

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 [the 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, 211 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 (190).

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 981 (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 (113). 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 (132). Additional incentives and dissemination tactics may be needed to change physician behavior in 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 (100).

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 in court. It is unclear how this decision will affect [the admissibility of clinical 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 of clinical situations (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 may be 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-1). 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 -

⁸42 U.S.C. Sec. 1326(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, intraoperative, 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

⁹It 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 com-

plications 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 not.¹⁵

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 (85,199), 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 States*, 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 (Cal. 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 (33,188). 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.