# SPECIAL ARTICLE

# RELATION BETWEEN MALPRACTICE CLAIMS AND ADVERSE EVENTS DUE TO NEGLIGENCE

# **Results of the Harvard Medical Practice Study III**

A. Russell Localio, J.D., M.P.H., M.S., Ann G. Lawthers, Sc.D., Troyen A. Brennan, M.D., J.D., M.P.H., Nan M. Laird, Ph.D., Liesi E. Hebert, Sc.D., Lynn M. Peterson, M.D., Joseph P. Newhouse, Ph.D., Paul C. Weiler, LL.M., and Howard H. Hiatt, M.D.

Abstract Background and Methods. By matching the medical records of a random sample of 31,429 patients hospitalized in New York State in 1984 with statewide data on medical-malpractice claims, we identified patients who had filed claims against physicians and hospitals. These results were then compared with our findings, based on a review of the same medical records, regarding the incidence of injuries to patients caused by medical management (adverse events).

*Results.* We identified 47 malpractice claims among 30,195 patients' records located on our initial visits to the hospitals, and 4 claims among 580 additional records located during follow-up visits. The overall rate of claims per discharge (weighted) was 0.13 percent (95 percent confidence interval, 0.076 to 0.18 percent). Of the 280 patients

THE frequency of malpractice claims among pa-L tients injured by medical negligence has been the subject of much speculation and little empirical investigation. Two fundamental questions about malpractice litigation have been how well it compensates patients who are actually harmed by medical negligence, and whether it promotes quality and penalizes substandard care. If negligent medical care infrequently leads to professional censure or a malpractice claim, then the deterrence of substandard care may be suboptimal<sup>1,2</sup> and the civil justice system will compensate few patients for their medical injuries.<sup>3</sup> If, as some allege,<sup>4</sup> sizable numbers of malpractice claims are filed for medical care that is not negligent, then the costs of claims may be excessive, and the credibility and legitimacy of malpractice litigation as a means of obtaining civil justice may be reduced.

Danzon<sup>5</sup> estimated on the basis of reviews of medical records and claims data from California in the mid-1970s<sup>6</sup> that for each malpractice claim, 10 injuries were caused by negligent care. That study estimated

Supported in part by a contract from the New York State Department of Health and by a grant (12415) from the Robert Wood Johnson Foundation, Princeton, N.J. who had adverse events caused by medical negligence as defined by the study protocol, 8 filed malpractice claims (weighted rate, 1.53 percent; 95 percent confidence interval, 0 to 3.2 percent). By contrast, our estimate of the statewide ratio of adverse events caused by negligence (27,179) to malpractice claims (3570) is 7.6 to 1. This relative frequency overstates the chances that a negligent adverse event will produce a claim, however, because most of the events for which claims were made in the sample did not meet our definition of adverse events due to negligence.

*Conclusions.* Medical-malpractice litigation infrequently compensates patients injured by medical negligence and rarely identifies, and holds providers accountable for, substandard care. (N Engl J Med 1991; 325:245-51.)

only the relative frequency of claims and negligence; without a method of determining the fraction of claims that did not involve negligence, Danzon could not estimate the probability that a claim would follow medical negligence.

To calculate this probability, the Harvard Medical Practice Study linked clinical reviews of 30,195 inpatient records with statewide records of malpractice claims. Linking these two data sets permitted a determination of the frequency with which negligent and nonnegligent medical care, as evaluated by a team of physician-reviewers, led to malpractice claims.

#### Methods

#### Data from Medical Records

Our review of the records of a random sample of 31,429 patients discharged in 1984, drawn from 51 hospitals across New York State, is described in detail elsewhere.<sup>7</sup> In brief, the review proceeded in three stages.

In the first stage, a group of specially trained nurses and medicalrecords administrators used standard protocols to screen records for at least 1 of 18 events signaling a possible adverse event.

In the second stage, medical records that met at least 1 of these 18 criteria were referred to two physicians who independently evaluated the cause of the patient's injury and whether there had been negligence. The physicians first decided whether the patient had suffered an injury caused at least in part by medical management. Injuries that either prolonged hospitalization or led to disabilities that continued after discharge were deemed to be adverse events. Negligence was considered to have occurred if the medical care that caused the adverse event was below the expected level of performance of the average practitioner who treated problems such as the patient's at that time.

