admissions were orthopedics (n=315, 31.2%), cardiovascular and thoracic surgery (n=223, 22.1%), gastrointestinal surgery (n=155, 15.4%), urology and gynecology surgery (n=119, 11.8%), and neurosurgery, plastic and reconstructive surgery, endocrine surgery, head and neck surgery, oral surgery, or eye surgery (n=198, 19.6%).

Adverse events incidence rates in weighted random sample

Within the weighted random sample of 1009 admitted patients, we identified at least one adverse event in 383 (38.0%) and at least one major adverse event (ie, serious harm resulting in substantial intervention or prolonged recovery, life threatening event, or death) in 160 (15.9%) (table 2). Overall, 292 (28.9%) admissions involved at least one clinically significant adverse event, 143 (14.2%) at least one serious adverse event, 25 (2.5%) at least one life threatening event, and 6 (0.6%) a fatal event.

Among all admitted patients, at least one adverse event was deemed potentially preventable in 258 (25.6%) patients, with 103 (10.2%) classified as probably or definitely preventable. Additionally, 85 (8.4%) patients had at least one potentially preventable major adverse event, and 31 (3.1%) had a major event that was deemed probably or definitely preventable (fig 1).

Table 2 shows the incidence of adverse events for each admitted patient according to population characteristics and surgical specialty. The percentage of patients with at least one adverse event was higher among older patients and among those who underwent cardiovascular and thoracic surgery compared with orthopedic surgery and urology and gynecology procedures (fig 2).

Adverse events description in weighted random sample

We identified 593 adverse events during the index surgical admissions. Of these, 353 (59.5%) were potentially preventable and 123 (20.7%) were probably or definitely preventable (table 3). Among the 225 major adverse events, 107 (47.6%) were potentially preventable and 35 (15.6%) were probably or definitely preventable. Supplementary table S4 shows examples of adverse events, including severity category and preventability assessment.

The most common types of adverse events were surgery related, accounting for 292 (49.3%) of the overall adverse events identified (table 3), followed by adverse drug events (n=158, 26.6%), healthcare associated infections (n=74, 12.4%), patient care events (n=66, 11.2%), and blood transfusion reactions (n=3, 0.5%). Surgery related adverse events were more likely to be rated as major adverse events and less likely to be preventable than adverse drug and patient care events.

The most common setting for adverse events was the general care unit, representing 289 (48.8%) of all incidents, followed by the operating room (n=155, 26.1%), intensive care unit (n=77, 13.0%), recovery room (n=20, 3.3%), emergency department (n=11, 1.8%), and other in-hospital locations (n=42, 7.0%). Adverse events in operating rooms or intensive care units were more severe than in general care units. Attending physicians were involved in 531 (89.5%) adverse events, followed by nurses (349 (58.9%), residents (n=294, 49.5%), advanced level practitioners (n=169, 28.5%), and fellows (n=68, 11.5%). Supplementary figures S2 and S3 present the distribution of adverse events by setting, type of adverse event, and healthcare profession.

Discussion

Two decades after the release of the "To Err is Human" report, this study found that adverse events persist as a major problem in delivery of perioperative care across diverse surgical specialties. We observed that adverse events affected more than one third of patients admitted to hospital for surgery, with nearly half constituting major events resulting in serious or life threatening harm to patients, or death. About one fourth of all patients experienced potentially preventable adverse events, with one in 10 concerning events that were probably or definitely preventable. The most common types of adverse events were associated with surgical procedures, followed by adverse drug events, healthcare associated infections, and patient care events. Half of these incidents took place in general care units and a quarter in operating rooms. The professions most frequently involved in adverse events were attending physicians, nurses, residents, and advanced level practitioners.

