ORIGINAL INVESTIGATION

Analysis of Medication-Related Malpractice Claims

Causes, Preventability, and Costs

Jeffrey M. Rothschild, MD, MPH; Frank A. Federico, RPh; Tejal K. Gandhi, MD, MPH; Rainu Kaushal, MD, MPH; Deborah H. Williams, MHA; David W. Bates, MD, MSc

Background: Adverse drug events (ADEs) may lead to serious injury and may result in malpractice claims. While ADEs resulting in claims are not representative of all ADEs, such data provide a useful resource for studying ADEs. Therefore, we conducted a review of medication-related malpractice claims to study their frequency, nature, and costs and to assess the human factor failures associated with preventable ADEs. We also assessed the potential benefits of proved effective ADE prevention strategies on ADE claims prevention.

Methods: We conducted a retrospective analysis of a New England malpractice insurance company claims records from January 1, 1990, to December 31, 1999. Cases were electronically screened for possible ADEs and followed up by independent review of abstracts by 2 physician reviewers (T.K.G. and R.K.). Additional in-depth claims file reviews identified potential human factor failures associated with ADEs.

Results: Adverse drug events represented 6.3% (129/2040) of claims. Adverse drug events were judged preventable in 73% (n=94) of the cases and were nearly evenly divided between outpatient and inpatient settings. The most frequently involved medication classes were antibiotics, antidepressants or antipsychotics, cardiovascular drugs, and anticoagulants. Among these ADEs, 46% were life threatening or fatal. System deficiencies and performance errors were the most frequent cause of preventable ADEs. The mean costs of defending malpractice claims due to ADEs were comparable for nonpreventable inpatient and outpatient ADEs and preventable outpatient ADEs (mean, $64 700-74 200), but costs were considerably greater for preventable inpatient ADEs (mean, $376 500).

Conclusions: Adverse drug events associated with malpractice claims were often severe, costly, and preventable, and about half occurred in outpatients. Many interventions could potentially have prevented ADEs, with error proofing and process standardization covering the greatest proportion of events.

Arch Intern Med. 2002;162:2414-2420

From the Division of General Medicine, the Department of Medicine, Brigham and Women's Hospital (Drs Rothschild, Gandhi, Kaushal, and Bates and Ms Williams), and the Risk Management Foundation of the Harvard Medical Institutions (Mr Federico), Boston, Mass.

THE RECENT Institute of Medicine report[1] on medical errors has led to an increased interest in the quality of health care. This report relied heavily on the Harvard Medical Practice Study,[2] which found that adverse events occurred in 3.7% of hospitalized patients, with more than half attributable to errors (and, therefore, being preventable), including more than a quarter due to negligent care. Medication-related complications were the most common type of adverse event (19%).[3]

Adverse drug events (ADEs) are injuries resulting from the use of a drug. Adverse drug events include preventable ADEs (resulting from medication errors) and adverse drug reactions, in which no error occurred. In one study[4] of hospitalized patients, the ADE rate was 6.5 per 100 adult medical-surgical admissions; among those ADEs, 28% were preventable. Preventable ADEs also frequently occur in other settings, including nursing homes[5] and the outpatient setting,[6] although fewer epidemiologic data are available for nonhospital settings.

Preventable adverse events, including ADEs, usually result from various underlying systems failures.[3,7-10] Systems-related factors may set up a health care provider (physician, nurse, pharmacist, etc) to commit errors at the "sharp end" of the system.[11] Human factor analyses of adverse events seek to determine the underlying reasons that allow errors to occur that can then result in patient harm. Malpractice claims, which include detailed information from disparate sources, may be used for systems analyses, which may in turn allow assessment of the potential impact of prevention strategies.[12]

Malpractice claims analyses have several strengths: (1) claims costs are substantial, and quantifying these costs are important; (2) claims records provide detailed description of care in specific cases; (3)

claims analyses provide a valuable window into events in the outpatient world; and (4) malpractice claims often include the most serious ADE cases. Limitations of claims analyses include the "tip of the iceberg" phenomenon: (1) claims represent only a small proportion of ADEs, (2) there is an inability to study data in real time, (3) claims records may not always reflect the actual circumstances surrounding an event, and (4) there is a poor relationship of claims (including closed claims resulting in plaintiff payments) to actual adverse events or negligence.[13-18] Despite these limitations, closed claims analyses of adverse events have made important contributions to patient safety, particularly regarding anesthesia.[19] An analysis of medication-related claims may provide opportunities to "make medical errors into medical treasures"[20(p1867)] and may reveal systems-related factors that are amenable to prevention.[21,22]

Thus, we reviewed claims data to determine the preventability of ADEs and contributing human factor failures at the system level and the individual performance level to inform the development of medication safety strategies. In addition, we assessed the potential benefit on claims prevention of proved ADE prevention strategies, such as computerized physician order entry (CPOE) with decision support[23] and pharmacist participation during patient rounds.[24,25] Finally, we determined the financial costs associated with defending these claims.