Physicians recorded their judgments about causation and negligence on an ordered, categorical scale ranging from "no possible adverse event (or negligence)" to "virtually certain evidence of an adverse event (or negligence)." Reviewers also judged the degree of disability resulting from the adverse event and described briefly the

From the Center for Biostatistics and Epidemiology, Penn State University College of Medicine, Hershey (A.R.L.); the Departments of Health Policy and Management (A.R.L., A.G.L., L.E.H., J.P.N., H.H.H.) and Biostatistics (N.M.L.), Harvard School of Public Health, Boston; the Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston (T.A.B., H.H.H.); the Division of Medical Ethics, Department of Social Medicine (L.M.P.), and the Department of Health Care Policy (J.P.N.), Harvard Medical School, Boston; the Kennedy School of Government, Harvard University, Cambridge, Mass. (J.P.N.); and Harvard Law School, Cambridge, Mass. (P.C.W.). Address reprint requests to Mr. Localio at the Center for Biostatistics and Epidemiology, Penn State University College of Medicine, P.O. Box 850, Hershey, PA 17033.

nature of the injury, its relation to medical management, and the negligent act or omission.

In the third stage, when the two physicians disagreed on the existence or description of an adverse event, the discrepancy was resolved by a supervising physician who was blinded to their decisions and made his or her own judgment about causation and negligence.

Injuries were classified as adverse events, and then as negligent, when the average of the two final physicians' evaluations represented a judgment of at least "more likely than not." Multiple reviews permitted the analysis of results under alternative assumptions about thresholds for identifying causation and negligence.

The record review produced five groups of cases: (1) cases that met no screening criteria for adverse events or negligence, (2) those referred for review by the physicians but without evidence of an adverse event, (3) cases of "low-threshold adverse events" with judgments of causation that were borderline or lower, (4) cases of adverse events with no evidence of negligence, and (5) cases of adverse events due to negligence.

We performed sensitivity analyses to identify possible biases due to missing records or misclassified reviews. To assess the effect of false negative findings in the stage 1 screening by medical-records administrators, we conducted a second review of a random sample of 1 percent of all the records located.<sup>7</sup> A second team of physicians independently reviewed 318 records from two hospitals to assess the reliability of the initial physicians' reviews.<sup>8</sup>

Several months after the initial visits, the participating hospitals searched again for missing records and explained why some charts remained unavailable. At six randomly selected facilities, our medical-review team conducted another three-stage review to determine whether adverse events were more likely to have occurred when records were missing. At the remaining hospitals, the medical-records administrators referred for physician review only cases for which there was evidence of legal action in the patients' charts. At all hospitals, we obtained identifying data on patients for later use in matching the records with data on malpractice claims.

#### **Data on Malpractice Claims**

The data on malpractice claims included all formal claims filed against physicians and hospitals and reported to the Office of Professional Medical Conduct (OPMC) at the New York Department of Health. The data base at the OPMC lists claims according to the defendant, not the patient making the claim. We have referred to each claim in the OPMC records as a "provider claim." Because one patient could sue several defendants for a single injury, the number of defendants exceeded the number of patients. We have referred to counts of claims by patients as number of "patient claims."

New York statutes and regulations require regular reporting of claims by domestic and out-of-state insurance carriers,<sup>9</sup> self-insurance programs,<sup>10-12</sup> and all hospitals.<sup>13</sup> Both the Insurance Department and the Department of Health formally advised all insurance and health care organizations about the needs of our study and about the reporting mandates.<sup>14</sup> The OPMC allowed us complete access to all computer files and paper abstracts. The OPMC data base, which contained 67,900 provider claims reported from 1975 through May 1989, became our starting point for estimating patient claims, computing lengths of time between injuries and claims, determining the chances that payment would result from a claim, identifying claimants in the sample, and linking their claims to the sampled patients' hospital records. When necessary, members of the study team contacted and visited individual hospitals to supplement the OPMC data with more comprehensive information.