Comparison with other studies

Compared with adverse event incidence rates previously estimated from the SafeCare study across all inpatient admissions, the higher rates observed in this subsample suggest that adverse events are more likely to occur in surgical care than in non-surgical care.[7] In line with a similar study conducted in 1992, which provided a detailed analysis of surgical adverse events in hospitals in Colorado and Utah, we found that most of these events were potentially preventable.[16] Since then, systematic reviews have successively compiled previous studies worldwide, estimating the frequency and preventability of adverse events. One review estimated an overall incidence of adverse events in 2008 at 9.2%, with most associated with surgical care and nearly half deemed preventable.[17] A review in 2013 found that surgical adverse events had occurred in 14.4% of patients, and that 5.2% were preventable.[18] A review in 2019 reported a 20% rate of adverse events in surgery, including a 10% prevalence of preventable patient harm.[19] Interpreting data from the national surgical quality improvement programme over time also revealed stable outcomes or modest trends for improvement in surgical safety since 2008,

Table 3 | Weighted severity and preventability of adverse events, overall and according to type of event, location, and professions involved*. Values are number (percentage) unless stated otherwise

Variables	No (%) of events	Type of adverse event								
		Potentially preventable†	Definitely or probably preventable‡	Clinically significant	Serious	Life threatening	Fatal	Major	Potentially preventable major†	Preventable major‡
Overall No of events, % (95% CI)	593 (100.0)	353, 59.5 (55.2 to 63.9)	123, 20.7 (16.6 to 24.8)	368, 62.1 (58.6 to 65.5)	185, 31.2 (27.0 to 35.3)	34, 5.7 (2.7 to 8.8)	6, 1.0 (0.0 to 2.2)	225, 37.9 (34.5 to 41.4)	107, 18.0 (14.1 to 21.9)	35, 5.9 (3.7 to 8.0)
Type of adverse event:										
Surgery related	292 (49.3)	157 (53.5)	39 (13.5)	151 (51.5)	113 (38.7)	27 (9.2)	2 (0.7)	142 (48.5)	65 (22.3)	16 (5.5)
Drug related	158 (26.6)	89 (56.3)	42 (26.8)	115 (72.9)	39 (24.5)	2 (1.3)	2 (1.3)	43 (27.1)	19 (12.2)	10 (6.3)
Healthcare associated infections	74 (12.4)	52 (70.2)	12 (16.7)	45 (61.4)	22 (30.2)	4 (5.6)	2 (2.8)	28 (38.6)	14 (19.5)	5 (6.9)
Patient care related§	66 (11.2)	55 (83.4)	28 (43.1)	56 (83.7)	10 (14.8)	1 (1.5)	0 (0.0)	11 (16.3)	7 (10.2)	4 (5.6)
Blood transfusion reaction	3 (0.5)	1 (33.7)	0 (0.0)	2 (66.3)	1 (33.7)	0 (0.0)	0 (0.0)	1 (33.7)	1 (33.7)	0 (0.0)
Setting of adverse event:										
General care unit	289 (48.8)	187 (64.8)	69 (23.7)	211 (72.8)	72 (25.1)	5 (1.8)	1 (0.4)	78 (27.2)	45 (15.6)	15 (5.1)
Operating room	155 (26.1)	87 (56.4)	20 (13.0)	75 (48.8)	62 (40.4)	15 (9.5)	2 (1.3)	79 (51.2)	36 (23.2)	6 (3.8)
Intensive care unit	77 (13.0)	42 (53.9)	15 (19.7)	36 (46.1)	30 (38.2)	10 (13.1)	2 (2.6)	42 (53.9)	17 (21.1)	10 (13.1)
Recovery room	20 (3.3)	11 (54.7)	7 (34.0)	12 (64.2)	5 (25.3)	2 (10.4)	0 (0.0)	7 (35.8)	3 (15.5)	1 (5.2)
Emergency department	11 (1.8)	5 (46.2)	3 (26.9)	8 (71.0)	3 (29.0)	0 (0.0)	0 (0.0)	3 (29.0)	1 (9.7)	0 (0.0)
Other in-hospital location	42 (7.0)	21 (51.1)	9 (22.0)	27 (63.3)	12 (29.4)	2 (4.9)	1 (2.4)	15 (36.7)	5 (12.3)	3 (7.3)
Professions involved:										
Attending physicians	531 (89.5)	306 (57.7)	96 (18.1)	316 (59.6)	178 (33.5)	31 (5.8)	6 (1.2)	215 (40.4)	101 (18.9)	31 (5.8)
Nurses	349 (58.9)	219 (62.7)	76 (21.7)	231 (66.2)	101 (28.8)	15 (4.4)	2 (0.6)	118 (33.8)	59 (16.9)	18 (5.3)
Residents	294 (49.5)	176 (59.8)	55 (18.8)	174 (59.3)	98 (33.6)	20 (6.7)	1 (0.3)	119 (40.7)	58 (19.8)	17 (5.9)
Advanced level practitioners	169 (28.5)	84 (49.8)	20 (11.5)	101 (59.5)	56 (33.4)	10 (5.8)	2 (1.2)	69 (40.5)	26 (14.9)	4 (2.1)
Fellows	68 (11.5)	34 (49.3)	8 (11.9)	37 (55.1)	24 (35.9)	5 (7.5)	1 (1.5)	31 (44.9)	10 (15.0)	2 (3.0)