METHODS

CASE FINDING

The Risk Management Foundation (RMF) of the Harvard Medical Institutions provides claims management and services related to loss prevention, quality improvement, underwriting, and research for the Controlled Risk Insurance Company (CRICO), Cambridge, Mass. The CRICO insures 8300 physicians, 23 hospitals with approximately 4700 beds, and 430 additional organizations in Massachusetts and New Hampshire. Altogether, CRICO provides malpractice insurance for 27% of Massachusetts' physicians.

We conducted a retrospective search of RMF's medication-related malpractice claims for cases asserted between January 1, 1990, and December 31, 1999. The RMF database was searched using the following terms in the allegation descriptions: *improper treatment*, *medication mismanagement*, *medication monitoring*, *medication errors*, *ADEs*, and *adverse drug reactions*. Claims file reviews were completed in February 2001.

The RMF claims files included the following data sources: case abstracts; defense expert opinions; narrative statements from involved health care personnel; peer reviews; communications between the insurer's attorneys, claims representatives, and the defendant; clinical records deemed pertinent to the case's defense; depositions; and, for closed claims, legal and financial determinations (**Table 1**). A pharmacist investigator (F.A.F.) initially screened case abstracts for medication-related claims following an electronic search of abstract allegations. Claims not associated with patient injury or clearly unrelated to medications were excluded from further analysis.

CASE ABSTRACT REVIEW

Secured deidentified case abstracts were permitted off-site for physician review. Two independent physician reviewers (T.K.G. and R.K.) with expertise in judging adverse events evaluated case abstracts using a structured implicit review to validate the presence, severity, and preventability of an ADE.[4] When reviewer disagreements affected classification, a third reviewer (J.M.R.) evaluated the event for resolution.

Table 1. Definitions of Terminology Associated With Malpractice Claims

Term	Definition
Negligence	A legal theory based on the duty of an individual to act and use such care as a reasonably prudent person would do in the same or similar circumstances (includes acts of commission or omission)
Malpractice claim	A demand for compensation for an alleged injury in which the patient (or his or her representative) had indicated intent to pursue the demand; to prevail in medical malpractice lawsuits, the plaintiff must prove a duty, a breach of the standard of care, ascertainable damages, and direct causation between the breach of the standard of care and the damages*
Open malpractice claim	A claim in which there is ongoing legal action
Closed malpractice claim	A claim in which legal action has been completed
Case or loss abstract	Case summary, including clinical, risk management, and claims information; prepared by the insurer's claims representative
Expense payment	Insurer payment associated with the defense of the claim (eg, legal fees and medical expert fees)
Indemnity payment	The payment made to a claimant for damages under an agreement of insurance as a result of settlement, arbitration, or jury verdict
Total claim payment	Sum of indemnity and expenses payments
Reserves	Money set aside, usually as the highest potential, for open cases; includes expense reserves and indemnity reserves in the event of a settlement or plaintiff verdict
Incurred loss	Sum of indemnity paid and reserved plus expenses paid and reserved

*From Liang and Cullen.[26]

Patient-related variables of interest included age and sex. Event-related variables collected included the presence of an ADE, event location, medication class, primary personnel involved in an incident, and the specialty and level of experience of the primary physicians involved in an incident. Regarding preventability, ADEs were rated as follows: definitely preventable, probably preventable, probably not preventable, or definitely not preventable. In the analysis, these categories were collapsed into preventable and not preventable.[27] The severity of an ADE was rated as significant, serious, life threatening, or fatal.[4]

The degree of deviation from accepted practice norm was rated as none or little vs moderate or severe. Evidence for negligence was categorized into levels of confidence: little or none, slight to moderate, not quite likely—less than 50-50, more likely than not—more than 50-50, strong evidence, virtually certain, and unable to determine. These categories were later collapsed into no negligence, negligence, and unable to determine. Judgment was made as to the potential of preventing each ADE with an intervention, such as clinical pharmacists participating with physicians during patient rounds or CPOE with decision support.

Table 2. Characteristics of Medication-Related Malpractice Claims*

Characteristic	Adverse Drug Events: Preventable (n = 94)	Adverse Drug Events: Nonpreventable (n = 35)	*P* Value
Patient (defendant) age, mean, y	39.5	50.1	.02
Patient (defendant) sex			
Female	56 (60)	17 (49)	.26
Male	38 (40)	18 (51)	
Setting of adverse drug event			
Outpatient	44 (47)	17 (49)	.86
Inpatient†	50 (53)	18 (51)	
Academic medical center	41	16	
Affiliated teaching hospital	7	1	
Nonteaching community hospital	2	0	
Extended-care facility	0	1	
Severity of adverse drug event			
Significant	16 (17)	9 (26)	.68
Serious	34 (36)	10 (29)	
Life threatening	29 (31)	10 (29)	
Fatal	15 (16)	6 (17)	

*Data are given as number (percentage) of adverse drug events unless otherwise indicated. Percentages may not total 100 because of rounding.