To test the robustness (resistance to errors in assumptions) of the estimate of the frequency of claims, we calculated the number of patient claims for 1984 in three ways. First, we summed the casesampling weights (the population of patients represented by each sampled record) of the claims linked to medical records through the matching process described below and extrapolated from the sample to the New York State population. Second, we calculated the number of patient claims from the OPMC's statewide records for injuries that occurred in 1984, regardless of when the patient filed the claim. Third, we estimated the annual frequency of patient claims by averaging the number of claims filed by year from 1984 through 1986. Adverse events discovered in 1984 would probably have been reflected, if at all, in malpractice claims filed during this period.

#### **Matching Process**

Our study protocol precluded interviews with patients about malpractice claims. Claimants were identified by linking their hospital records to OPMC claims records. This linkage proceeded only after the completion of the review of medical records. Physician-reviewers were unaware of the existence of a claim unless the medical record mentioned it.

We used both computer-based and manual matching techniques to link the records of patients in the sample to malpractice claims. Identifying characteristics for linking patients to claimants included the patient's name, address, ZIP Code, social security number, and age, the geographic location where the injury occurred, and the hospital from which he or she was discharged. Lack of complete data on the identifiers with strong discriminating power such as the social security number forced us to rely on a combination of matching characteristics. The matching algorithm, described in detail elsewhere,<sup>7</sup> allowed for errors or differences in the spelling of names, so that actual matches were not erroneously excluded.<sup>15</sup> Manual matching, a common step in record-linkage procedures,<sup>16</sup> helped to confirm links because of the amount of descriptive information not in machine-readable format. The OPMC requested additional descriptive data from the insurers to assist us in confirming or ruling out matches.

After identifying the sampled patients who had filed claims, we considered whether their allegations of malpractice referred to the medical care delivered or discovered in the sampled hospitalization. A team consisting of an attorney experienced with malpractice data, a health services researcher, and a physician-lawyer compared clinical information from the review of medical records with coded data and summary descriptions from the OPMC claims records. This team rated by consensus its degree of confidence in the match by first eliminating cases for which the group was confident that no match existed and those that lacked sufficient information to permit a judgment. For all other cases, the team's degree of confidence in the match was rated on a six-point confidence scale (Table 2).

# Estimates of Statewide Rates of Adverse Events and Claims

The medical-record-sampling design permitted us to extrapolate from the sample to the population of all patients discharged from hospitals in New York State in 1984. The analysis of the cases that produced claims required separate adjustments of sampling weights to account for missing records. These adjustments assumed that the rate of claims among the patients whose hospital records were never found equaled the rate among those whose records were initially not located but were found on follow-up. The standard errors of rates of claims account for the effects of a stratified, unequal-cluster sampling design.<sup>17</sup>

#### RESULTS

#### Adverse Events and Adverse Events Due to Negligence

As we reported in detail earlier,<sup>8</sup> the three-stage review of medical records detected 1133 adverse events (after adjustment for double counting of the same hospitalizations). Two hundred eighty adverse events, representing 1 percent of all discharges (95 percent confidence interval, 0.8 to 1.2 percent), were judged to have been caused by negligence (Table 1).

## Analysis of Matched Records

Ninety-eight patients in the sample filed claims against 151 health care providers (Table 2). Not all these patients alleged malpractice during the episodes of care covered by the study. When we considered only matches designated "more likely than not," we Table 1. Results of the Review of a Sample of 31,429 Medical Records from New York State, 1984.\*

Category	NO. OF Records	Comments	
Sample selected	31,429	Random sample from 51 hospitals	
Records not located on initial visit	1,234		
Records screened for pos- sible AE (first stage)	30,195		
Records referred for physi- cian review after screening	7,817	Satisfied 1 or more of 18 screening criteria	
Reviewed by physicians for presence of AE and neg- ligence (second stage)	7,743†	Two physicians judged the likeli- hood of AE and negligence independently	
Reviewed by a third physi- cian to resolve disagree- ment (third stage)	1,808	Third review provided majority opinion	
AEs identified	1,133	Majority of reviewers' combined co fidence level at least "more likely than not" (adjusted for incidence)	
AEs due to negligence identified	280	Majority found AE caused by neg- ligence with confidence level at least "more likely than not" (adjusted for incidence)	

\*AE denotes adverse event

†Seventy-four of the 7817 records referred for review in stage 2 were not reviewed. Casesampling weights were reallocated among the 7743 cases actually reviewed.

linked 47 of these malpractice claims to the sampled hospitalizations. These 47 cases represent a rate of malpractice claims per discharge in New York State of 0.11 percent (95 percent confidence interval, 0.06 to 0.16 percent).

