WISCONSIN STATE LEGISLATURE COMMITTEE HEARING RECORDS

2005-06

(session year)

Assembly

(Assembly, Senate or Joint)

Committee on Insurance (AC-In)

(Form Updated: 11/20/2008)

COMMITTEE NOTICES ...

➢ Committee Reports ... CR
**

➢ Executive Sessions ... ES
**

➢ Public Hearings ... PH
**

➢ Record of Comm. Proceedings ... RCP
**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL ...

➢ Appointments ... Appt
**

Name:

➢ Clearinghouse Rules ... CRule
**

➢ Hearing Records ... HR (bills and resolutions)
**

➢ Miscellaneous ... Misc

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(misc. 1994 documents)

Appendix G: Summary of State Studies on Tort Reforms

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Study	Data and methodology	Major reported findings	Comments
U.S. General Accounting Office, Medical Malpractice: Six State Case Studies Show Claims and Insurance Costs Still Rise Despite Reforms, HRD-87-21 (Washington, DC U S Government Printing Office, December 1986)	**Data:** Claim frequency, payment per paid claim insurance premiums, and the cost of resolving claims in Arkansas, California, Florida Indiana New York and North Carolina from 1980 to 1986 **Method:** Comparison of trends among states	• Despite the implementation of tort reforms, every state continued to experience increases in claim frequency payment per paid claim, and insurance premiums • Indiana, the only state with a cap on both economic and noneconomic damages, experienced smaller insurance premium increases relative to other states.	• The study was unable to determine whether tort reforms had slowed the growth in claim frequency, payment per paid claim, or insurance premiums because no data were collected on trends prior to the reforms • The methodology did not control for other factors that might affect malpractice claim activity
W.P. Gronfein, and E. Kinney, Controlling Large Malpractice Claims The Unexpected Impact of Damage Caps, *Journal of Health Politics, Policy and Law* 16(3) 441-483, 1991	**Data:** 1,282 closed claims in Indiana, Michigan and Ohio from the period 1977 through 1988 in which $100,000 or more in total damages were awarded **Method:** Statistical regression analysis to determine whether Indiana's $500,000 cap on total malpractice damages lowered the average payment per paid claim for large claims The analysis controlled for the effects of plaintiff's age and sex, year of settlement, severity of injury, and allegations of negligence (e g diagnosis, anesthesia surgery medication patient monitoring, etc.)	• Mean and median payments per paid claim with damages $100,000 or more were approximately 18 and 42 percent higher in Indiana compared with Michigan and Ohio, respectively. The regression analysis suggested that the higher average award in Indiana is attributable to Indiana's tort reform • In Michigan and Ohio, payments of $1 million or more were made in 3.1 and 2.6 percent of claims, respectively Payments for these claims accounted for 21 percent of all payments in Michigan and 14 percent in Ohio There were no payments above $1 million in Indiana	• There was no pre-reform and post-reform comparison of payment levels for malpractice claims • The higher mean and median payment per claim may be a result of the operation of Indiana's Patient Compensation Fund, which was passed at the same point as the cap on damages and not the result of the cap on damages • Although the average payment per paid claim was higher in Indiana the study could not determine whether Indianas tort reforms resulted in an overall savings in malpractice claims payments
California Medical Association, Actuarial Study of Professional Liability Insurance prepared by Future Cost Analysts Newport Beach CA May 31 1985	**Data:** Malpractice claims costs* from 1966 to 1985 n California **Method:** Actuarial methods used to assess the impact of California's 1975 package of tort reforms Medical Insurance Compensation Reform Act (MICRA) on malpractice claims costs (see chapter 4 for a description of these reforms) *Claims costs include payments made to plaintiffs (including the payments by plaintiffs to their attorneys) and the malpractice insurers' direct costs attributable to the claim (fees for investigative work, expert witnesses, and legal defense work)	• Prior to MICRA (1966-75) claims costs were increased at an annual rate of 15 percent in California After MICRA (1976-85), claims costs increased 7 percent annually	• According to data gathered by the U S Health Care Financing Administration national average premiums increased at a compound annual rate of approximately 12 percent between 1976 and 1985 (51 F R 28772, 28774 57 F R 5903) Therefore California claims costs (a proxy for premiums) Increased at a slower rate after MICRA than national malpractice insurance premiums • The reductions in claim costs may be unrelated to MICRA especially since MICRA was not upheld by the courts until 1985, which may have limited its impact There may be alternative explanations for the findings for example after 1975 most commercial Insurers were replaced by physlclan-owned companies

Study	Data and methodology	Major reported findings	Comments
Californians Allied for Patient Protection, The Coalition to Preserve MICRA, MICRA Information, January 1 1993	**Data for various years between 1976 and 1991:** • Physician fees—American Medical Association survey • Malpractice premiums in California—Physician Insurance Association of America • Malpractice premiums in New York Florida Michigan—Medical Liability Monitor • National Malpractice Premiums—Tillinghast **Method:** Comparison of trends in California with those in other states and the nation to assess the impact of MICRA reforms	• No pre-reform, post-reform comparisons between states • Physician fees declined physician fees in California increased by 9.2% compared with 13.1% nationally • Average California malpractice insurance premiums, after adjusting for inflation, declined from $18,000 in 1976 to $7,000 in 1991 • 1992 average malpractice Insurance premiums were lower in California than in New York, Florida, or Michigan	• The magnitude of the decline may have been overstated by comparing a peak in premium levels (1 976) to a relative trough in premiums (1991) "In addition comparisons of single-year premiums can be misleading because premiums are based on expected revenue needs and are often adjusted upward or downward when better Information is available • The study did not control for any other factors in California that may have led to lower insurance premiums or physician fees e g changes in the malpractice insurance market or health care delivery market
Harvey **Rosenfeld,** California MICRA Profile of a Failed Experiment in Tort Law Restrictions , Voter Revolt, Los Angeles CA (no date)	**Data:** • National per capita health care spending data—U S Health Care Financing Administration and the Center for National Health Statistics U S Public Health Service Estimate of California's personal health care expenditures—California Almanac (5th Ed 1991) • Average medical consumer price index from Los Angeles, San Francisco, and San Diego • Malpractice Insurance premiums, profits, and losses—National Association of Insurance Commissioners **Methods:** Comparison of trends in the measures listed above from 1975 to 1991, and comparison of these measures among states in various years	• In 1990 the average California malpractice insurance premium was $7,741 as compared with a national average premium cost of $8,327 • Incurred malpractice Insurance losses as a percent of health care costs declined in California between 1987 and 1990 at a greater rate than in the nation	• In 1985 California's average premium was 65 percent above the national average, therefore, the decline to less than the national average is noteworthy [b] • The study did not control for other factors that contribute to changes in malpractice and health costs therefore, one cannot conclude that MICRA was solely responsible for lower premiums or moderate growth in health care costs

Study	Data and methodology	Major reported findings	Comments
Academic Task Force for Review of the insurance and Tort Systems, Preliminary Fact-Finding Report on Medical Malpractice, Gainesville, FL, August 14, 1987. #	**Data:** Florida insurance company data on claims closed between 1975 to 1986. **Method:** Analysis of trends in malpractice cost indicators. **Tort reforms:** Florida passed three malpractice reform acts: The 1976 act implemented:* • limitation on *res ipsa loquitur* doctrine, • abolishment of collateral source rule, • periodic payment of future damages, and • standard of care determined by reference to same or similar locality. 1985 and 1986 acts included: • pretrial screening, • patient compensation fund, • cap on noneconomic damages, • attorney fee limits, and • certificate of merit. * For a definition of these reforms, see chapter 4, box 4-2 or appendix K.	• The rate of closed claims per 100 physicians remained stable from 1975 to 1986 • The average payment per paid claim increased 14.8% per year from 1975 to 1986 • Claims with million dollar plus awards accounted for **4.9%** of total paid claims in 1981 but 29 1% in 1986 • The average cost of defending a claim increased at an annual rate of 17% from 1975 to 1986, • Increases in payment per paid claim were the primary factor driving Increases in premiums in Florida	• The study did not do a pre-post reform comparison of trends The 1985-86 reforms were unlikely to have had an effect on the data analyzed because most claims were closed prior to implementation of reforms. • The study looked at gross trends in malpractice cost indicators, but made no attempt to assess the individual impact of particular reforms on those Indicators
Pretrial screening studies			
P.E., Carlin, Medical Malpractice Pre-trial Screening Panels: A Review of the Evidence, Intergovernmental Health Policy Project, The George Washington University, Washington, DC October 30, 1980	**Data:** Various statistics on the operations of 15 pretrial screening panels in Arizona (Maricopa County), Delaware, Hawaii. Indiana Louisiana, Massachusetts, Montana, Nevada, New Jersey, New Mexico, New York, Pennsylvania, Tennessee, Virginia, and Wisconsin **Method:** • Analysis of data • Review of the empirical literature • Interviews with pretrial panel administrators and members of state medical societies and state bar associations	• Majority of panel decisions found no liability, physicians won an average of 73% of panel decisions. • Plaintiffs only appealed approximately 5% to 22% of adverse decisions in Delaware. Hawaii. Massachusetts Arizona (Maricopa County). and Wisconsin. indicating that pretrial screening panels may lead some claims to be settled earlier. • Nearly every state had failed to convene a panel within the statutory time limit and there were long delays and backlogs of cases.	• There were no comparisons of claim disposition prior to the implementation of the panel • Because pretrial panels offer plaintiffs a relatively inexpensive mechanism for screening the merits of a case, their existence may have encouraged plaintiffs with nonmeritorious suits to file This could explain the high rate of decisions for defendants and the low rate of plaintiff appeals • The long delays in panel hearings may lead some plaintiffs to drop claims or settle after proceeding through the pretrial screening process