†The number of adverse drug events in each inpatient setting is specified.

Malpractice claims variables collected were as follows: claims status at claims file review (open or closed), date of injury, claims close date, claims disposition, and indemnity and expense payments. Closed claims dispositions were categorized as verdict, either trial or tribunal, and settlement, including mediation. Verdicts for the defense included claims that were denied, dropped, or dismissed, or resulted in a favorable tribunal or trial. Settlements for the defense were cases with no indemnity payments to the plaintiff.

CLAIMS FILE REVIEW

The complete claims files for all cases initially screened as possible ADEs were also reviewed by a physician investigator (J.M.R.) in the CRICO offices. Human factor assessment of claims data, completed during on-site claims file reviews, sought to categorize latent or systemic errors and individual performance (active) errors that may have caused or contributed to an ADE.[28] Methods to examine the chain of events leading to an adverse outcome have previously been described.[29] The framework of Reason[30] and Vincent et al[31] for incident investigation and analysis for addressing conditions that predispose to risky and unsafe practices was used as a model. Latent causes of errors were categorized according to deficiencies in the following domains: operations and maintenance, managerial or organizational, and design.

Operational deficiencies included team or group behavioral deficiencies, such as communication failures among team members, inadequate handoffs of relevant information, supervisory failures, confused lines of authority, and failure to appropriately use consultants; and deficient environmental conditions, such as ergonomic problems (eg, look-alike equipment), equipment malfunctions, inadequate staffing levels, poorly educated staff, excessive workload, and interruptions.

Managerial and organizational factors included poor communication across departments or disciplines, absent processes to prevent an error from reaching patients or mitigating harm from errors, faulty or incorrectly followed policies and procedures addressing processes involved in an error, inadequate standardization of processes, inadequate training, or the use of substitute or inexperienced professionals.

Design factors included technology errors; system complexity, such as frequent handoffs or complicated protocols; and poor interfaces between technology and workers.

Individual performance errors included the following: knowledge-based errors, mistakes related to inadequate information (eg, unknowingly prescribing a teratogenic agent to a pregnant patient) or unavailable information (eg, unawareness of a patient's documented allergy history); rule-based errors, mistakes that resulted from either applying the wrong rule (eg, an adult dosage given to a child) or misapplying the right rules (eg, prescribing a thrombolytic agent for a patient with a recent intracranial hemorrhage); skill-based errors, lapses or failures to execute an action (eg, failure to monitor renal function while prescribing a nephrotoxic drug); and slips or unintended actions (eg, giving one patient another patient's medication).[30]

A review of the claims records was also used to judge the potential role of preventive strategies for ADEs. In addition, judgments regarding the potential roles of human factor improvement efforts were made. The claims file reviewer (J.M.R.) judged whether improved preparation or planning, standardization of processes, or built-in design redundancies (eg, callback techniques and mandatory second opinions) could potentially have reduced the likelihood of an ADE or the likelihood of injury from an ADE.

STATISTICAL ANALYSIS

Interrater judgments were compared for level of agreement using the κ statistic. Categorical variables were compared using the χ^2 test or the Fisher exact test. Nonparametric continuous variables were compared using the Wilcoxon rank sum test. Preventable ADEs were often associated with multiple systems and/or multiple individual performance failures, so that the total percentages of ADEs with these failures often exceed 100%.

RESULTS

There were 2040 claims against RMF insureds with claim dates between January 1, 1990, and December 31, 1999. Electronic screening of abstract terms followed by the initial pharmacist evaluation resulted in 140 medication-related claims (6.9% of all claims). Physician ratings judged 129 cases (6.3% of all claims) as ADEs, with 11 cases excluded (92% agreement, $\kappa = 0.50$). Among the ADEs, 94 (73%) were rated as preventable and 35 (27%) as nonpreventable (86% agreement, $\kappa = 0.64$). Overall, 39 ADEs (30%) were judged as life threatening and 21 (16%) resulted in death (**Table 2**).

Preventable ADEs were judged as to the degree of deviation from accepted practice norm: 32 (25%) were associated with no or little deviation, 77 (60%) were associated with moderate to severe deviation, and for 20 (16%), the degree could not be determined (percentages do not total 100 because of rounding) (84% agreement, $\kappa = 0.65$). In assessments of the presence of negligent care, 69 cases (53%) were judged negligent, 27 (21%) were judged not negligent, and in 33 (26%), negligence could not be determined (74% agreement, $\kappa = 0.48$).