In most cases, the reviewing team's judgments went clearly for or against linking the claim to a sampled hospitalization. For example, in 30 of the 44 cases in which there was considered to be no possible match, the main reason was a mismatch between the date of

Table 2. Results of Matching Malpractice Claims to Hospitalizations in New York State, 1984.3

DECISION ON MATCHING (CONFIDENCE SCORE)	No.	PERCENT
(CONFIDENCE SCORE)	NO.	FERCENI
Claimants in sample	98	
Medical records reviewed	30,121†	
Claimants linked to sampled hospitalizations		
Virtually certain (6)	41	41.8
Strong evidence (5)	2	2.0
More than likely (4)	4	4.1
Subtotal	47	
Claimants in sample but not link to sampled hospitalizations	ed	
Not quite likely (3)	1	1.0
Slight-to-modest evidence (2)	0	0.0
Little evidence (1)	1	1.0
Definite nonmatch	44	44.9
Insufficient data	4	4.1
AE discovered after discharge‡	1	1.0
Subtotal	51	

\*AE denotes adverse event. Because of rounding, percentages do not total 100

<sup>†</sup>Seventy-four of 30,195 records located were not reviewed. None of the cases involved claimants. Case-sampling weights have been reallocated among the usable observations

‡AEs that occurred during the sampled hospitalization and were discovered after discharge have been omitted.

the injury or the date when the claim was filed and the date of the sampled hospitalization. In the four cases for which there were insufficient data, we chose to vote against linkage rather than guess. None of these cases involved adverse events. Another matched case did not qualify for inclusion according to the sampling design because the adverse event was discovered after the sampled hospitalization, rather than before or during it.7

Table 3 shows the distribution of malpractice claims according to the five groups of cases defined by the outcome of the medical-record review. The percentage of claimants in each subgroup increased as the findings of the reviewers increased in severity from "no screening criteria met" to "adverse events caused by negligence." For all outcomes groups, the rate of malpractice claims was low. The chance that an injury caused by medical negligence would result in litigation was 1.53 percent (95 percent confidence interval, 0 to 3.24 percent).

For 12 of the 47 matched observations, the medicalrecords administrators found that none of the 18 screening criteria were satisfied, and the review process ceased without participation by the physicians. Five of these 12 claimants alleged the failure to diagnose a condition during outpatient visits before the sampled hospitalizations. Among the remaining 35 cases, all of which were reviewed by physicians, clinical judgments about the cause of the adverse outcome and the contribution of negligence were often contradictory. In some cases the two physicians disagreed on the presence of an adverse event in the second stage of the process, and a third physician resolved the issue by finding no adverse event. In others the physicians agreed on causation but differed about the occurrence of, or their levels of confidence about, negligence. In nine cases, the reviewing team knew of pending malpractice claims but found no evidence of adverse events. (Details of the reviews of the 47 cases are available elsewhere.\*)

#### Statewide Estimates of Adverse Events Due to Negligence Not Resulting in Malpractice Claims

Ninety-eight percent (weighted rate) of all adverse events due to negligence in our study did not result in malpractice claims (Fig. 1). The group of these cases for which the reviewers could determine the existence of disability and for which their combined score indicated either "strong" or "certain" evidence of negligence can be extrapolated to about 13,000 discharges statewide in 1984. Within this group, 58 percent of the patients had only moderately incapacitating injuries and recovered within six months. The remaining patients — those with moderate-to-severe disability correspond to about 5400 patients discharged from

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<sup>\*</sup>See NAPS document no. 04877 for three pages of supplementary material. Order from NAPS c/o Microfiche Publications, P.O. Box 3513, Grand Central Station, New York, NY 10163-3513. Remit in advance (in U.S. funds only) \$7.75 for photocopies or \$4 for microfiche. Outside the U.S. and Canada add postage of \$4.50 (\$1.50 for microfiche postage). There is an invoicing charge of \$15 on orders not prepaid. This charge includes purchase order.