CI=confidence interval.
Clinically significant adverse event=caused unnecessary harm but resulted in rapid recovery; serious adverse event=caused harm that resulted in substantial intervention or prolonged recovery; life threatening adverse event=caused a potentially fatal situation that required immediate intervention; fatal adverse event=caused the death of the patient; major adverse event=a serious, life threatening, or fatal occurrence.
*As a result of weighting, counts, and percentages of all events may not sum to total number of adverse events in each row or to total number of events within an adverse event type.
†Includes adverse events assessed as definitely, probably, or possibly preventable.
‡Includes adverse events assessed as definitely or probably preventable.
§Related to nursing care, including falls and pressure ulcers.

with somewhat inconsistent patterns observed across different surgical procedures and complications.[20 21] Our study found higher incidences of adverse event rates, possibly attributed to improved traceability of care incidents with the use of electronic health records, and increased sensitivity in screening all events along a patient's perioperative care pathway. The increased incidence of surgical complications might also be explained by our emphasis on inpatient surgery, which concentrated on patients with more complex issues, while excluding less risky procedures that have gradually transitioned from inpatient to outpatient settings over the past decades. Overall, while this may suggest a lack of improvement over the decades, direct comparisons of our findings with previous estimates of adverse event rates are challenging owing to changes in data quality and the context of care.

Strengths and limitations of this study

This study has notable strengths and limitations. We relied on a multicenter random sample of patients admitted to hospital for surgery to estimate incidence rates for adverse events. A comprehensive review of medical records by trained nurses and physicians enabled us to systematically categorize the seriousness and preventability of each adverse event, along with the main characteristics of the events. The study population was, however, confined to the US state of Massachusetts in 2018 and may not fully represent hospitals at large. This limitation affects the generalizability of the findings to other healthcare settings, warranting replication outside of the US. We could have opted for larger available datasets, such as the US National Inpatient Sample of the Healthcare Cost and Utilization Project or the registry of the national surgical quality improvement programme, to allow for greater generalizability and the interpretation of temporal changes. However, neither dataset offers both the representativeness and sufficient data validity to assess surgical outcomes nationwide.[22 23] Additionally, these data lacked the granularity needed to categorize adverse events based on preventability, severity, setting, and professionals involved through an in-depth analysis of patient electronic health records and an accurate nurse-physician adjudication process. Another study limitation was the study's retrospective design, which relied heavily on the validity of data retrieved from electronic health records. Although these records are valuable, they are prone to inaccuracies, missing information, and variability in documentation practices across healthcare systems, potentially biasing the identification and categorization of adverse events. Owing to the limited sample size, accurate estimates of adverse event rates for each surgical specialty could not always be provided separately, and our approach likely overlooked some surgery specific adverse events. We deliberately chose to focus on a random subsample of admissions, as conducting exhaustive chart reviews for more than 60 000 admissions would represent a disproportionate effort. Furthermore, preventability is a time dependent concept, reflecting only what reviewers deemed avoidable based on the best available practices at the time. Some events considered preventable nowadays may not have been deemed so at the time when the care was initially delivered. As medical knowledge continually advances, it could be argued that essentially all patient harm may be preventable.