Claims judged as preventable ADEs were divided nearly evenly between inpatients (53%) and outpatients (47%) (Table 2). Among all inpatient ADEs (n = 68), events most commonly occurred in patient rooms (34%), the operating room or the postoperative care unit (16%), the emergency department (15%), the intensive care unit (7%), and the radiology department (6%).

Table 3. Medication-Related Malpractice Claims Defendants and Outcomes*

Variable	Adverse Drug Events: Preventable (n = 94)	Adverse Drug Events: Nonpreventable (n = 35)	*P* Value
Primary defendant personnel			
Physician	55 (59)	29 (83)	.03
Nurse	14 (15)	1 (3)	
Pharmacist	9 (10)	0	
Other or unknown	16 (17)	5 (14)	
Primary defendant physician service†			
Primary care‡	15 (27)	12 (41)	.67
Surgery (general and specialists)	13 (24)	4 (14)	
Anesthesiology	10 (18)	4 (14)	
Internal medicine subspecialists	8 (15)	4 (14)	
Psychiatry	4 (7)	1 (3)	
Other	5 (9)	4 (14)	
Time to close, mean, y	2.07	2.44	.22
Claim disposition§			
Pending or open	22 (23)	12 (34)	.21
Closed	72 (77)	23 (66)	
Verdict‖			
For defense	15 (16)	21 (60)	
For plaintiff	2 (2)	0	
Settlement (or mediation)¶			
For defense	0	0	
For plaintiff	55 (59)	2 (6)	

*Data are given as number (percentage) of adverse drug events unless otherwise indicated. Percentages are based on the total for each category and may not total 100 because of rounding.

†For cases with multiple defendant physician services, the physicians identified as the primary service were used.

‡Internal medicine, family practice, general practice, and pediatrics.

§As of February 1, 2001.

‖For defense, denied, dropped, dismissed, or favorable tribunal or trial; and for plaintiff, unfavorable tribunal or trial.

¶For defense, no financial payment made to plaintiff; and for plaintiff, financial payment made to plaintiff.

Among claims abstracts providing information concerning the primary defendant personnel for preventable ADEs, physicians were most frequently identified, followed by nurses and pharmacists (**Table 3**). When several physician services were identified with a claim, we used the primary physician(s) defendant service identified by RMF. Among preventable ADEs, primary care, surgery, anesthesiology, and internal medicine subspecialties were the most common responsible medical services (Table 3).

Many medication classes were associated with claims resulting from ADEs, including antibiotics, antidepressants or antipsychotics, cardiovascular drugs, and anticoagulants (**Table 4**). Among preventable ADEs, medication classes most frequently causing inpatient events were anesthetics, anxiolytic or sedative agents, and potassium supplements. Analgesics, anticoagulants, cardiovascular drugs, and antidepressant or antipsychotic drugs most often caused preventable outpatient ADEs.

HUMAN FACTOR ANALYSIS

Preventable ADEs were analyzed for systems-related causes and individual performance failures. Usually, several failures occurred for an error to result in patient harm;

Table 4. Medication Classes and Medication-Related Malpractice Claims*

Medication Class	Adverse Drug Events: Preventable (n = 94)	Adverse Drug Events: Nonpreventable (n = 35)	Total (N = 129)
Antibiotics	10 (11)	2 (6)	**12** (9)
Antidepressants or antipsychotics	8 (9)	3 (9)	**11** (9)
Cardiovascular drugs	9 (10)	1 (3)	**10** (8)
Anticoagulants	6 (6)	4 (11)	**10** (8)
Analgesics	6 (6)	2 (6)	**8** (6)
Anxiolytic or sedative agents	5 (5)	1 (3)	**6** (5)
Anesthetics	4 (4)	2 (6)	**6** (5)
Potassium supplements	5 (5)	0	**5** (4)
Corticosteroids	2 (2)	2 (6)	**4** (3)
Intravenous contrast dye	1 (1)	3 (9)	**4** (3)
Others	38 (40)	15 (43)	**53** (41)

*Data are given as number (percentage) of adverse drug events. Percentages may not total 100 because of rounding.

for example, an excessively high dose was selected, the error was not intercepted by the pharmacist, and the patient did not notice that the dosage was much higher than his or her last prescription. Failures included latent failures, related to systems mechanisms, and active failures, related to human performance.

The system deficiencies associated with preventable ADEs were judged most commonly to be operational system failures (**Table 5**). These included poor team communication, inadequate handoffs, supervisory failures, inadequately trained staff, ergonomic problems, and failure to appropriately use consultants. Failures that were rare or could not be determined from the available records included confused lines of authority, equipment malfunctions, inadequate staffing levels, excessive workload, and work flow interruptions.