Study	Data and methodology	Major reported findings	Comments
J.K. Mardfin, Medical Malpractice in the State of Hawaii, Department of Commerce and Consumer Affairs, Honolulu HI, January 1986	**Data:** 453 pretrial screening panel decisions between 1979 and 1984 in Hawaii Method: Comparison of disposition of pretrial screening panel decision and subsequent disposition of claim	• The majority of claims were settled or dropped after a panel hearing ▪ Of the 109 cases in which the panel found the physician liable, 18 claims (16%) were subsequently settled, and 53 claims (49%) were apparently dropped. ▪ In the **328** cases in which no liability was found, 3% settled without filing suit and 221 claimants (67%) apparently took no further action • A majority of plaintiffs who filed suit after a panel decision of no-liability received a payment ▪ Data was available on 71 suits filed following a panel finding of no-liability Only 51 were closed by the time the study was completed In 28 cases (55%), plaintiffs received a payment In 10 of these cases, the amount paid to the plaintiff exceeded $100,000 • The average time from filing a claim to the panel's decision was 7'/₂ months, with **55%** Of claims beinq settled within 1 month	The majority of claimants took no further action following the pretrial screening panel hearing This indicates that the panel promoted early settlement However, the researchers were not completely confident about the status of the cases they reported as taking no further action They did not know whether plaintiffs were still considering a suit or engaged in settlement negotiations The relatively large number of no-liability panel decisions that resulted in payment to the plaintiff raises a question about the accuracy of the panels' decisions
Howard, D.A An Evaluation of Medical Liability Review Panels in Arizona *State Courts Journal* 519-25, 1981	**Data:** ▪ Aggregate data for malpractice claims filed in Maricopa County (Phoenix). Arizona. 1975 to 1979 ▪ Individual case data for cases in Maricopa County from primary malpractice Insurers in Arizona, 1975 to 1979 ▪ Insurance claim data for Arizona, 1975 to 1979 • Interviews with judges and attorneys in Arizona (circa 1980) **Method:** Analysis of trends before and after implemnentation of pretrial screening panels in 1976	**Court data:** • The percentage of malpractice cases that went to trial dropped from 15°/0 in 1975 to 6°A in 1978 ▪ The percentage of stipulated dismissals (indicating settlement prior to trial) Increased after 1975 ▪ Median time for resolution of claims Increased after panels were Instituted Cases that went through the panel process were slowest • There were significant delays in convening panels and scheduling hearings. **Insurance claims data:** • Probability of payment remained stable • Average payment per paid claim similar for screened and nonscreened claims • Average cost to the insurer to defend a claim increas'd • Average time to resolve a claim Increased • Claim frequency increased after the implementation of the panel (1 978 1979)	▪ The data set only Included 1 year of data for claims filed prior to the enactment of pretrial screening, and 3 years of claims data postpanel The use of only a single year of prepanel data is inadequate for comparison of trends The decline in the number of trials may result from delay in claim resolution, 27% of claims filed in 1977 and 56% of those filed in 1978 had not been closed by the time the study was completed in May 1980 Changes in patterns of disposition of claims may be a result of changes in the malpractice Insurance market A major shift from commercial to physician-owned Insurance companies occurred at the same time panels were implemented

Study	Data and methodology	Major reported findings	Comments
S. Shmanske, and T. Stevens, The Performance of Medical Malpractice Review Panels, *Journal of Health Politics, Policy and Law* 11 (3) 525-535, 1986	**Data:** Claims data from two Insurance companies in Arizona prior to (1 972-75) and after (1 976-79) pretrial screening panels were implemented The data set Included only claims that closed within 2 years of filing and claims that were filed within 1 year of the incident **Method:** Pre-post comparison of differences in claims disposition before and after 1976	• Claim frequency Increased • Claims took longer to resolve • Probability of payment remained the same • There was no overall Increase in average indemnity payment, but claims that closed quickly had higher average payment	• There were no controls for other factors that may have led to changes in malpractice claim activity for example, the change from commercial insurer to a physician-owned mutual company, changes in demographics, and national trends in malpractice claims activity
J. Goldschmidt, Where have All the Panels Gone? A History of the Arizona Medical Liability Review Panel, *Arizona State Law Journal* 23 1013-1109, 1991.	**Data:** Interviews with 69 Superior Court judges, 47 defense attorneys, 41 plaintiff attorneys, 250 physicians, and 73 malpractice plaintiffs	• Participants tended to believe that pretrial screening panels did not promote settlement • Pretrial screening Increased the cost of litigation • General dissatisfaction with the operation of the pretrial screening panel system • About one-third of plaintiff attorneys said there was no reason to enter settlement negotiations prior to the panel decision	• No empirical data • Response rates to surveys were as follows Defense attorneys—60% Plaintiff attorneys—42% Physicians—50% Plaintiffs—24% Superior court judges—68% Thus, there was potential for response bias in results
arbitration studies			
U.S. Department of Health, Education and Welfare, Public Health Service, Health Resources Administration, National Center for Health Services Research, An Analysis of the Southern California Arbitration Project, January 1966 Through June 1975, prepared by D H Heintz, HHEW Pub 77-3159 (Washington DC: U.S. Government Printing Office, 1975)	**Data:** 1,353 malpractice claims brought between 1966 and 1975 against Southern California hospitals One group of 8 hospitals had Implemented an arbitration project in which patients were presented with an arbitration agreement upon entering the hospital (the 'arbitration hospitals") The other group of 8 hospitals did not promote arbitration (the "nonarbitration hospitals") **Method:** Comparison of claims experience in arbitration and nonarbitration hospitals before and after implementation of the arbitration program in 1970	• Fewer claims were filed in arbitration hospitals as compared with nonarbitration hospitals • The amount paid per closed claim was lower in arbitration hospitals • There was a statistically significant decline in the defense cost per claim in the arbitration hospitals over the period of the study • The average length of time to resolve a claim was shorter For arbitration hospitals the time period was measured from the filing of the claim Prior to the initiation of the arbitration project the arbitration hospitals had taken longer to resolve a claim than the nonarbitration hospitals	• Hypotheses were stated in terms of differences between arbitration hospitals and nonarbitration hospitals in the levels of certain variables (e. g. , the number of malpractice claims) but the test statilstic measures the difference between the two groups of hospitals in the rates of change in those variables A number of hypotheses were tested using a test statistic that appears to be Incorrectly specified. Consequently, the statistical significance-though not necessarily the direction-of the findings must be questioned • There was evidence that arbitration hospitals were using "more intensive efforts to resolve claims earner in the process "

Study	Data and methodology	Major reported findings	Comments
Ladimer, I., Solomon, J.C., Mulvihill, M., Experience in Medical Malpractice Arbitration. *The Journal of Legal Medicine*, 2(4):433-469, 1981	**Data:** • 130 California medical malpractice arbitration cases filed between 1971 and 1980. These cases arose in hospitals from the Southern California Arbitration Project (see previous study reviewed in this table). • 500 to 3,200 California malpractice claims that were filed in a court between 1975 and 1978. (The number of litigated cases used for comparison varied depending on the data available.) **Method:** Comparison of trends in arbitration cases and litigated malpractice cases.	• Fewer defendants per arbitration claim. The percent of claims involving a single defendant were as follows: arbitration - 62% litigation - 23% • Plaintiffs' injuries were less serious in arbitrated cases: arbitrated cases less frequently involved death and more frequently involved temporary injuries. • There were no statistically significant differences in the probability of payment between arbitration and litigation cases. • Arbitration claims were filed more quickly following the incident than were claims filed for litigation. • The average time to resolve an arbitrated claim was 28 weeks less than for a litigated claim.	• Exact methods used to control for confounding factors were not clearly specified. • Arbitration claims may be filed more quickly because claimants with temporary injuries may be able to file their claims sooner. • The quicker settlement time for arbitration claims may be a result of fewer defendants in arbitration claims or the plaintiffs with less serious injuries choosing arbitration. • Since arbitration is voluntary, the patients who select arbitration may differ from the patients that chose litigation. Moreover, patients were permitted to revoke the arbitration agreement within 30 days after being discharged. Therefore, plaintiffs with obvious, serious injuries upon discharge may have decided to proceed to trial.

[a] U.S. Congress, Office of Technology Assessment, *Impact of Legal Reforms on Medical Malpractice Costs*, OTA-BP-H-119 (Washington, DC: U.S. Government Printing Office, 1993).
[b] S. Zuckerman, S. Norton, and B. Wadler, *A State-Based Survey of Malpractice Premiums: Implications for Medicare Physicians Payment Policy*, Report 6090-02 (Washington, DC: The Urban Institute, March 1993).

SOURCE: Office of Technology Assessment, 1994

Appendix H: Clinical Practice Guidelines and Malpractice Liability

Clinical practice guidelines have been hailed as tools that can help reduce defensive medicine, improve the quality of care, and protect health care providers from unpredictable liability by clarifying the legal standard of care (59,101 ,188). Medical professional societies have been developing clinical practice guidelines for some years now. In 1989, Congress established the federal Agency for Health Care Policy and Research (AHCPR), which is charged with conducting medical effectiveness research and developing and disseminating national clinical practice guidelines (249).

Despite high hopes in Congress and the Administration and continuing enthusiasm among academics for the clinical practice guidelines movement (30,59), a number of factors are likely to limit the impact of guidelines on medical liability and physician behavior. This appendix examines the potential impact of clinical practice guidelines on medical liability. First, it describes the existing legal standard of care and the current role of clinical practice guidelines in helping to determine it. Second, it discusses limitations of guidelines as legal standards of care. Third, it describes some state initiatives to promote the use of guidelines in litigation. Finally, it comments on the potential role of guidelines in bringing about more cost-effective medical care as our health care system struggles to contain costs.

CURRENT USE OF GUIDELINES AS LEGAL STANDARDS

Because they are more or less concise statements of what the profession deems to be appropriate care, clinical practice guidelines developed by groups of physicians are clearly relevant evidence of the legal standard of care, which is based on customary practice. In fact, the development and acceptance of national guidelines for hospital care provided impetus for abandoning the strictly local standard of care for hospitals in some jurisdictions.[2] However, factors inherent in both the legal

[1] In this appendix, *guideline* refers to a clinical practice guideline itself, and *standard* refers to the legal standard of care. In general practice, as well as in certain places in this appendix, these terms as well as others (e. g., *parameter* and *protocol*) are used interchangeably.

[2] In *Cornfeldt v. Tongen*, 262 N.W. 2d 684 (Minn.1977), the appeals court determined that [he trial court had erred in not admitting Joint Commission on the Accreditation of Hospitals as evidence of the legal standard of care. See also *Darling v. Charleston Community Hospital*, 33 Ill. 2d *326,2* 11 N.E. 2d *253 (Ill. 1965) (55).*

system and in guidelines themselves limit the role guidelines currently play in the litigation process.