GROUP OF RECORDS	No. of Discharges in Sample	No. of Claimants in Sample	Estimated No. of Claimants in New York	Estimated Rate of Claims per Discharge (95% CI)†	Comments
Cases not referred by MRA	22,378	12	899	0.045 ()	5 Cases: alleged failure to diagnose during outpatient visit
Cases referred; no pos- sibility of AE	6,275	14	1000	0.18 ()	<ul> <li>9 Cases: physician-reviewers knew about claim, found no AE</li> <li>4 Cases: disagreement settled by third reviewer</li> </ul>
Low-threshold AEs (less than likely)	335	3	92	0.30 ()	1 Case: one of two reviewers found negligence
AEs (more than likely) not caused by negligence	853	10	561	0.79 (—)	6 Cases: one of two reviewers found negligence
AEs (more than likely) caused by negligence	280	8	415	1.53 (0-3.24)	1 Case: single reviewer only
Total	30,121‡	47	2967	0.11 (0.06-0.16)	

Table 3. Rate of Patient Malpractice Claims in the Sample of 30,121 Medical Records from New York State, 1984.\*

\*CI denotes confidence interval, MRA medical-records administrator, and AE adverse event.

<sup>†</sup>Based on population-based estimates of discharges. For example, 1.53 percent = 415 of 27,179. See Figure 1.

\$Seventy-four of 30,195 cases did not undergo physician review; they were dropped from the calculations of population estimates, and their weights were reallocated among the usable observations.

hospitals in New York State. Over half these patients were under 70 years of age and thus likely to have lost wages as a result of the injury.

## Follow-up Reviews of Medical Records and Claims

Medical records located after intensive follow-up were a richer source of claims than those found on the initial hospital visits, but there was no difference in the rates of adverse events or negligence between the initial review and follow-up.<sup>7</sup> Twelve of the 580 patients whose records were found during follow-up filed malpractice claims against 18 providers, and four of these claims related to the treatment received during the

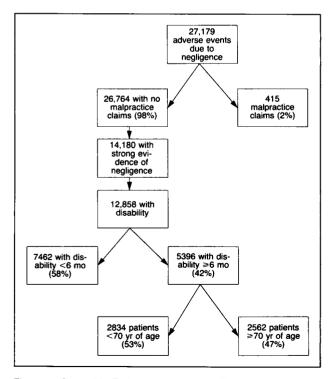


Figure 1. Statewide Estimates of Adverse Events Due to Negligence That Did Not Lead to Malpractice Claims.

sampled hospitalizations. The rate of claims among these patients (0.66 percent; 95 percent confidence interval, 0 to 1.37 percent) was six times higher than the rate for the initial review (0.11 percent), but the difference was not statistically significant.

In the cases of three of the four newly identified patient claims related to the sampled hospitalizations, one physician-reviewer found evidence of negligence whereas the other did not. Thus, the combined scores were below the threshold for a finding of negligence. The fourth case was not reviewed because the followup protocol for that hospital did not call for physician review.

#### **Relative Frequency of Negligence and Malpractice Claims**

By combining the results of the initial and follow-up reviews, we estimated the number of claims statewide to be 3570, or a rate of claims per discharge of 0.13 percent (95 percent confidence interval, 0.08 to 0.18 percent) in 1984. This estimate suggests a ratio of negligence to claims of 7.6 to 1 (27,179 to 3570). Our inability to link four claims to hospitalizations (or to rule out linkage) because of insufficient data had little effect on this figure. If two of these four claims had been matched to the sample, the relative frequency would have changed little (7.3 to 1). The samplebased estimate of the number of patient claims statewide (3570) is comparable to the estimate based on the OPMC records of the number of patient claims for injuries in 1984 (3780) and the average annual number of patient claims filed from 1984 through 1986 (3670). Thus, claims occur only 13 to 14 percent as often as injuries due to malpractice. Our estimate of the fraction of adverse events due to negligence that led to claims is, however, far lower (1.53 percent).