Managerial or organizational system failures included poor interdisciplinary communication and the use of substitute or inexperienced professionals. Latent design failures included system complexity and deficient automated systems or technology, such as poor intravenous pump designs. Individual human performance errors included knowledge-based errors (54 [57%] of the 94 preventable ADEs), skill-based errors (46 [49%] of the 94 ADEs), and rule-based errors (19 [20%] of the 94 ADEs) (errors could be in >1 category).

PREVENTION OF ADEs

The potential impact of various strategies was judged regarding the likelihood that they might have prevented the error and/or the injury resulting from the identified error. Computerized physician order entry with decision support was judged to have likely prevented 40% (20/50) of inpatient preventable ADEs and 36% (16/44) of outpatient ADEs. On-site clinical pharmacists could potentially have prevented 64% (32/50) of the inpatient ADEs. Types of general error-proofing methods judged to have the potential to prevent ADEs included staff training and planning (83 [88%] of the 94 preventable ADEs), improved standardization of processes (85 [90%] of the

Table 5. Human Factor Analysis of Preventable Adverse Drug Events: System Failures

Type of System Failure	No. (%) of Preventable Adverse Drug Events (N = 94)*
Operational system failures	
Poor team communication	45 (48)
Inadequate handoffs of relevant information	22 (23)
Supervisory failures	15 (16)
Inadequately trained staff	15 (16)
Ergonomic deficiencies	15 (16)
Failure to appropriately use consultants	9 (10)
Managerial or organizational system failures	
Poor interdisciplinary communication	28 (30)
Use of substitute or inexperienced professionals	22 (23)
Design failures	
System complexity (eg, complicated protocols)	23 (24)
Deficient automation or technology design	13 (14)

*Each preventable adverse drug event may be associated with several human factor failures.

94 ADEs), and the use of built-in design redundancies (82 [87%] of the 94 ADEs). Examples of ADEs and the potential benefits of built-in design redundancies and standardization of processes are provided (**Table 6**).

Table 6. Case Examples of Adverse Drug Events and Prevention Approaches With Built-in Design Redundancies and Standardization of Processes*

Case Example	Prevention Approach
A 54-year-old woman has lorazepam and colchicine refilled at the same pharmacy visit. The pharmacist mixes up the bottles, resulting in the patient following the wrong instructions for each medication and causing gastrointestinal distress, confusion, and disorientation.	The pharmacist should refill the bottles separately and check them independently and in the presence of the patient. The patient should receive information about the pills, including what each looks like.
A 69-year-old man receiving home infusion therapy is given a 3-week supply of intravenous hydromorphone hydrochloride via the wrong intravenous port, resulting in bypassing the reservoir bag. The medication was delivered as a bolus, and the patient died of respiratory arrest.	Home infusion pumps should have unique intravenous connections for the reservoir and bolus ports and enhanced identification labeling. Pumps could include software identifying overdoses.
During a carotid angiogram, a 59-year-old is inadvertently given a lidocaine injection instead of the contrast dye into the carotid artery, resulting in transient confusion and overnight observation.	Unique syringe styles, improved labeling, better work tray setup to clearly separate different syringes, and increased physician attention could have prevented this medication mix-up.

*Age and/or sex may have been modified to protect patient confidentiality. Closed claims were used for examples.

DEFENSE COSTS FOR MALPRACTICE CLAIMS

The ratio of closed-open claims depended on the date of the claims: more recent claims were less likely to have been closed when the claims file reviews were completed. Overall, 74% (95/129) of the ADE claims cases were closed by February 1, 2001, including 77% (72/94) of the preventable ADEs and 66% (23/35) of the nonpreventable ADEs.

The costs of defending medication-related claims for closed cases were determined from malpractice insurance payments (**Table 7**). Mean total payments for preventable inpatient ADEs were significantly greater than for nonpreventable inpatient ADEs. This difference was because of the greater mean indemnity payments for preventable ADEs than for nonpreventable ADEs. Outpatient preventable ADEs also resulted in higher mean indemnity payments than nonpreventable ADEs, but mean total payments were not significantly different. When analyzed by year, there were no trends in the number of closed claims or payment amounts per year. The incurred costs for the 34 open claims are considerable (in the millions of dollars) but, until closed, remain confidential.

COMMENT

Analysis of medication-related malpractice claims provided valuable information complementing other methods used to study ADEs. We found that ADEs resulting in claims were often life threatening or fatal, costly to defend, and preventable in nearly three fourths of cases. Also, ADEs resulting in malpractice claims were associated with multiple systems-related deficiencies that are amenable to prevention efforts.