The Legal Standard of Care

To prove that a medical practitioner committed medical malpractice, a plaintiff must establish:

1) that the provider owed a duty *of care* to the patient,
2) that the provider breached this duty by failing to provide care that met the applicable *standard of care* for that practitioner under the specific circumstances,
3) that the patient sustained *compensable damages,* and
4) that the physician's breach of duty was the *proximal cause* of those damages.

It is in establishing the second element, negligent conduct, that clinical practice guidelines have a potential role.

The applicable standard of care in a given case is established through expert testimony. Both the plaintiff and defense counsel call to the stand expert witnesses who testify as to what constituted an appropriate level of care in the patient's case and whether or not the defendant physician breached this standard. Expert testimony is based on the experience of the witnesses themselves as well as their knowledge of the literature (which may include textbooks, journal articles, or clinical practice guidelines); hence, the courts defer to the medical profession rather than to some objective or lay standard in determining the scope of a physician's duty to a patient.[3] After testimony has been delivered, it is up to the jury to decide whether or not the physician has breached the standard of care, although in extreme cases the court may take this decision away from the jury by directing a verdict.

Until relatively recently, the legal standard of care was articulated as a strictly local standard:

> A physician is bound to bestow such reasonable and ordinary care, skill, and diligence as physicians and surgeons in good standing in the same neighborhood, in the same general line of practice, ordinarily have and exercise in like cases (1 90).

Today, most jurisdictions apply a national standard for medical specialists that allows plaintiffs and defendants access to expert witnesses from outside their locality.[4] The specific standard varies from state to state. In some jurisdictions, the standard recognizes situational resource constraints--e.g., a practitioner would not be held liable for failing to perform a magnetic resonance imaging study if no facilities were available (86).

Additional safe harbors under the customary standard are the "respectable minority" rule, which allows practices that deviate from the professional norm as long as they are followed by a respected minority of practitioners;5 and the "error in judgment" rule, which protects a physician who chooses between two or more legitimate courses of treatment (109).

How Guidelines Are Admitted as Evidence

Courts generally bar written guidelines from being admitted as evidence under the hearsay rule, which prohibits the introduction of out-of-court statements as evidence (150). In these cases, guidelines can only color the evidence to the extent that expert witness testimony reflects their contents. Certain guidelines, however, may be ad-

[3] The professionally determined standard was challenged successfully in *Helling v. Carey*, 83 Wash. 2d 514, 519 P. 2d 98 I (Wash. 1974). in which the court rejected the professional standard for glaucoma screening in favor of its own higher standard. The precedent set by this case, which sparked considerable concern in the provider community, has since been restricted to apply (rely to situations of obvious negligence (83).

[4] Most jurisdictions apply a national standard of care for board-certified specialists, but a significant number still apply a local standard for general practitioners. The most common formulation of the standard currently is a modified locality rule, which requires physicians to meet the standard of physicians practicing in "the same or similar" localities (9).

[5] *See, e.g., Chumbler v. McClure*, 505 F. 2d 489 (6th Cir. 1974).

mitted into evidence as "learned treatises," a class of statements that are granted exception from the hearsay rule in many jurisdictions (1 13). Federal Rules of Evidence, which have been adopted in a similar form by most states, define the "learned treatise" exception as follows:

> ... statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice (150).

There is no hard and fast rule as to which guidelines have "reliable authority." Guidelines reflecting comprehensive analysis of scientific evidence and broad consensus among members of the profession are likely candidates, but courts themselves are likely to defer to expert opinion regarding the scientific validity of a guideline rather than make such judgments themselves (113).6

Use of Guidelines in Establishing the Legal Standard of Care

Once admitted as evidence of the legal standard of care, guidelines do not carry greater legal weight than any other expert testimony—i.e., they are not regarded as definitive statements of the standard of care. Once all testimony has been heard, it is left to the jury to decide the applicable legal standard of care. Even when a guideline is quite explicit and straightforward, it is not clear how much weight it will be accorded by the jury. OTA knows of no studies that have examined the reactions of juries to the use of guidelines as evidence.

Under the current customary standard of care, clinical practice guidelines can only influence the standard to the extent that they are adopted into common medical practice. The existence of a guideline might not be persuasive if expert witnesses testify that most physicians do not follow it. In spite of extensive and focused guidelines development in some areas of practice, physicians are sometimes slow to incorporate them (1 32). Additional incentives and dissemination tactics may. be needed to change physician behavior m accordance with guidelines.

A recent study suggests that guidelines currently play only a small role in litigation but that this role may be increasing (100). The authors studied guideline use from the three different perspectives in order to assess their use in the various phases of medical malpractice litigation.

- A national review of all published court opinions between 1980 and 1993 found only 32 cases in which the opinion indicated that guidelines had been used as evidence of the standard of care.
- A review of a sample of 259 claims—both open and closed—from two malpractice insurance companies found that only 17 involved the use of guidelines.
- In a random sample survey of medical malpractice plaintiff and defense attorneys, 36 percent of attorneys reported that they had at least one case per year where guidelines played an important role. Moreover. 30 percent of attorneys reported they felt the use of guidelines in litigation was increasing (1 00).

The study identified more claims involving the use of guidelines by plaintiffs than claims involving the use of guidelines by defendants. In many cases, attempts to use guidelines as proof or rebuttal of negligence or nonnegligence were unsuccessful. The most frequently cited guidelines were those published by the American College of Obstetricians and Gynecologists (100).

6 A recent U.S. *supreme* Court decision, *Daubert v. Merrell Dow Pharmaceuticals,* 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), gives judges greater responsibility for making independent judgments of the scientific validity of evidence before it is admitted m court. It is unclear how this decision wilt affect [he admissibility of cl inical practice guidelines as evidence of the professional standard of care. but it does herald a shift away from relying solely on expert opinion to make such judgments.

BARRIERS TO THE USE OF GUIDELINES AS LEGAL STANDARDS

One factor limiting the impact of guidelines in litigation is that their language and form are often not amenable to use as legal standards. Some guidelines offer several treatment options, while others offer a single option but do not hold it forward as the only acceptable one. A typical guideline frequently includes allowances for deviation based on professional judgment.

Many medical societies consciously avoid the use of words such as always and *never* when drafting guidelines and avoid referring to their guidelines as standards for fear of potential adverse legal consequences (232). AHCPR has also been concerned with potential legal consequences of guidelines development and has sought immunity from civil liability for the members of its guidelines panels (2.54).

The American Medical Association (AMA) shares these concerns about the legal implications of guidelines. Although it encourages the development and dissemination of practice guidelines as a means of improving and further standardizing the practice of medicine, the AMA resists the use of guidelines as an absolute legal standard of care:

> . . . the evidentiary value of practice parameters will vary depending upon the origins and content of the parameter and the circumstances of the case. As a policy matter, this result seems entirely appropriate. Rules of law, *like parameters, must maintain sufficient flexibility to adjust to the needs of the particular case.* (emphasis added) (6)

The AMA endorses and encourages building flexibility into guidelines in order to avoid "'cookbook medicine" (6). Such flexibility may be warranted: however, it may limit the usefulness of guidelines in a legal context.

The vastness and complexity of medical knowledge pose additional barriers to the courts' ability to depend on practice guidelines. While it may be possible to develop explicit criteria for diagnosis and treatment of certain pathologies, the current state of medical knowledge is insufficient to support the development of explicit criteria for the majority ofclinicalsituations(101). One study estimated that there could be over 10 billion possible pathways for diagnosing common medical problems (56). Adding treatment algorithms would increase the number even further.

Even if good evidence were available on which to base guidelines for a subset of medical conditions. its complexity could be daunting in a court of law. Court decisions could be complicated further in cases where conflicting guidelines were introduced into evidence. In a 1992 survey, a random sample of state trial and appellate judges ranked clinical practice guidelines third among 30 scientific topics on which they felt a need for greater information (262). To satisfy this need, a major project is currently under way to publish "desk books" that will give judges guidance on the evaluation of scientific evidence. However, because the medical community is still debating the relative merits of different types of evidence on the effectiveness of medical treatments,[7] it maybe some time before judges have the tools necessary to evaluate clinical practice guidelines from an evidentiary standpoint.

Finally, the continuing evolution of medical practice presents a challenge for efforts to keep guidelines current. Some critics argue that the adoption of rigid guidelines as legal standards of care could hinder the development and adoption of new medical technologies in the future.

INITIATIVES TO PROMOTE LEGAL USE OF GUIDELINES

Today, clinical practice guidelines carry limited evidentiary weight in medical malpractice litigation. To enhance the role of guidelines in the

[7] A concurrent OTA study is reviewing and critiquing medical effectiveness research methodologies and the development and dissemination of those research results to practitioners. The study includes a review of the activities of the federal Agency for Health Care Policy and Research.

courts, two different approaches could be taken. One approach would be to give greater evidentiary weight to certain guidelines in the litigation process (e.g., by authorizing judges to exercise more discretion with respect to admissibility of guidelines or by adopting certain guidelines under administrative law). A mere passive approach would be to continue current efforts in guidelines development at the national level in the expectation that, over time, guidelines would figure increasingly in medical malpractice litigation.

The first approach requires legislative action. In fact, such action was taken in the early 1970s as a part of the Medicare Program. A provision of the Medicare Act8 grants immunity from civil liability to practitioners who exercise "due care" in complying with treatment criteria developed by Medicare peer review organizations (PROS). Although this provision has been on the books for over two decades, it has never been invoked, probably because the criteria developed are not explicit enough to be of much use in a legal context (85, 116). Even if sufficiently explicit criteria were available, legal scholars dispute how much additional protection the provision would confer because of a lack of clarity in the legislative language (17, 116, 169). Another likely explanation for the disuse of the Medicare provision is its link to the PRO program, which has itself been the subject of considerable controversy and change since the adoption of the immunity provision (85).

In recent years, however, several states have passed legislation that may allow for greater use of guidelines in determining the legal standard of care. Four states—Maine, Florida, Minnesota, and Vermont—recently passed legislation that accords greater weight to certain guidelines in medical malpractice litigation.