#### DISCUSSION

Other studies have examined the frequency of negligence in relation to the total number of claims.<sup>5,6</sup> Our study has taken the next step by matching individual clinical records with individual claims records to determine what fraction of instances of negligence leads to claims. Our data suggest that the number of patients in New York State who have serious, disabling injuries each year as a result of clearly negligent medical care but who do not file claims (5400) exceeds the number of patients making malpractice claims (3570). Perhaps half the claimants will eventually receive compensation.<sup>7,18</sup>

Why so few injured patients file claims has not been widely researched. Many may receive adequate health or disability insurance benefits and may not wish to spoil longstanding physician-patient relationships. Others may regard their injuries as minor, consider the small chance of success not worth the cost, or find attorneys repugnant.<sup>19</sup> Trial lawyers usually accept only the relatively few cases that have a high probability of resulting in a judgment of negligence with an award large enough to defray the high costs of litigation. A final possible explanation is that many patients may fail to recognize negligent care.<sup>20</sup>

Our results also raise questions about whether malpractice litigation promotes high quality in medical care. Historically, there has been scant empirical analvsis of this issue.<sup>21</sup> Our data reflect a tenuous relation between proscribed activity and penalty and thus are consistent with the view that malpractice claims provide only a crude means of identifying and remedying specific problems in the provision of health care. Our findings also support recent comments about the limited usefulness of the rate of claims as an indicator of the quality of care.<sup>22</sup> Unless there is a strong association between the frequency of claims and that of negligence, the rate of claims alone will be a poor indicator of quality<sup>23</sup> because rates can easily vary widely at the same underlying frequency of negligence or adverse events. The filing of a claim could, however, signal a need for further investigation because of the likelihood that an actual adverse event or actual negligence prompted the complaint.

Our study differs from previous work in that it goes beyond statements about the rate of negligence in relation to the rate of malpractice claims. The relative frequency 7.6 to 1 does not mean, as is commonly assumed,<sup>24</sup> that 13 to 14 percent of injuries due to negligence lead to claims. As the linking of the medical-record reviews to the OPMC claims files has shown, the fraction of medical negligence that leads to claims is probably under 2 percent. The difference is accounted for by injuries not caused by negligence, as defined by our protocol, that give rise to claims.

This finding does not mean that the 39 cases of claims in which our physician-reviewers did not find evidence of an adverse event due to negligence are groundless under prevailing malpractice law. Our study was not designed to evaluate the merits of individual claims. Patients sometimes file claims regarding medical outcomes that do not qualify as adverse events by our definitions; without access to the full insurance records, we cannot assess the prospects of individual cases.

More generally, the process of and criteria for making decisions about causation and negligence differ in a scientific study and in civil litigation. In this study, majority rule determined whether there had been an adverse event or an adverse event due to negligence. Our reviewers sometimes disagreed about causation and negligence; when only one found negligence, the case did not qualify as an adverse event due to negligence (except in the rare case when there was only a single reviewer). In a lawsuit, a single expert opinion might be sufficient to support a finding of negligence; under our protocol it would not. When experts differ, the final judgment is especially sensitive to the process of decision making.25 Thus, our findings are not directly comparable to the results of civil litigation.

Although this lack of strict comparability should warn us against drawing conclusions about the merits of individual malpractice claims, it does not undermine our findings about the small probability (under 2 percent) that a claim would be filed when medical negligence caused injury to the patient. This result remains robust in spite of the possibility of misclassification of individual cases, the effect of using different criteria for negligence, and the likelihood of missing medical records and missing data on malpractice claims.

Disagreement about or misclassification of an individual case need not bias our results. In the duplicate review of a subsample of 318 medical records, reported earlier,<sup>8</sup> a second team of physicians did not identify the same group of adverse events as did the first team, but they did find about the same incidence of adverse events and adverse events due to negligence. A replication of the study might generate the same rates of adverse events and negligence but would not necessarily classify the same claims as backed up by evidence of negligence. Therefore, as in other studies based on implicit review of medical records,<sup>26</sup> disagreement about individual cases does not imply bias in our estimates.