While medical record review has been the (albeit imperfect) gold standard for finding and assessing ADEs,[2,32,33] other methods successfully used to study ADEs include direct observation,[34,35] solicited voluntary reporting,[4] physician and nursing interviews,[36] and computerized approaches.[37,38] Malpractice claims records are an additional resource, including information not always available in medical records.[12] Depositions provide the narratives of the circumstances associated with the events. New knowledge learned after the event can be reviewed by interested parties. Expert opinions provide alternative perspectives and explanations surrounding an event and patient injuries. On the other hand, closed claims data do not provide a denominator for determining the risk of injury from an ADE or rates of ADEs. Medication-related claims records provide a "snapshot of liability, not a comprehensive picture of injury."[19(p553)]

Claims records may also contain information leading to a better understanding of the underlying systems and human factor failures associated with preventable ADEs. Reason[28] has described the Swiss cheese model to explain unintentional injuries. When the holes in the error defense barriers and safeguard layers built into a system occasionally line up, adverse events can occur. We found that preventable ADEs associated with malpractice claims were often associated with multiple systems-related and individual performance failures. Individual performance failures, especially knowledge- and rule-based errors, can be minimized by systems approaches.[1,39,40]

More than a third of the preventable ADEs in our study were judged to potentially have been preventable with CPOE. This compares to a study[41] in which 23% of ADEs were judged potentially preventable with CPOE as well as studies[23] in which CPOE with decision support reduced the actual serious medication error rate by 55%, including preventable ADEs by 17%. Clinical pharmacist participa-

Table 7. Costs of Closed Medication-Related Malpractice Claims (1990-1999)*

	Adverse Drug Events					
	Inpatients (n = 51)			Outpatients (n = 44)		
Variable†	Preventable (n = 41)‡	Nonpreventable (n = 10)§	*P* Value	Preventable (n = 31)‖	Nonpreventable (n = 13)¶	*P* Value
Mean payments						
Indemnity	332.5	30.0	<.01	58.6	30.8	<.01
Expense	44.0	44.2	.56	15.1	33.9	.09
Indemnity and expense	376.5	74.2	.02	73.7	64.7	.61
Total indemnity and mean payments	15 438.6	742.0	. . .	2282.0	840.9	. . .

*Closed as of February 1, 2001.
†Payments in thousands of dollars.
‡Of the 41 cases, 34 favored the plaintiff and 7 favored the defense with 0 indemnity payments.
§Of the 10 cases, 1 favored the plaintiff and 9 favored the defense with 0 indemnity payments.
‖Of the 31 cases, 23 favored the plaintiff and 8 favored the defense with 0 indemnity payments.
¶Of the 13 cases, 1 favored the plaintiff and 12 favored the defense with 0 indemnity payments.

tion during clinician rounds was judged to have the potential to prevent two thirds of the inpatient preventable ADEs. In one study,[24] pharmacist participation during intensive care unit physician rounds reduced the rate of ordering-related ADEs by 66%. In the present study, one of the more striking findings was the potential role of built-in design redundancies into the medication prescribing and delivery system (Table 6). Our analyses suggested that most errors and/or subsequent injuries could have been prevented with these improvements.

Litigation may be considered a double-edged sword. Malpractice claims and their subsequent legal defense can have detrimental effects on providers, including uninsurable losses, lost practice time, damage to reputation, and emotional stress.[18] Physicians may perceive malpractice litigation as a barrier to reducing errors and improving quality.[42,43] This study does not address the appropriateness of these malpractice claims. On the other hand, Vincent[44(p1776)] has interpreted litigation as not simply a threat but as a "way of revealing unsafe conditions of practice and putting pressure on those with the authority to implement change."

In addition to obtaining information on the causes and preventability of ADEs, claims review provided information on costs as well. We found that the costs for compensation and defending claims associated with ADEs were considerable. These costs were greatest for inpatient preventable ADEs, with most of this expense covering indemnity payments. For the 10-year period, CRICO payments made to date for closed claim ADEs (n=95) were in excess of $19 million.

While the financial costs for representing defendants are substantial, these costs are only part of the total expenses associated with ADEs. Financial expenses can also be considerable for the patient or plaintiff. Adverse drug events for inpatients have been estimated to cost an additional $2000 to $2600 per patient in hospital costs, and preventable ADEs cost almost twice as much.[45,46] Additional financial costs associated with ADEs include the out-of-pocket costs of medical care, the loss of work for the patient, and financial costs not covered by plaintiffs' attorneys. An analysis of medical injuries in Utah and Colorado in 1992 estimated the costs for health care and the costs due to lost wages and household production.[47,48] Preventable ADEs were estimated to cost $50.7 million, or 16% of all preventable adverse event costs. An additional cost (and not available to malpractice claims reviews) is the plaintiffs' legal expenses, and while usually the responsibility of the attorneys, should also be considered in evaluating the societal costs of medication-related claims.