Maine's 5-year Medical Liability Demonstration Project, begun in 1991, makes state-developed guidelines admissible as a defense in medical malpractice proceedings (24 M.R.S. Sees. 2971 *et. seq.* (1993)). The project's goals include reducing malpractice suit rates and insurance premiums; reducing defensive medicine; reducing variation in practice patterns; and containing overall health care costs. Guidelines for selected areas of practice in obstetrics/gynecology, emergency medicine, radiology, and anesthesia were developed by four medical specialty advisory committees appointed by the Maine Board of Registration in Medicine (see box H-l). Guidelines were developed in areas of practice where defensive medicine was believed to be extensive.

The statute permits physicians electing to participate in the demonstration to use these guidelines as an *affirmative defense* in medical malpractice proceedings. Under the affirmative defense provision, use of guidelines as evidence is no longer a matter of the judge's discretion. If a physician introduces the guideline as a defense, he or she must prove only that the guideline was followed. In order to deny a physician this affirmative defense, the plaintiff must either: 1) prove that the physician did not follow the guideline, or 2) prove, through expert testimony, that the guideline is not applicable to the given case. If the plaintiff is unable to do this and the physician proves that he or she complied, the physician is cleared of liability.

Another provision of the Maine Statute prohibits plaintiffs from introducing a state guideline into evidence in an effort to prove that the physician's performance was substandard (24 M. R. IS. Sec. 2975 (1993)). This provision was included to allay fears on the part of physicians that the guidelines, instead of protecting them from liability, would be used against them (212). Some critics, however, claim that this provision may be subject to challenge on state or federal constitutional grounds because it selectively denies plaintiffs the use of evidence that may be critical to proving malpractice (215). A hearing on such a constitutional challenge would probably not occur for sev -

*42U.S.C.Sec. 1 32&'-6(c)

BOX H-1: Guidelines Adopted for Use in the Maine Medical Liability Demonstration Project

Emergency Medicine

- Criteria for performing cervical spine x-rays on asymptomatic trauma patients in the emergency room
- Checklist for criteria to be met in accordance with federal statute before affecting a patient transfer

Obstetrics and Gynecology

- Caesarean delivery for failure to progress
- Assessment of fetal maturity prior to repeat cesarean or elective induction of labor
- Management of singleton breech presentation
- Management of Intrapartum fetal distress
- Antepartum management of prolonged pregnancy
- Hysterectomy for diagnosis of abnormal uterine bleeding in women of reproductive age or diagnosis of leiomyomata
- Tocolysis
- Diagnosis and management of ectopic pregnancy
- Management of perinatal herpes simplex virus infection

Anesthesiology

- Preoperative testing
- Preoperative, interoperative, and postoperative monitoring

Radiology

- Screening mammography
- Antepartum ultrasound
- Outpatient angiography
- Adult barium enema examination

SOURCE State of Maine Board of Registration in Medicine Department of Professional and Financial Regulation, Rule 02-373 chs 20 22 24 26 Medical Liability Demonstration Project—Specialty Practice Parameters and Risk Management Protocols

eral years. As of May 1994, the state's largest medical malpractice insurance carrier had only received one claim for which the adopted guidelines were potentially relevant (29).

Florida legislation in 1993 authorized a 4-year demonstration project similar to that in Maine. Outcomes data on hospital patients collected through a statewide mandatory reporting system will be used to help develop "practice parameters" for inpatient care. These parameters, as well as parameters for selected outpatient services, will be developed by the Florida Agency for Health Care Administration in conjunction with relevant state health professional associations and boards. Once adopted under state rulemaking procedures. these parameters will be admissible as an affirmative defense in medical malpractice proceedings (Fla. Stat. Sec. 408.02 (1993)). Unlike Maine, however, the Florida legislation does not bar plaintiffs from trying to use the parameters to prove that a physician's care was substandard. A plaintiff might be able to introduce the parameter as evidence, but the parameter would not be accorded greater weight than any other expert testimony.

Minnesota recently passed legislation that allows guidelines developed or adopted by a special

state commission to be used as an *absolute defense* in malpractice litigation (164).[9] Like the Maine statute, Minnesota's law also bars the plaintiff from introducing the guideline as evidence that the physician *failed* to meet the standard of care. As of May 1994, the first round of guidelines had yet to be developed (72).

Vermont's approach is more moderate, amounting to a change in the rules of evidence that would allow a wider variety of guidelines--e. g., guidelines developed by health care professional groups, the federal government, or health care institutions—to be directly admitted as evidence of the standard of care by either the plaintiff or the defendant in future mandatory medical malpractice arbitration proceedings (18 V. S. A., part 9, chapter 21, Sec. 1 (1992)). This provision would make it easier to introduce guidelines as evidence but would not give them legal weight any greater than other expert testimony.

Maryland, in a departure from the strategies adopted by other states, recently adopted legislation that mandates the development of state guidelines but explicitly *prohibits* them from being introduced as evidence by any party in a malpractice suit (Maryland, State House of Representatives, House Bill 1359, enacted Apr. 13, 1993.) A few other states have passed legislation authorizing the development of guidelines and encouraging consideration of their use in the future as legal standards of care.

Some patient rights advocates may oppose the approach taken by Maine and Minnesota because it offers no safeguard against "bad" guidelines—i.e., the plaintiff cannot contest the reasonableness of the guidelines themselves (179). Some critics contend that the use of guidelines as rigid legal standards may be problematic due to the continual evolution of medical practice and the inability of written guidelines to reflect changes in a timely manner (94).

State guidelines initiatives raise the potential for conflict between national, state, and even institutional guidelines. For example, most of Maine's guidelines were based on nationally recognized guidelines, but others were developed de novo by Maine physicians (53) and could be construed as setting a precedent for reconversion to a more local standard of care. Guidelines developers in Minnesota anticipate using national guidelines as models and amending them if necessary to conform to the realities of health care delivery in the state (72). In Vermont, the statutory description of guidelines could be interpreted as including even written hospital protocols.

It will be some time before evidence of the effects of these state efforts is available. Some early reports suggest that the Maine initiative has reduced defensive practices in selected areas (e.g., the use of cervical spine x-rays in the emergency room) (115). Given the modest nature of the changes and the limited number of guidelines adopted, however, it is unlikely that these programs will have much of an impact overall on the practice of medicine. The extent to which Maine and Minnesota's programs will streamline the litigation process is also questionable. In both states, expert testimony will still be required to establish whether the guidelines are relevant to the case and, because of the complicated nature of medical practice, whether they were in fact followed. In cases where several different guidelines can be introduced as evidence, expert testimony may also be necessary to determine which, if any, represents the legal standard of care.

PRACTICE GUIDELINES IN AN ERA OF COST CONTAINMENT

Increasing concern over the costs of medical care has sparked the introduction of cost as a factor in medical decisionmaking (204). Costs as well as

[9] It is unclear exactly how Minnesota's *absolute defense* provision differs from Maine's *affirmative defense*. The legal meaning may be essentially the same+. c., the plaintiff must prove that the physician didn 't follow the guideline or that the guideline is not applicable to the specific case in order to deny the physician this avenue of defense. However, until there have been test cases involving the guidelines, it remains unclear how exactly how judges will interpret the statutes (83).

effectiveness have been used as criteria by payers and institutions to help decide which of two or more diagnostic or treatment alternatives to reimburse or use for a given condition—for example, low versus high osmolar contrast media for radiologic diagnosis (103). AHCPR is now required to consider cost implications when developing guidelines (42 U.S.C. Sec. 299b-1 (1994)).

Judges have traditionally been averse to accepting the high cost (to the provider) of performing a procedure as a defense against medical malpractice (168). A physician may refuse to accept a patient on the basis of that patient's ability to pay (48,98,143). However, once a physician has established a relationship with a patient, the law generally holds that he or she is responsible for ensuring that the care that patient receives measures up to the "customary practice" standard,[10] although in some cases courts have allowed departures from customary practice due to cost constraints. For example, in *Youngberg v. Romeo*,[11] the court found that a physician in a state-operated facility could not be held liable for failing to meet normal professional standards due to institutional budget constraints.

A more recent case, *Wickline v. State of California*,[12] illustrates the legal system's increasing consciousness of the tension between cost constraints and appropriate care. The case involved a claim of negligence against the state Medicaid program for not approving a medically necessary extension of an inpatient stay for complications following coronary artery bypass surgery. The patient's primary physician had requested an 8-day extension, but the Medicaid program authorized only 4 days. The patient was discharged after a 4-day extension and suffered post-discharge complications that ultimately resulted in a leg amputation. The court concluded that the state Medicaid program was not liable for Wickline's injury because the decision of when to discharge was the responsibility of the treating physician. The primary physician testified that "he felt that Medi-Cal had the power to tell him, as a treating doctor, when a patient must be discharged from the hospital."13 However, all three physicians involved in the patient's care testified that the decision to discharge after the 4-day extension was consistent with customary practice. 14 The court stated that, although:

> . . . *cost* consciousness has become a permanent feature of the health care system, it is essential that cost limitation programs not be permitted to corrupt medical judgment. We have concluded, from the facts in issue here, that in this case it did n{~[.15.16

Some legal scholars have argued that, as cost concerns enter increasingly into physicians treatment decisions, the customary standard will come to reflect these concerns either implicitly or explicitly (85,1 99), as suggested in *Wickline*. Practice guidelines, to the extent that they reflect cost considerations and are given evidentiary weight in court, are clearly one of the more systematic ve-

[10] See, e.g., *Smith v. Yohe*, 194 A. 2d 167 (Pa. 1963), *Clark v. United state* 402 F. 2d 950 (Cir. D.C. 1968), *Wilkinson v. Vesey*, 295 A. 2d 676 (R.I. 1972), *Ricks v. Budge*, 64 P.2d 208 (1937), *Rise v. United States*, 630 F. 2d 1068 (5th Cir. 1980); *Wickline v. State of California*, 183 Cal. App. 3d 1064, 228 Cal. Rptr. 661 (Cl. Ct. App. 1986); see also (47,88,111,251).

[11] *Youngberg v. Romeo*, 457 U.S. 308 (1982).

[12] *Wickline v. State of California*, 288 Cal. Rptr. 661 (Cal. Ct. App. 1986).

[13] *Wickline v. State of California*, 288 Cal. Rptr. 661 (Cal. Ct. App. 1986).