Policy implications

By establishing an updated reference point, this study showed that adverse events remain widespread in contemporary healthcare, causing substantial and preventable patient harm during hospital admission. Furthermore, the study addressed a critical need by exploring the specifics of these surgical events, including the important roles of post-surgical care and non-physician staff. This study found that the problem is not solely a concern for surgeons in operating rooms but involves healthcare professions throughout the hospital during perioperative care. However, the surgeon, while being part of the team, remains the leader in many aspects of perioperative care, and the admission process typically falls under the surgeon's domain. Despite the efforts made in patient safety since the Harvard Medical Practice Study, progress has stagnated.[24] By comparison, the noticeable decrease in fatal incidents in commercial airlines over the past half century has been largely attributed to the firm establishment of safety culture among crew members, strong support from companies' leadership, and transparent communication of incidents.[25]

Our findings suggest that errors persist in surgery, indicating the need to reassess how the structure of healthcare contributes to these ongoing challenges. While emphasizing safety as a collective responsibility for all health professionals is important, it is essential to recognize the expertise of those ultimately responsible for patient care, such as attending physicians. In modern healthcare systems where organizational and administrative factors often drive delivery of care, concern is growing that physicians have limited input into decision making processes. This is particularly concerning given reports of moral injury, burnout, high turnover rates, and resignations among healthcare professionals.[26] By valuing the perspectives of frontline staff and promoting collaborative approaches to care delivery, we can strive towards a system that prioritizes patient safety while also supporting the wellbeing of health professionals.

In surgery, the fundamental premise behind the national surgical quality improvement programme initiative was that measuring adverse events is pivotal to fostering patient centered and safe care. However, hospital enrolment in this programme, or pay for performance based on indicators benchmarking, did not directly result in marked improvements.[27-29] Supplementing these strategies with dynamic monitoring of surgical outcomes and regular feedback to healthcare professionals has the potential to reduce patient harm over time.[30] In accordance with Codman's intuition, learning healthcare systems need

to embrace a transformative approach grounded in the timely and accurate interpretation of all available data.[31] This entails prospectively tracking surgical outcomes, identifying the drivers, and proposing adaptive solutions.

Conclusion

The findings of this study suggest that adverse events remain frequent and preventable in surgery, rendering perioperative care as a high risk environment for patients. This underscores the urgent need to persist in enhancing patient safety through ongoing efforts. Emphasizing the active involvement of all healthcare professionals throughout the hospital is paramount in this endeavor.

Contributors: DWB obtained funding and supervised the study. AD, SRL, and DWB conceived and designed the study. AD, MLF, CI, SRL, ZC, JSW, and DWB acquired, analyzed, or interpreted the data. AD, MLF, and CI performed data management. AD and SRL performed statistical analyses. AD, SRL, and DB drafted the manuscript. AD, MLF, CI, SRL, ZC, JSW, and DWB critically revised the manuscript for important intellectual content and approved the final published version. ZC, JSW and DWB provided administrative, technical, or material support. All authors agreed to be accountable for all aspects of the work. AD, MLF, SRL, and DWB had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. DWB is the guarantor and had final responsibility for the decision to submit for publication. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding: This study was supported by a grant from the Controlled Risk Insurance Company and the Risk Management Foundation of the Harvard Medical Institutions. The funder of the study had no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The researchers confirm that they are independent from the funder of the study.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/disclosure-of-interest/ and declare: support from Controlled Risk Insurance Company and the Risk Management Foundation of the Harvard Medical Institutions for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: All the participating hospitals agreed to undergo review by the Mass General Brigham institutional review board, which approved this study (IRB 2017-P-001929) and waived the need for patient informed consent at each participating site.

Data sharing: Supplementary method S3 shows the SAS code for data preparation and analysis. Owing to confidentiality requirements, the data for this project are primarily reserved for the immediate research team at Mass General Brigham. However, deidentified data can be accessed on secured servers by contacting the principal investigator (DWB). Additionally, the protocol and adverse events chart review training manual used for the project, along with further details about data management and analysis, are available to interested researchers.

Transparency: The lead author (AD) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The study has important relevance for policy and will be presented to students, shared with patients through media outreach and social media, and posted on publicly searchable websites in lay summary format, accompanied by a press release. To extensively disseminate our research findings to the public, we will collaborate with the Betsy Lehman Center for Patient Safety (https://betsylehmancenterma.gov) the Massachusetts Coalition for the Prevention of Medical Error, and other organizations that support the development of public health policies and transformative efforts aimed at enhancing patient safety (https://www.whitehouse.gov).

Provenance and peer review: Not commissioned; externally peer reviewed.

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Supplementary information: Additional tables S1-S4, figures S1-S3, and methods S1-S3