Finally, there can be significant costs for the defendant physician or other health care provider. These costs include loss of wages associated with defending the claim (eg, time spent in court) and out-of-pocket expenses when defendant payments exceed insurance limits. Neither cost savings resulting from reductions in medication-related malpractice claims nor the possible additional expenses associated with certain prevention interventions transcend patient consequences as the primary reason for ADE prevention.

Beyond the financial impact of medication-related claims, the events surrounding the alleged incidents and legal proceedings often have an important impact on the patient and the physician, or defendant, alike. Medical malpractice claims may deleteriously affect long-term physician-patient relationships, such as lost trust. While ADEs have been well documented to be associated with serious patient consequences,[4,8,45] less well studied has been the impact on the defendant clinician, sometimes referred to as the "second victim." The impact of an ADE and subsequent malpractice claim can be emotionally and professionally devastating for physicians.[18]

This study has several limitations. We used data from a single malpractice insurance carrier. The RMF insures physicians and health care institutions associated with a single medical school, and these insureds may, thus, not be a representative sample of all physicians and health care institutions in the New England region. Malpractice behavior differs in other regions of the country, and the proportion of ADEs that result in a claim may vary considerably, also reducing generalizability. In addition, this insurance carrier's policies for handling claims may differ from others, locally and nationally (some carriers preferentially settle rather than go to trial). Because as few as 1.5% to 2.5% of negligent injuries result in malpractice claims,[13] we cannot extrapolate the findings in this study to be representative of all ADEs due to negligent care. In addition, ADEs resulting in claims and their preventability are not representa-

tive of all serious or fatal ADEs. Claims file reviews assessing human factor failures, unlike the claims abstract reviews, required on-site review, were conducted by a single investigator (J.M.R.), and did not include interrater reliability testing. However, the system failures identified in this study are the same issues identified by institutions in reviewing their own ADEs and close calls. Finally, the costs associated with these claims may differ because of different local legal costs and insurance company philosophies in preferring trial or settlement resolutions.

In summary, ADEs represented about 6% of malpractice claims and were preventable in two thirds of cases. Many resulted in substantial harm or death, and would be preventable using known effective strategies such as pharmacist participation during physician rounds and CPOE with decision support. The costs associated with ADEs are considerable and may provide additional incentives to invest in error prevention strategies. Error prevention strategies should inform the development of systemwide redundancies that should reduce the likelihood that medication errors will result in patient harm.

Accepted for publication April 3, 2002.

This study was supported by a grant from the RMF of CRICO.

This study was presented in abstract form at the Society of General Internal Medicine 2001 Annual Meeting, San Diego, Calif, May 3, 2001.

We thank Kathy Dwyer, Anthony Chamberas, and Priscilla Dasse of the RMF and Atul Gawande, MD, of Brigham and Women's Hospital for their valuable assistance; and David Studdert for his thoughtful review of the manuscript.

Corresponding author: Jeffrey M. Rothschild, MD, MPH, Division of General Medicine, Department of Medicine, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115 (e-mail: jrothschild@partners.org).