[14] *Wickline v. State of California*, 288 Cal. Rptr. 661 (Cal. Ct. App. 1986).

[15] *Wickline v. State of California*, 288 Cal. Rptr. 661 (Cal. Ct. App. 1986).

[16] The differing court opinions in *Wickline* and *Youngberg* regarding physicians' duties under cost constraints may have turned on the difference in employment status between the physicians. In *Youngberg*, the physician was an employee of a state institution; in *Wickline*, the physicians were private practitioners. Physician employment status is yet another factor that may influence decisions as to the applicable standard of care or, alternatively, the locus of responsibility for treatment decisions.

hicles that might be used to bring about such a change. There is still considerable argument regarding the incorporation of cost concerns into practice guidelines (33,1 88). The AMA does not include cost as one of its criteria for guidelines development (8) and maintains that practice guidelines should be developed independent of considerations of cost (227). An entire area of law is under development that may expose payers to liability for negligent utilization review and payment decisions that result in harm to patients (84).

It remains to be seen whether courts will come to accept economic factors as determinants of the legal standard of care for physicians. Resolution of these difficult questions maybe central to effective health care reform. If they can be used to protect physicians from liability, clinical practice guidelines may be a potential means for reconciling broader social goals (e.g., health care cost containment) with a more individual-oriented legal standard of medical care.

Appendix I: Description of 32 Direct Physician Surveys of Defensive Medicine Reviewed by OTA

Appendix I—Description of 31 Direct Physician Surveys of Defensive Medicine Reviewed by OTA

Author, year of release	Survey year	Sample population location	Specialty	Survey characteristics	Response rate (percent)
Porter, Novelli & Associates, 1983a	1983	National	Obstetrician/ Gynecologists (Ob\Gyn)	Survey of random sample of American College of Obstetricians and Gynecologists (ACOG) members regarding medical liability Insurance premiums, claims experience, and practice changes in response to malpractice risks	50.1%.
Reynolds et al 1987[b]	1983/1 984	National	All	Data from the 3rd quarter 1983 and 4th quarter 1984 American Medical Association (AMA) Socioeconomic Monitoring Surveys on practice changes made in response to liability risk	630
Bligh, American College of Surgeons, 1984C	1984	National	Surgeons	Survey of members regarding medical liability Insurance premiums, claims experience, and practice changes in response to medical liability	36
Kansas Medical Society, 1985[d]	1984	Kansas	All	Survey of all members for data and opinions on the medical professional liability environment	50
Needham, Porter, Novelli, 1985[e]	1985	National	Ob\Gyn	Survey of random sample of ACOG members regarding medical liability Insurance premiums, malpractice claims experience, and practice changes in response to malpractice risks	397
Texas Medical Association, 1985f	1985	Texas	All	Survey regarding professional liability and defensive medicine	232
Charles, Wilbert, & Frankel 1985g	1985	Chicago	All	Survey of physicians to assess the personal and professional impact of malpractice litigation	366
Alabama Academy of Family Physicians 1986[h]	1985	Alabama	Family and General Practitioners (F\GP)	Survey of all members regarding obstetric practice	84
Iowa Family Physician Survey 1985	1985	Iowa	F\GP	Survey on medical liability	47
Michigan State Medical Society, 19851	1985	Michigan	Ob\Gyn	Survey to measure the potential impact of the professional liability Insurance problem	56
University of Nevada, School of Medicine, 1985[k]	1985	Nevada	Ob\Gyn and F\GP	Phone survey of rural doctors regarding obstetrical care and malpractice concerns	62

(continued)

Appendix I—Description of 31 Direct Physician Surveys of Defensive Medicine Reviewed by OTA (cont'd).

Author, year of release	Survey year	Sample population location	Specialty	Survey characteristics	Response rate (percent)
The Oregon Medical Association 1986[l]	1985	Oregon	Ob\Gyn and F\GP	Survey to assess the impact of professional liability issues on access to obstetrical care	81 1
Rosenblatt and Wright, 1987[m]	1985	Washington	F\GP	Survey to assess the impact of rising malpractice Insurance premiums on the practice of obstetrics	803
Rosenbach and Stone, 1990[n]	1986	National	All	Interview survey regarding costs and availability of malpractice Insurance and their impact on physician practice	742
American Academy of Family Physicians 1987[o]	1986	National	F\GP	Survey to assess impact of cost and availability of liability insurance on the practice of obstetrics	337
Opinion Analysts, Inc , 1986[p]	1986	Texas	All	Survey to measure the impact of professional liability Insurance rates on the medical profession	355
Georgia Obstetrical and Gynecological Society, 1987[q]	1986	Georgia	Ob\Gyn	Survey of how malpractice liability affects obstetric care	61
Kentucky Medical Association, 1987[r]	1986	Kentucky	Ob\Gyn and F\GP	Survey regarding professional liability	42
Michigan Academy of Family Physicians, 1989 (Smith et al., 1989)[s]	1986	Michigan	F\GP	Survey to describe the characteristics of family physicians who practice obstetrics and identify factors prompting them to discontinue practice	815
Rosenblatt and Detering, 1988[t]	1986	Washington	Ob\Gyn, F\GP, and midwives	Survey to describe the impact of rapidly rising malpractice premiums on obstetric practice and to assess the impact of tort reform on professional liability costs	635
Opinion Research Corp , 1988[u]	1987	National	Ob\Gyn	Survey of random sample of ACOG members regarding medical liability Insurance premiums, claims experience and practice changes in response to malpractice risks	484
Shapiro et al , 1989[v]	1987	Wisconsin	All	Survey to assess the impact of malpractice litigation on the doctor-patient relationship and to collect data that might suggest effective tort reform	427
Illinois Department of Public Health, 1987 (Ring, 1987)[w]	1987	Illinois	Ob\Gyn and F\GP	Survey on changes in availability of obstetrical services	256
Weisman et al , 1989[x]	1987	Maryland	Ob\Gyn F\GP and Internal Medicine	Telephone survey regarding practice changes as a result of the current malpractice liability cilmate	65

(continued)

Appendix I—Description of 31 Direct Physician Surveys of Defensive Medicine Reviewed by OTA (cont'd).

Author, year of release	Survey year	Sample population location	Specialty	Survey characteristics	Response rate (percent)
Texas Medical Association, 1988Y	1988	Texas	All	Survey to assess impact of malpractice Insurance premiums cost and liability risk on physician practice	41
Louisiana Section of ACOG, 1988Z	1988	Louisiana	Ob\Gyn	Survey on professional liability	384
Lawthers et al , 1992aa	1989	New York	All	Survey of physicians' perceptions of the risk of being sued and their impact on physician practice	405
Opinion Research Corp 1990[bb]	1990	National	Ob\Gyn	Survey of random sample of ACOG members regarding medical liability Insurance premiums, claims experience, and practice changes in response to malpractice risks	540
Opinion Research Corp ,1992[cc]	1992	National	Ob\Gyn	Survey of random sample of ACOG members regarding medical liability insurance premiums, claims experience, and practice changes in response to malpractice risks	51
Minnesota Ob\Gyn Survey (Meader, no date)dd	no date	Minnesota	Ob\Gyn	General survey regarding income and malpractice Insurance cost concerns	Not provided
West Virglnia State Medical Association, no date[ee]	no date	West Virginia	All	Survey regarding professional liability Insurance problems facing physicians	50

[a]Porter, Novelli &Associates, "Professional Liability Insurance and Its Effects Report of a Survey of ACOG's Membership, " prepared for the American College of Obstetricians and Gynecologists, Washington, DC, August 31, 1983

[b]R A Reynolds, J A Rizzo, and M L Gonzalez, "The Cost of Medical Professional Liability," *Journal of the American Medical Association 257(20)* 2776-2781, May 22/29, 1987

[c]T J Bligh, "American College of Surgeons Professional Liability Survey Report, 1984 ," Executive Services Department for the Regents' Ad Hoc Committee on Professional Liability, American College of Surgeons, Washington, DC, 1984

[d]Kansas Medical Society, "Professional Liability Survey, " *Kansas Medicine* P 43, February 1985

[e]Needham, Porter, Novelli, "Professional Liability Insurance and Its Effect Report of a Survey of ACOG's Membership, " prepared for the American College of Obstetricians and Gynecologists, Washington, DC, November 1985

[f]Texas Medical Association, "Texas Medical Association's 1985 Professional Liability Survey" (unpublished), Austin, TX September 1985

[g]S C Charles, J R Wilbert and K J Franke, "Sued and Nonsued Physicians' Self Reported Reactions to Malpractice Litigation, " *American Journal of Psychiatry* 142(2) 437-440, April 1985

[h]Alabama Academy of Family Physicians, "A Survey of Family Physicians Providing Obstetrical Care A Preliminary Report, " Alabama Academy of Family Physicians, Montgomery, AL, February, 1986

[i]Iowa Medical Society, "Iowa Family Physician Survey Findings" (unpublished),1 987

[j]M Block, "Professional Liability Insurance and Obstetrical Practice, " commissioned by Michigan State Medical Society, July 1985

[k]H E Crow University of Nevada School of Medicine. Off Ice of Rural Health, Survey of Rural Doctors Regarding Their Participation (Or not) in Obstetrics, " Off Ice of Rural Health, University of Nevada School of Medicine, Mar 11, 1985

[l]The Oregon Medical Association, Ad Hoc 06 Task Force on Professional Liability, "The Impact of Professional Liability Issues on Access to Obstetrical Care in Oregon, " Oregon Medical Association, March 1986

[m]R A Rosen blatt and C L Wright, "Rising Malpractice Premiums and Obstetric Practice Patterns The Impact on Family Physicians in Washington State , " *The Western Journal of Medicine* 146(2) 246-248, February 1987

[n]M L Rosenbach and A G Stone "Malpractice Insurance Costs and Physician Practice, 1983 -1986," *Health Affairs 9(4)* 176-185, 1990

(continued)

Appendix I—Description of 47 Direct Physician Surveys of Defensive Medicine Reviewed by OTA (cont'd).