The use of less strict criteria for negligence would not alter the rate of claims among the cases of adverse events due to negligence, but it would affect the overall frequency of negligence as well as estimates in this and earlier studies of the ratio of adverse events due to negligence to claims (7.6 to 1). New criteria for negligence would change our estimate of 1.53 percent only if they affected the rate of negligence among the claims differently from the rate of negligence among cases in which no claim was made. Our data suggest, however, that an increase in the rate of adverse events due to negligence among cases in which no claim was made matches any increase in the rate of negligence among claims. Had a judgment by either physician-reviewer that negligence had occurred been sufficient to count a case as an adverse event due to negligence under our protocol, the probability that an adverse event due to negligence would result in a malpractice claim would remain virtually unchanged (1.51 percent).

The existence of overlooked adverse events due to negligence would also not influence this estimate unless the proportions of cases of negligence missed among the claimants and among the nonclaimants were unequal. The medical-records administrators might have overlooked adverse events due to negligence during the first-stage screening. As reported earlier, however, the medical-records administrators missed evidence of negligence in only 4.5 percent of the charts randomly selected for a duplicate review.<sup>8</sup> Alternatively, the hospital records might have met none of the criteria for further review but still have involved negligent care.

On the one hand, undercounting instances of negligence among the cases in which malpractice claims were made would cause the estimate of 1.53 percent to be low. Although we cannot calculate the probability that an adverse event due to negligence took place among the 12 malpractice claims that were classified as having no evidence of negligence, we can calculate that probability for the claims found on screening to have evidence of negligence (0.20) (Table 3). The assumption that these 12 cases should have been identified as positive (as having evidence of a possible adverse event) would raise the estimate of the probability of litigation among adverse events due to negligence from 1.53 to 2.2 percent.

On the other hand, the medical-records administrators might also have missed adverse events due to negligence that were not in litigation, thus causing our estimate to be too high. Medical-records administrators may have been more likely to miss adverse events in the records of nonclaimants than in those of claimants because evidence of legal action was 1 of the 18 screening criteria. Assuming that 4.5 percent of the negative screens were falsely negative, as suggested by the duplicate review, and that the rate of adverse events due to negligence among these missed cases equaled the rate among the cases in which no claim was made that were identified as positive on screening, there would be additional adverse events due to negligence among the nonclaimants. Assuming further a much lower rate of negligence among the cases in which no claim was made that had truly negative screens, for example 1/20 the rate of those identified on screening as positive, the estimate of the rate of claims among the adverse events due to negligence would be lowered from 1.53 to 1.2 percent.

These potential biases in the medical-records review are small as compared with the size of the confidence interval produced by sampling variation. Even with a rate at the upper limit of the 95 percent confidence interval (3.2 percent), the probability that a claim would be filed when a patient was injured as a result of medical malpractice remains well below previous estimates.

Malpractice claims would have been missed — another possible source of bias — if we had failed to locate a claimant's medical record and could not identify a claim through the record-matching process. The results of the extensive follow-up search for missing records suggest that hospitals may have selectively withheld the medical records of some claimants, but not of large numbers of them. The higher rate of claims per discharge in the records identified at follow-up is within the degree of variation expected with small samples. In addition, hospitals may have relinquished all records without regard to patient outcome but may have failed to report malpractice claims to the OPMC. The effort of the state government to achieve complete reporting suggests that we used the most complete, reliable data available, although no external sources can substantiate the completeness of the data.

Unrestricted access to medical records and full reporting of claims would not eliminate potential bias due to claims relating to medical care received in 1984 but not yet filed by May 1989, when our data collection ended. According to the OPMC data base, 90 percent of claims were filed within 4.4 years of the date of the injury. In addition, 43 percent of the adverse events were due to medical care that was provided before the sampled hospitalization in 1984.<sup>7</sup> Thus, we expect that fewer than 10 percent of all possible claims were absent from the OPMC data base and that our estimates of the incidence of litigation are no more than 10 percent too low.

The similarity of sample-based and populationbased estimates of the frequency of patient claims makes substantial bias due to missed claims unlikely. The similarity of the estimates suggests that in linking claims to medical records we missed few actual matches, and that by 1989 few claims related to our sample of hospitalizations from 1984 remained to be filed.