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System: Institute of Medicine.* Washington, DC: National Academy Press; 1999.
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *N Engl J Med.* 1991;324:370-376.
3. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. *N Engl J Med.* 1991; 324:377-384.
4. Bates DW, Cullen DJ, Laird N, et al, for the ADE Prevention Study Group. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA.* 1995;274:29-34.
5. Gurwitz JH, Field TS, Avorn J, et al. Incidence and preventability of adverse drug events in nursing homes. *Am J Med.* 2000;109:87-94.
6. Gandhi TK, Burstin HR, Cook EF, et al. Drug complications in outpatients. *J Gen Intern Med.* 2000;15:149-154.
7. Leape LL, Bates DW, Cullen DJ, et al, for the ADE Prevention Study Group. Systems analysis of adverse drug events. *JAMA.* 1995;274:35-43.
8. Cullen DJ, Sweitzer BJ, Bates DW, Burdick E, Edmondson A, Leape LL. Preventable adverse drug events in hospitalized patients: a comparative study of intensive care units and general care units. *Crit Care Med.* 1997;25:1289-1297.
9. Donchin Y, Gopher D, Olin M, et al. A look into the nature and causes of human errors in the intensive care unit. *Crit Care Med.* 1995;23:294-300.
10. Wilson RM, Harrison BT, Gibberd RW, Hamilton JD. An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Med J Aust.* 1999;170:411-415.
11. Cook R, Woods D. Operating at the sharp end: the complexity of human error. In: Bogner MS, ed. *Human Error in Medicine.* Hillsdale, NJ: Lawrence A Erlbaum Associates; 1994:255-310.
12. Keats AS. The Closed Claims Study. *Anesthesiology.* 1990;73:199-201.
13. Localio AR, Lawthers AG, Brennan TA, et al. Relation between malpractice claims and adverse events due to negligence: results of the Harvard Medical Practice Study III. *N Engl J Med.* 1991;325:245-251.
14. Burstin HR, Johnson WG, Lipsitz SR, Brennan TA. Do the poor sue more? a case-control study of malpractice claims and socioeconomic status. *JAMA.* 1993;270: 1697-1701.
15. Posner KL, Caplan RA, Cheney FW. Variation in expert opinion in medical malpractice review. *Anesthesiology.* 1996;85:1049-1054.
16. Brennan TA, Sox CM, Burstin HR. Relation between negligent adverse events and the outcomes of medical-malpractice litigation. *N Engl J Med.* 1996;335:1963-1967.
17. Edbril SD, Lagasse RS. Relationship between malpractice litigation and human errors. *Anesthesiology.* 1999;91:848-855.
18. Studdert DM, Thomas EJ, Burstin HR, Zbar BI, Orav EJ, Brennan TA. Negligent care and malpractice claiming behavior in Utah and Colorado. *Med Care.* 2000; 38:250-260.
19. Cheney FW. The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future? *Anesthesiology.* 1999;91:552-556.
20. Blumenthal D. Making medical errors into "medical treasures." *JAMA.* 1994; 272:1867-1868.
21. Evans RS, Pestotnik SL, Classen DC, Horn SD, Bass SB, Burke JP. Preventing adverse drug events in hospitalized patients. *Ann Pharmacother.* 1994;28:523-527.
22. Bates DW, Kuperman G, Teich JM. Computerized physician order entry and quality of care. *Qual Manag Health Care.* 1994;2:18-27.
23. Bates DW, Leape LL, Cullen DJ, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA.* 1998;280:1311-1316.
24. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA.* 1999;282:267-270.
25. Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA.* 2001;285:2114-2120.
26. Liang BA, Cullen DJ. The legal system and patient safety: charting a divergent course: the relationship between malpractice litigation and human errors. *Anesthesiology.* 1999;91:609-611.
27. Dubois RW, Brook RH. Preventable deaths: who, how often, and why. *Ann Intern Med.* 1988;190:582-589.
28. Reason J. Human error: models and management. *BMJ.* 2000;320:768-770.
29. Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. *BMJ.* 2000;320:777-781.
30. Reason J. *Human Error.* New York, NY: Cambridge University Press; 1990.
31. Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ.* 1998;316:1154-1157.
32. O'Neil AC, Petersen LA, Cook EF, Bates DW, Lee TH, Brennan TA. A comparison of physicians self-reporting with medical record review to identify medical adverse events. *Ann Intern Med.* 1993;119:370-376.
33. Karson AS, Bates DW. Screening for adverse events. *J Eval Clin Pract.* 1999;5: 23-32.
34. Allan EL, Barker KN. Fundamentals of medication error research. *Am J Hosp Pharm.* 1990;47:555-571.
35. Andrews LB, Stocking C, Krizek T, et al. An alternative strategy for studying adverse events in medical care. *Lancet.* 1997;349:309-313.
36. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA.* 1998;279: 1200-1205.
37. Jha AK, Kuperman GJ, Teich JM, et al. Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and stimulated voluntary report. *J Am Med Inform Assoc.* 1998;5:305-314.
38. Classen DC, Pestotnik SL, Evans RS, Burke JP. Computerized surveillance of adverse drug events in hospital patients. *JAMA.* 1991;266:2847-2851.
39. Leape LL. Error in medicine. *JAMA.* 1994;272:1851-1857.
40. Bates DW. Using information technology to reduce rates of medication errors in hospitals. *BMJ.* 2000;320:788-791.
41. Bates DW, O'Neil AC, Boyle D, et al. Potential identifiability and preventability of adverse events using information systems. *J Am Med Inform Assoc.* 1994;1: 404-411.
42. Mohr JC. American medical malpractice litigation in historical perspective. *JAMA.* 2000;283:1731-1737.
43. Gostin L. A public health approach to reducing error: medical malpractice as a barrier. *JAMA.* 2000;283:1742-1743.
44. Vincent C. Risk, safety, and the dark side of quality. *BMJ.* 1997;314:1775-1776.
45. Classen DC, Pestotnik SL, Evans RS, Lloyd JF, Burke JP. Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality. *JAMA.* 1997;277:301-306.
46. Bates DW, Spell N, Cullen DJ, et al, for the Adverse Drug Events Prevention Study Group. The costs of adverse drug events in hospitalized patients. *JAMA.* 1997; 277:307-311.
47. Thomas E, Studdert DM, Newhouse JP, et al. Costs of medical injuries in Utah and Colorado. *Inquiry.* 1999;36:255-264.
48. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care.* 2000;38:261-271.