"Amerlcan Academy of Family Physicians Commitee on Professional Liablility and Division of Research and Information Services Family Physicians and Obstetrics A Professional Liability Study 1987

p Opinion Analysts Inc The Texas Medical Association Professional Liability Insurance Survey prepared for the Texas Medical Association September 1986

q Georgia Obstetrical and Gynecological Society GOGS 1987 Survey Results Atlanta GA 1987

r G S Bonham Survey of Kentucky Obstetric Practice *Jolurnal of fhe Kentucky Medical Assocliation 349 353,* June 1987

s M A Smith L A Green and T L Schwenk "Family Practice Obstetrics in Michigan Factors Affecting Physician Participation on *The Journal of Family Practice 28(4) 433 437* 1989

t R A Rosenblatt and B Deterlng "Changing Patterns of Obstetric Practice in Washington State The Impact of Tort Reform *Famlily Medicine 20(2)* 101 107, March/April 1988

u Opinion Research Corp , "Professional Liability and Its Effects Report of a 1987 Survey of ACOG's Membership prepared for the American College of Obstetricians and Gynecologists Washington, DC March 1988

v R S Shapiro, D E Simpson, S L Lawrence et al "A Survey of Sued and Nonsued Physicians and Suing Patients " Archives *of Internal Medicine* 1492190 2196 October 1989

w M C Ring, ' Draft Report Changes in Availability of Obstetrical Services in in Illinois" Division of Local Health Administration, Illinois Department of Public Health 1987

'C S Weisman, L L Morlock, M A Teitelbaum et al , Practice Changes in Response to the Malpractice Litigation Climate *Medical Care* 27(1) 16 24 January 1989

Y Texas Medical Association, ' Texas Medical Assocition 1988 Professional Liability Survey" summer 1988

'W P Begneaud, "Obstetric and Gynecologic Malpractice in Louisiana Incidence and Impact " prepared for the Louisiana Section of the American College of Obstetrics and Gynecology, Lafayette, IA 1988

aaA.G. Lawthers, A R Localio and N M Laird, Physicians Perceptions of the Risk of Being Sued " *Journal of Health Politics, Policy and Law* 17 (3) 463-482, 1992

bbOpinion Research Corporation, "professional Liability and Its Effecfs: Report of a 1990I *Survey* Of *ACOG's* Membership, " prepared for the American College of Obstetricians and Gynecologists, Washington, DC, September 1990

ccOpinion Research Corporation, "Professional Liability and Its Effects Report of a 1992 Survey of ACOG's Membership, " prepared for the American College of Obstetricians and Gynecologists, Washington DC, October 1992

ddE.C. Meader, Jr., , Minnesota Obstetrics and *Gynecology Practice Survey Summary,* prepared for the Minnesota Section of the American College Of Obstetrics and Gynecology, no date

eeWest Virglnia State Medical Association, "West Virglnia State Medical Association's Physician Survey" (unpublished), undated

SOURCE Off Ice of Technology Assessment, 1994

Appendix J: Detailed Critique of Reynolds et al. and Lewin-VHI Estimates

In chapter 3 of this report, the Office of Technology Assessment (OTA) reviewed two wide] y publicized estimates of the costs of defensive medicine and the medical malpractice system-one published in 1987 by Reynolds and colleagues at the American Medical Association (194) and the other published in 1993 by Lewin-VHI, Inc. (1 25). This appendix provides a detailed critique of the data, methods, and assumptions that underlie those estimates.

THE REYNOLDS ESTIMATES

Method 1: Survey of Physicians

Reynolds and colleagues tried to estimate the full impact of the malpractice system on physician costs, including:

- malpractice insurance premiums;
- the time lost in defending against malpractice claims and lawyers' fees not covered by malpractice insurance; and
- practice changes, including
  - —increased recordkeeping,
  - —use of more tests or treatment procedures,
  - —increased time spent with patients. and
  - —increased followup visits.

Of all the practice changes, only two-increases in tests or treatment procedures and followup vis--its—fall within OTA's definition of defensive medicine. Though some observers would claim that more time spent with patients or in documenting medical records is defensive medicine, OTA excluded these practices because it is extremely difficult to measure their frequency and magnitude and because the positive impact of these practices on the
quality of care is less equivocal. In contrast, procedures and followup visits are documented in utilization data, offering an empirical check.

Estimation of malpractice insurance premiums was based on the American Medical Association (AMA) Socioeconomic Monitoring System (SMS) survey, which asks physicians to report their malpractice insurance premiums and other practice costs. The SMS also gives information on days lost from work to defend against malpractice claims and the amount paid for outside attorneys. These data items, though subject to the usual problems of recall bias, are sufficiently accurate for the purposes at hand. (They are also subject to verification with objective premium data and other survey data.) The main problem comes in esti-

mating the net costs of practice changes resulting from malpractice liability.

In its fourth quarter 1984 survey, the AMA asked a series of questions about whether physicians were maintaining mm-e detailed records, prescribing more diagnostic tests and treatment procedures, spending more time with patients. and having more followup visits with patients in the last 12 months in response to their malpractice risks (194). If physicians answered in the affirmative to any of these items, they were asked to quantify the change over the past 12 months in percentage terms.

Table J-1 summarizes the results of the survey. The physicians reported that in 1984 they increased tests and procedures by 3.2 percent and followup visits by 2.6 percent in response to changes in the frequency of malpractice claims. These two practice changes fall within OTA's definition of defensive medicine. The other practice changes, such as increasing recordkeeping and time spent with the patient, may result from the same desire to avoid a malpractice suit, but these practice changes lead to increases in the cost per visit or procedure. Such cost increases would be passed on to consumers in the form of higher fees rather than additional procedures or visits.

Reynolds estimated the cost of all of the 1984 practice changes *except* the cost of extra tests and procedures, which was excluded because the researchers could not find a good way to estimate the average cost of such a diverse array of services. The average cost per physician of the remaining practice changes was $4.600. of which $1,900 was the cost of reported changes in followup visits.

The authors computed the ratio of the 1984cost of practice changes ($4,600) to the 1984 increase in malpractice insurance premiums ($ 1,300), and applied this ratio (3.53) to the average 1984 malpractice premium ($8,400) to arrive at a per-physician cost of practices done in response to the malpractice system: $29,700. or 14percent of average physician revenues. In the aggregate, this cost corresponds to $10.6 billion in 1984.

To summarize, under method 1. Reynolds' total estimate of the cost of the malpractice system for physicians—$ 13.7 billion in 1984---comprises the following elements:

- premiums-$3.O billion.
- other costs of incurring malpractice claims-$0.1 billion, and
- practice changes-$ 10.6 billion.

Of the $13.7 billion in total cost, about $4.3 billion, or 30 percent, represents defensive medicine under OTA's definition.

The estimate of the cost of practice changes has several potential sources of bias. On the one hand, there is reason to believe that Reynolds' estimate of the malpractice system's impact on health care costs is too low because Reynolds and colleagues excluded the reported 1984 cost impact of increased tests and treatment procedures. The importance of this exclusion is unknown. but it rep-

TABLE J-1: Reported Practice Changes in Response to Increasing Liability Risk, 1984

Activity	Percent of physicians making change in 1984	Average percent change in 1984*
Increased recordkeeping	31.0%	2 9%
Prescription of more test or treatment procedures	200	3 2
Increased time spent with patients	170	2 4
Increased followup visits	170	2 6
Percent of physicians with at least 1 listed practice charge	41 8	

*Calculations include zeros for physicians who did not make practice change

SOURCE American Medical Association Socioeconomic Monitoring System survey as reported in R A Reynolds J A Rizzo and M L Gonzalez "The Cost of Medical Professional Liability *Journal of American Medical Association* 257(20) 2776-2781 May 2229 1987

resents the essence of OTA's definition of defensive medicine and means that the Reynolds estimate probably does not capture the greatest part of defensive medicine.

On the other hand, there is reason to believe that Reynolds' estimate is too high, because the survey may have prompted physicians, who regularly articulate negative feelings about malpractice liability, to overestimate the impact of rising malpractice claims on their practices. Data from the National Ambulatory Medical Care Survey (NAMCS) show no change between 1981 and 1985 in the per-capita number of followup visits; they also show an annualized rate of increase of less than 1 percent in total per-capita physician office visits over the period (70). Barring some dramatic factor at work between 1983 and 1984 to otherwise reduce the frequency of followup visits by as much as 2.3 percent, physicians' responses to the AMA survey appear to exaggerate their actual change in behavior. 1 If physicians overestimated the malpractice system's impact on follow up visits, they may also have done so with the other practice changes.

Finally, Reynolds' approach involved an arbitrary assumption with unknown effects on the validity of the estimate. Reynolds assumed that the ratio of the *change* in practices (in response to malpractice risk) to the *change* in premiums can predict the ratio of the level of such activities to the *level* of premiums in 1984. The authors had no empirical evidence for this assumption, and there is reason to believe that it may be inaccurate.[2] As a consequence of these issues, OTA concluded that Reynolds' first method does not offer a sufficiently reliable estimate of the full cost impacts of malpractice liability and does not offer a basis for estimating the costs of defensive medicine.

Method 2: Relationship Between Reported Malpractice Risk and Physician Fees and Utilization

The researchers examined the relationship between the level of malpractice liability risk, as measured by the 1984 malpractice premium reported by each physician responding to the AMA survey, and the physician's fees and volume of' selected services reported in the same survey. Regression of utilization and fees on premiums[3] and other demographic variables (e.g., physicians per 1,000 population, years in practice, board certification, etc.) gave estimates of the impact of each $1 of premium on the utilization or fee for a given procedure. Doctors with higher premiums were found to have higher fees, but they had lower lev-

1 It is theoretically feasible that physicians responding to the AMA survey were able to differentiate between extra followup visits they would like to have provided and extra visits that they actually realized, after other independent impacts on visits were taken into account. If, for example, the demand for visits declined over the period, physicians might have ordered more follow up visits for defensive reasons but nevertheless actually provided fewer net visits overall. To accept this possibility y, one would have to believe that physicians responding to surveys could accurately estimate the partial impact of their defensive behavior on the volume of visits.