The results of this study, in which malpractice claims were matched to inpatient medical records, demonstrate that the civil-justice system only infrequently compensates injured patients and rarely identifies and holds health care providers accountable for substandard medical care. Although malpractice litigation may fulfill its social objectives crudely, support for its preservation persists in part because of the perception that other methods of ensuring a high quality of care<sup>27,28</sup> and redressing patients' grievances<sup>29</sup> have proved to be inadequate. The abandonment of malpractice litigation is unlikely unless credible systems and procedures, supported by the public, are instituted to guarantee professional accountability to patients.

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#### References

- 1. Bovbjerg RR. Medical malpractice on trial: quality of care is the important standard. Law Contemp Probl 1986; 49:321-48.
- Bell PA. Legislative intrusions into the common law of medical malpractice: thoughts about the deterrent effect of tort liability. Syracuse Law Rev 1984; 35:939-93.
- Abel RL. The real tort crisis: too few claims. Ohio State Law J 1987; 48:443-67.
- 4. Lewis R. AMA presses plan to change state tort law. American Medical News. March 1, 1985:1, 25.
- 5. Danzon PM. Medical malpractice: theory, evidence, and public policy. Cambridge, Mass.: Harvard University Press, 1985.

- California Medical Association. Report on the medical insurance feasibility study. San Francisco: California Medical Association, 1977.
- Harvard Medical Practice Study. Patients, doctors, and lawyers: medical injury, malpractice litigation, and patient compensation in New York. Cambridge, Mass.: President and Fellows of Harvard College, 1990.
- 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; 324:370-6.
- 9. N.Y. Laws 1975, ch. 109, sec. 2.
- 10. N.Y. Laws 1978, ch. 141, sec. 1.
- 11. N.Y. Laws 1980, ch. 866, sec. 17.
- 12. N.Y. Laws 1981, ch. 357, sec. 1.
- 13. N.Y. Laws 1988, ch. 184, sec. 6 (amending N.Y. Insurance Law sec. 315(b)(2)).
- 14. State of New York, Insurance Department Circular letter no. 14. 1988.
- Newcombe HB, Kennedy JM, Axford SJ, James AP. Automatic linkage of vital records. Science 1959; 130:954-9.
- 16. Department of Commerce. Statistical policy working paper 5. Washington, D.C.: Government Printing Office, 1980:12-3.
- Shah BV. SESUDAAN: standard errors program for computing of standardized rates from sample survey data. Research Triangle Park, N.C.: Research Triangle Institute, 1981.
- General Accounting Office. Medical malpractice: characteristics of claims closed in 1984. Washington, D.C.: General Accounting Office, 1977. (Publication no. GAO/HRD-87-55.)
- 19. Meyers AR. "Lumping it": the hidden denominator of the medical malpractice crisis. Am J Public Health 1987; 77:1544-8.

- Doherty EG, Haven CO. Medical malpractice and negligence: sociodemographic characteristics of claimants and nonclaimants. JAMA 1977; 238:1656-8.
- Brook RH, Brutoco RL, Williams KN. The relationship between medical malpractice and quality of care. Duke Law J 1975; 1975;1197-231.
- Office of Technology Assessment. The quality of medical care: information for consumers. Washington, D.C.: Government Printing Office, 1988:121-41. (SUDOC no. Y3.T22/2:2 M46/12.)
- Sloan FA, Mergenhagen PM, Burfield WB, Bovbjerg RR, Hassan M. Medical malpractice experience of physicians: predictable or haphazard? JAMA 1989; 262:3291-7.
- 24. Bennett WI. Pluses of malpractice suits. New York Times Magazine. July 24, 1988:31-2.
- Gustafson DH, Shukla R, Delbecq A, Walster G. A comparative study of differences in subjective likelihood estimates made by individuals, interacting groups, Delphi groups, and nominal groups. Organ Behav Hum Performance 1973; 9:280-91.
- Rubenstein LV, Kahn KL, Reinish EJ, et al. Changes in the quality of care for five diseases measured by implicit review, 1981 to 1986. JAMA 1990; 264:1974-9.
- 27. Gaumer GL. Regulating health professionals: a review of the empirical literature. Milbank Mem Fund Q 1984; 62:380-416.
- Kusserow RP, Handley EA, Yessian MR. An overview of state medical discipline. JAMA 1987; 257:820-4.
- Miller FH. Medical malpractice litigation: do the British have a better remedy? Am J Law Med 1986; 11:433-63.

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