2 The assumption implies a linear relationship between the frequency of the cited practices and the level of malpractice insurance Premiums, with the graph of the line intersecting the y-axis at the origin. Because ordering extra tests, procedures, and visits does not cost physicians money and is often financially remunerative, there is no reason to believe that as malpractice premiums decline, the motive to practice defensively declines in a linear fashion to the origin. Indeed, one would expect that physicians in 1984 were practicing on the "flat of the curve" where they were already as defensive as they knew how to be. Thus, to the extent that their reported 1984 behavior changes reflect reality, the linearity assumption would understate the amount of defensive medicine. On the other hand, practice changes that take up more time (such as increased time with the patient) would increase the physician's costs and presumably be more directly responsive to increases in premiums. Whether the relationship is linear or not is unknown.

3 The malpractice premium used in the regression analysis was an estimated value based on a first-stage regression of premiums on demographic characteristics, the status of various malpractice reforms in the physician state, and the malpractice claim frequency in the state. This two-stage method of estimation is referred to as the *instrumental variable* technique. The rationale for such an approach is to make the instrumental variable (premiums m this case) a better measure of the actual variable (malpractice risk in this case) than it would be were the actual value used in the regression.

els of use of the most important services studied. Table J-2 summarizes the results for each service.

Reynolds took the findings presented in table J-2 as the basis for estimating what utilization and fees would have been if malpractice insurance premiums (and, presumably, malpractice liability risk) had been zero in 1984. These rates were compared with actual reported utilization and fees to obtain an estimate of the impact of premiums on physician revenues.

The eight services chosen for the analysis represented about 70 percent of the average revenues of self-employed physicians in 1984. Without any malpractice insurance premiums, these revenues would have been reduced (according to the regression estimates) by 11.2 percent of average revenues. In the aggregate, a reduction of 11.2 percent in average physician revenues represents an $8.4 billion saving in expenditures if there were no malpractice insurance premiums (and presumably no malpractice liability system). If the services constituting the 30 percent of average revenues not studied by Reynolds were influenced by premiums to the same extent as the eight studied, the physician revenues saved by no malpractice liability would amount to $12.1 billion in 1984.

The most striking feature of this analysis is that virtually all of the impact on cost comes through increased fees, *not* through increases in utilization of procedures. In fact, utilization of most of the procedures studied appeared to be reduced by higher malpractice insurance premiums. Any pos-

TABLE J-2: Effects of Professional Liability Premiums on Physician Fee and Utilization Levels, 1984

Procedure	Coefficient	Standard Error	% change in fee or utilization per % change in premiums*
Fees			
Established patient office visit	O 85	0 17b	O 272
New patient office visit	1 16	0 .37b	0212
Followup hospital visit	1 18	0 .22b	0340
Electrocardiogram	148	0 .46c	O 205
Obstetric care, normal delivery	2224	4 .53b	O 427
Hysterectomy	2538	5 .74b	0349
Hernia repair	311	566	0069
Cholecystectomy	-238	860	-0033
Monthly utilization			
Established patient office visit	-6641	28 .97b	-0171
New patient office visit	-1381	7 .33c	-0209
Followup hospital visit	-4515	20 .84b	-0297
Electrocardiogram	606	3499	0073
Obstetric care, normal delivery	146	1 31	0168
Hysterectomy	-049	063	-0276
Hernia repair	-051	1 12	-0224
Cholecystectomy	070	095	0217

*The premium levels used in the computation are the averages for the specialties used in estimating the premium effect for each procedure For patient visits these include all specialties except radiology, psychiatry, pathology and anesthesiology for electrocardiograms general family practice and internal medicine for obstetric care and hysterectomies, obstetrics-gynecology, and for hernia repairs and cholecystectomies, general surgery

b Indicates regression coefficient is different from O at the 01 significance level

cIndicates regression coefficient is different from O al the 10 significance level

SOURCE R A Reynolds J A Rizzo and M L Gonzalez "The Cost of Medical Professional Liability *The Journal of American Medical Association 257(20) 2776-2781,* May *22/29 1987* table 2

itive effects of malpractice risk on defensive medicine are apparently overshadowed by the negative effect of malpractice risk on demand that results from the higher fees that physicians with higher malpractice risk charge their patients. Thus, if the statistical analysis is correct, high malpractice risk depresses the demand for services as much as or more than it increases defensive medicine.

The method underlying the estimates is based on a standard econometric technique, but as with all econometric analyses, the results might be sensitive to the specification of the statistical model and the ability to measure the relevant variables.[4] Just how sensitive they might be is impossible to tell without more analysis of the quality of the premium measure of malpractice risk or corroborating evidence from other analyses.

To turn the results of the statistical analysis into an estimate of the net costs of the malpractice system, the authors assumed that the relationship between malpractice insurance premiums and practice fees and volumes is linear throughout the range of potential premiums. The assumption that defensive medicine or other practice changes decline in lock-step linear fashion with declines in premiums all the way to the point of zero premiums is unlikely to be accurate, for reasons discussed above. Thus, OTA is unable to verify the accuracy of the estimates derived from the second method.

Even if the total cost estimates are accurate, they do not allow any inferences about the extent or cost of defensive medicine, whose practice is embedded in a larger set of utilization changes resulting from the malpractice system. High or low rates of defensive medicine are equally consistent with the results of the statistical model.

LEWIN-VHI ESTIMATES

Lewin-VHI began with the Reynolds" estimates of the cost of the malpractice system (an average $18.8 million in 1991 constant dollars) and added another $6.1 billion for extra costs incurred in hospitals. Lewin-VHI obtained this hospital cost estimate by assuming that the cost of hospital professional liability in excess of hospital malpractice insurance premiums ($2.7 per dollar of premium) was the same as the ratio of physicians costs to physicians' premiums estimated in the Reynolds study.[5] The preliminary total cost of malpractice—**$24.9** billion in 1991—was then reduced by three percentages (80, 60, and 40). This produced "low,"($5 billion) "medium" ($10 billion) and '*high" ($1 4.9 billion) final estimates of the net costs of defensive medicine to the health care system in 1991. The adjustments were made because Lewin-VHI researchers wanted to exclude that portion of defensive medicine not caused solely by liability concerns.

To help justify their estimates, Lewin-VHI researchers described three technologies whose utilization may be influenced by malpractice risk: electronic fetal monitoring in labor and delivery, skull x-rays in emergency rooms, and preoperative laboratory testing.[6] Lewin-VHI researchers concluded that the low estimate of defensive medicine costs ($5 billion) represents a reasonable lower bound on defensive medicine costs based on a brief review of the literature on "unneces-

[4] For example, the assertion that individual physicians premiums are a good measure of liability risk using the instrumental variables technique cannot be assessed with the information presented in the paper or its unpublished technical appendix Recent research suggests that if an instrumental variable is not a good one, it can lead to misleading and biased results (173,213). The authors had a measure of claim frequency available to them, which they might also have used as a direct measure of malpractice risk. Whether these factors would change the results is impassible to know without carrying out such analyses.

[5] Lewin-VHI obtained this ratio (2.7) from AMA researchers; it is lower than the ratio published in the Reynolds study (3,2).

[6] For example, the authors cited one study of preoperative tests that claimed about $2.7 billion extra is spent each year for unnecessary preoperative testing (138). Because doctors typically do not gain financially from ordering such tests, the Lewin-VHI authors concluded that an appreciable portion of these costs results from fear of malpractice liability (125).

sary" use of these three procedures. Lewin-VHI offered no justification for the upper bound of the range.

Although the Lewin-VHI researchers acknowledged the great uncertainty surrounding any estimate of defensive medicine, the objective basis for their specific adjustments from the Reynolds estimate is weak. The evidence presented in the three clinical examples used for the lower bound estimate does not necessarily reflect the percentage of unnecessary procedures motivated solely (or even primarily) by fear of malpractice liability. Also, the estimates of the number of unnecessary procedures in the studies cited by Lewin-VHI were based on small and sometimes subjective assessments. Finally, they represent only three relatively narrow areas of medicine.

To summarize, Lewin-VHI began with the estimates by Reynolds and colleagues, whose accuracy is unknown and unverifiable, and then made downward adjustments using a fragile base of evidence. Consequently, the Lewin-VHI estimate is not a reliable gauge of the possible range of defensive medicine costs.

Appendix K: Glossary

Accelerated compensation events (ACE)
A set of medical injuries deemed to be statistically "avoidable" with good medical care which would be compensated under a limited no-fault claims resolution system.

Affirmative defense
A response by the defendant in a legal suit that, if true, constitutes a complete defense to the plaintiff's complaint.

Alternative dispute resolution (ADR)
A process outside the judicial system for resolving legal claims. Decisions are made by dispute resolution professionals. ADR can be binding or nonbinding (see *arbitration).*

American Medical Association/Specialty Society Malpractice Liability Project (AMA/SSMLP) Administrative System
A proposed alternative to the malpractice system in which the medical licensing boards in each state would decide medical malpractice cases based on fault (negligence), using an administrative process designed to be more abbreviated and less costly than the current malpractice system.

Arbitration
A form of ADR in which the parties agree to have one or more trained arbitrators hear the evidence of the case and make a determination on liability or damages. The rules of evidence and other procedural matters may often be specified by the parties. There are two types of arbitration: binding and nonbinding. In binding arbitration the arbitration decision is subject to very limited judicial review. If arbitration is nonbinding, the parties may proceed to trial if they are not satisfied with the outcome of the arbitration. Some states require parties to submit a claim to nonbinding arbitration before trial (see also *pretrial screening).*

Attorney fee limits
Legislation that either limits a plaintiff attorney fees to a set percentage of the award or allows for court review of the proposed fee and approval of what it considers to be a "reasonable fee."

Awarding costs, expenses, and fees
Statutes that provide that the losing party in a frivolous suit may be required to pay the other party's reasonable attorney and expert witness fees and court costs. These provisions are designed to deter the pursuit of frivolous medical injury claims.

Caps on damages
Legislative limits on the amount of money that can be awarded to the plaintiff for economic or noneconomic damages in a personal injury claim. such as medical malpractice. The limit is imposed regardless of the actual amount of economic and noneconomic damages.

Certificate of merit
As a prerequisite to filing suit, some states require that a plaintiff obtain a written affidavit from an independent physic i an attesting that the plaintiff suit has merit. This provision is designed to limit nonmeritorious suits.

Claim frequency
A rate expressing the frequency with which physicians are named in malpractice claims. It is usually expressed as the number of malpractice claims per 100 physicians per year.

Collateral source rule
A rule of evidence that prohibits the introduction at trial of an y evidence that a patient has been compensated or reimbursed for the injury from any source (e.g., health or disability insurer). Legislation modifying the collateral source rule has taken two basic approaches: 1) permitting the jury to consider the compensation or payments received from some or all collateral sources and decide whether to reduce the award by the amount of collateral sources; or **2)** requiring a mandatory offset against any award in the amount of some or all collateral source payments received by the plaintiff.

Confidence interval
An interval that contains, with certain probability, the true value of a statistic. The mean is a typical statistic. The true mean lies within the bounds of the 95-percent confidence interval in 95-percent of all samples.

Correlation
A statistic that gauges the strength of association between two variables. The value of a correlation coefficient usually ranges from a minimum of zero (no association at all between the two variables) to a maximum of one (perfect association between the two variables). Some correlation coefficients also have a sign indicating the direction of association between the two variables: a positive sign indicates direct association (as one variable increases in value. the other also increases); and a negative sign indicates inverse association (as one variable increases in value, the other decreases).

Damages
See *economic damages* and *noneconomic damages.*

Defensive medicine
The ordering of extra tests, procedures, and visits or the avoidance of high-risk patients or procedures primarily (but not necessarily solely) to reduce their risk of malpractice liability. The performance of extra procedures for defensive purposes is positive defensive medicine. Avoidance of high-risk patients or procedures is negative defensive medicine.

Difference-of-means test
A test of the statistical significance of the difference between two groups in their mean scores on a single variable.

Direct malpractice costs
The net costs of compensating injuries through the medical malpractice system, including costs borne by malpractice insurers, defendants, and plaintiffs.

Discovery
Pretrial tools for obtaining information in preparation for trial. The tools include written and oral questioning of relevant parties, requests for documents, and physical examination of evidence and physical premises. The process of discovery is governed by federal and state rules of civil procedure.

Economic damages
Monetary damages that compensate the plaintiff for his or her actual economic losses—i.e., past and future medical expenses, lost wages, rehabilitation expenses, and other tangible losses,

Enterprise liability
A system under which a health care institution or health insurance plan assumes full legal liability for the actions of physicians acting as their agents, and individual physicians cannot be named as defendants.

Error in judgment rule
An exception to the general requirement that the physician must meet the prevailing standard of care provided by his or her profession. A physi-

cian's conduct will not be judged to fall below the standard of care if the physician chooses between two or more legitimate choices of treatment, even though a better result might have been obtained with a different treatment.

Guidelines
Generally referring to clinical practice guidelines, which are defined by the Institute of Medicine as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. " However, ● 'guidelines" in some cases refers to clinical practice guidelines developed with additional goals explicitly in mind, such as cost containment or reduction of defensive medicine.

Health maintenance organization (HMO)
A health care organization that, in return for prospective per capita payments (cavitation), acts as both insurer and provider of comprehensive but specific health care services. A defined set of physicians (and often other health care providers such as physician assistants and nurse midwives) provide services to a voluntarily enrolled population. Prepaid group practices and individual practice associations, as well as ● 'staff models," are types of HMOs.

Iatrogenic injury
Unintended, detrimental effects on a patient's health as a result of medical care. The term is commonly applied to secondary infections, adverse drug reactions, injuries, or other complications that may follow treatment.

Indirect malpractice costs
A cost of the malpractice system that is not directly associated with the compensation of persons injured by medical malpractice. Defensive medicine is an example of an indirect cost of the malpractice system (see *defensive medicine,* compare *direct malpractice costs).*

Informed consent
As applied to clinical care, a patient's agreement to allow a medical procedure based on full disclosure of the material facts needed to make an informed decision. The required elements of disclosure differ from state to state.

Joint and several liability
A rule under which each of the defendants in a tort suit can be held liable for the total amount of damages, regardless of his or her individual responsibility. In other words, even if a defendant was only 20 percent responsible, he or she could be held liable for 100 percent of the damages if other defendants are unable to pay. Several states have eliminated joint and several liability for medical malpractice so that physicians are liable only in proportion to their responsibility.

Low osmolality contrast agent (LOCA)
A contrast agent is a substance that is used to improve the visibility of structures during radiologic imaging-e. g., angiography, intravenous urography, or computerized tomography (CT) scans. A low osmolality contrast agent has an osmolality (i.e., concentration of dissolved particles in solution) that is closer to the osmolality of body fluids than the osmolality of traditional contrast agents.

Malpractice cost indicators
Factors that reflect direct costs of the medical malpractice system, such as claim frequency, payment per paid claim, and malpractice insurance premiums (see *direct malpractice costs).*

Multivariate analysis
Statistical analysis of three or more variables simultaneously. The most widely used form of multivariate analysis is multiple regression analysis, in which a single dependent variable (the presumed effect) is analyzed as a function of two or more independent variables (presumed causes).

Negligence
In medical malpractice, conduct that falls below the prevailing standard of care in the medical profession (see *standard of care).*

No-fault compensation program
A malpractice reform under which certain medical injuries would be compensated regardless of whether they are caused by negligence. This reform

would be administered in a manner analogous to worker's compensation programs in the states.

Noneconomic damages
Monetary damages that compensate the plaintiff for "pain and suffering," which includes:

- tangible physiologic] pain suffered by a victim at the time of injury and during recuperation,
- the anguish and terror felt in the face of impending death or injury,
- emotional distress and long-term loss of love and companionship resulting from injury or death of a close family member, and
- loss of enjoyment of life by the plaintiff who is denied pleasures of a normal person because of physical impairment.

Normal distribution
A bell-shaped frequency distribution of the values of a variable, so that most of the values fall in the middle of the distribution and few of them fall at the extremes.

Odds ratio
The ratio of the odds of an event occurring under one set of circumstances to the odds of the event occurring under mother set of circumstances.

Patient compensation fund (PCF)
A go~'ernment-operated" mechanism that pays the portion of any judgment or settlement against a health care providcr in excess of a statutorily designated amount. A PCF may pay the remainder of the award or it may have a statutory maximum (e.g.. $1 million).

Payment per paid claim
The average dollar amount awarded to plaintiffs for claims that result in payment.

Periodic payments
Payments to the plaintiff for future damages made over the actual lifetime of the plaintiff or for the actual period of disabi lity rather than in a prospective lump sum.

Point estimate
A sample-based estimate of the true population value of a statistic-e. g., the mean of a variable (see also *confidence interval).*

Pretrial screening
An alternative dispute resolution procedure that parties use prior to filing a legal suit. The pretrial screening panel usually comprises health care professionals, legal experts, and sometimes, consumers. The panel hears the evidence, including expert testimony, and makes a finding on liability and, in certain cases. on damages. Pretrial screening may be voluntary or mandatory, as specified by legislation. The panel decision is not binding on the parties, so parties may continue to pursue claims through the legal system.

Punitive damages
Monetary damages awarded when the defendant conduct is found to be intentional, malicious, or outrageous, with a disregard for the plaintiffs well-being. (Punitive damages are rarely awarded in malpractice suits.)

Reliability
The reproducibility of a measure. A measure is reliable if it yields similar results each time it is used on similar samples, or if its components yield similar results for the same or similar samples (compare *validity).*

Res ipsa loquitur
A legal doctrine that allows plaintiffs with certain types of injuries to prevail without having to introduce expert testimony of negligence. (Literall y, '*the thing speaks for itself.") A plaintiff must establish that the procedure or incident causing the injury was under the exclusive control of the physician and that such injuries do not occur in the absence of negligence.

Respectable minority rule
An exception to the general rule that a physician must meet the prevailing standard of care provided in his or her profession. A physician is shielded from liability when his or her clinical decision is consistent with the practices of a minority of physicians in good standing.

Right of subrogation
A provision typically found in health and disability insurance contracts that requires a plaintiff to reimburse the insurance company for any pay-

ments received from the tort system that were for services reimbursed by the insurer.

Scale
A composite statistical measure comprising several variables.

Schedule of damages
A set of guidelines for juries to use in deciding appropriate awards for noneconomic damages in malpractice cases.

Standard of care
A legal standard defined as the level of care provided by the majority of physicians in a particular clinical situation. In a malpractice action, a physician's actions are judged against the prevailing standard of care. Negligence is defined as failure to meet the standard of care.

Statistical significance
A statistically significant finding is one that is unlikely to have occurred solely as a result of chance. Throughout this report, a finding is considered to be statistically significant if the probability that it occurred by chance alone is no greater than five out of 100—i.e., a "p value" of 0.05 or less.

Statute of limitations
A legal rule that determines how long after an injury one can bring a lawsuit-e. g., t wo years after the injury. In many states, the "clock" does not start until discovery of the injury. The *discovery rule* states that the date of injury, from which the statutory time period is measured, is the date that it was reasonable for the plaintiff to have discovered the injury rather than the actual date of injury. Injuries may be discovered years after the treatment was provided, so the time period for filing action may be uncertain.

Stratified random sampling
A method of drawing a random sample from a population that has been grouped by population characteristics.

Tort law
A body of law that provides citizens a private, judicially enforced, remedy for injuries caused by another person. Legal actions based in tort have three elements: existence of a legal duty from defendant to plaintiff, breach of that duty, and injury to the plaintiff as a result of that breach.

Tort reform
A legal reform that changes the way tort claims are handled in the legal system or removes claims from the civil judicial system.

Tort signal
Direct or indirect signals from the malpractice system that apprise physicians of their liability risk (e.g., litigation exposure of self or peers, malpractice insurance rates, professional literature and popular media).

Unweighed results
Statistical results based on a disproportionate stratified sample (see *stratified random sampling)* without applying sampling weights (see *weight).*

Validity
Broadly, the extent to which an observed situation reflects the true situation. *Internal* validity is a measure of the extent to which study results reflect the true relationship of an intervention to the outcome of interest in the study subjects. *External* validity is the extent to which the results of a study may be generalized beyond the subjects of the study to other settings, providers, procedures, diagnostics, etc. (compare *reliability).*

Weight
A multiplier applied to each element of a given stratum of a sample (see *stratified random sampling) so* that the sample accurately represents the population from which the sample was drawn. A weight can be thought of as the number of members of the population represented by each respondent.

Weighted results
Results to which sampling weights have been applied (see *weight).*

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Index

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