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Stroke and the Law Principles and Practice

Mark Fisher, MD; Peter Schneider, JD

It is difficult to assess whether stroke neurology is disproportionately affected by the often adversarial relations between physicians and attorneys. Nevertheless, expansion of therapeutic options for patients with stroke has created increased potential for litigation. To address this issue rationally and productively, the stroke clinician must understand some fundamental principles of legal medicine. Knowledge of these principles will allow for their practical application to clinical settings and issues.

The purpose of this article is to describe some key fundamentals of legal medicine as applied to stroke neurology in the United States. Hypothetical cases are presented, allowing for application of theory to practice. In addition, selected topics in stroke neurology will be reviewed.

Competency

Competency (which may be referred to as *capacity* in some states) is a critical concept that allows for establishment of a vast array of legally recognized relationships. Competency is defined as the minimal mental ability necessary to perform a legally recognized act, or assume a legally recognized role.¹ Competence is considered task specific, so that competence for medical decision making may differ from competence for creating a will.¹ Competence is readily distinct from *sanity*, and an individual who does not meet the legal test of competency is considered incompetent.

Competency for medical decision making is generally determined by meeting a 3-part test: (1) the patient must be able to understand the treatment that is offered, (2) the patient must be able to decide to accept or reject the offered treatment, and (3) the patient must be able to communicate that decision. For competency to be established, all 3 elements must be met.¹ These elements can be quickly recalled by simply remembering that competency requires that the patient be able to understand, decide, and communicate.

Hypothetical No. 1

Patient A has sudden onset left middle cerebral artery syndrome. He becomes globally aphasic and hemiplegic. Is this patient competent to make medical decisions?

Answer

No. The presence of receptive aphasia precludes understanding the medical options, and expressive aphasia prevents communicating any decision regarding those options. For this case, the answer is simple: the patient is not competent to make medical decisions.

Physician–Patient Relationship

The *physician–patient relationship* (PPR) is an infrequently used term in medical circles. However, it represents an essential concept for understanding legal medicine, because it forms the basis of a legal duty (ie, obligatory conduct) that a physician has to a patient. Without this relationship, there is no legal duty and therefore no potential liability for breach of a duty.

In general, a physician does not have an affirmative duty to treat an individual. In other words, physicians do not have a duty to treat strangers. One may of course argue that physicians have an ethical duty to do so, but from a medical–legal perspective, there is generally no duty to treat in the absence of a PPR.

A PPR usually requires some form of physical contact between physician and patient, during which the formalities of the doctor–patient relationship are established.² However, telephone and, increasingly, internet contact are acceptable bases to establish a PPR. The PPR is generally considered a contract between doctor and patient, and this contract may be in writing or implied based on the circumstances and actions of the individuals seeking and providing medical care.²

The key consideration for establishing whether a PPR exists is whether the circumstances of the doctor–patient interaction create a reasonable expectation of treatment for the patient.² Alternately, a PPR exists when a physician initiates treatment, the latter defined broadly to include examination and diagnosis. Once established, a PPR continues as long as physician services are needed, or until the PPR is terminated. Termination of the PPR must be done appropriately (eg, treatment completion, mutual consent, or transfer

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to another physician), and failure to do so may constitute abandonment.²

Hypothetical No. 2

Patient B is at a cocktail party and a physician is pointed out to him. B approaches the physician and tells him that this morning he awoke with symptoms of right-sided weakness and difficulty speaking, clearing within an hour. The physician says nothing and walks away. What are the legal consequences?

Answer

In this classic cocktail party consult, there is no PPR, and therefore the physician is under no legal duty to provide advice or treatment of any kind. This interaction is ethically questionable to be sure, but from a medical–legal perspective, it is not problematic.

Defining the presence or absence of a PPR can sometimes be difficult. Telephone or telemedicine consults are good examples of potentially ambiguous situations. The existence of a PPR is based on the specific details and circumstances of those interactions.

Hypothetical No. 3

Patient C goes to her local emergency room for symptoms of hyperacute stroke. There is no neurologist on call, and the emergency room physician calls a university stroke center for input. After speaking with the university stroke neurologist, the patient is treated with intravenous tissue-type plasminogen activator (tPA). Unfortunately, the patient has a hemorrhagic complication, and it is later learned that the time of stroke onset placed the patient outside the window for tPA. What is the liability for the university stroke neurologist?

Answer

Liability will depend first on whether a PPR was established, and this requires knowing additional details of the case. Was there a contractual relationship between the local emergency room and the university stroke center? If so, there was a reasonable expectation of treatment, and the university stroke neurologist most likely had a duty to the patient and could be held liable for any errors in treatment. In determining whether there was actual liability, much will depend on the specifics of what was said between the 2 physicians. If the call to the stroke center was merely a spontaneous curbside consultation otherwise lacking in formalities, a PPR would arguably be absent, and it is unlikely that liability would be created.

Informed Consent

Informed consent is perhaps the most misunderstood concept in legal medicine. This uncertainty is based on confusion between the process of informed consent and its documentation. It is critical to understand that informed consent is first and foremost a process, a process that is typically documented by either an informed consent form or by entries made by a physician in the patient's medical record.

A physician is responsible for providing sufficient information so that a patient can make choices that are knowledgeable and informed. This physician duty to provide information goes well beyond simply offering to answer questions and involves

affirmatively providing the necessary information. Adequate informed consent is a fundamental basis for the practice of medicine and may be implicit or explicit, oral or written. For example, a patient presenting himself to a physician's office is considered to have implicitly agreed to a medical evaluation.

When obtaining consent from a patient, a physician is generally required to provide all information that a reasonable person (patient) would want to know under the circumstances to make an informed judgment. This information will typically include the diagnosis, nature and purpose of the proposed treatment, risks and consequences of proposed treatment, reasonable alternatives, and the likely outcome if recommended treatment is not provided.³ The legal consequence of a failure to obtain consent can be the characterization of any treatment rendered without consent as a legal battery. Because battery is considered intentional conduct, many, if not most, malpractice insurance policies exclude it from acts that are covered by the policy.

Informed consent obtained orally is generally valid. However, lack of written documentation may make the consent contestable, thereby creating an important incentive for obtaining written documentation. This phenomenon is the basis for the all-too-frequently asked physician question, "Do I need to obtain consent?" The simple answer is that consent is invariably necessary, but the physician generally has some discretion how consent will be documented.

The patient providing informed consent must be competent, as is the case in any medical decision making. Competency and informed consent are particularly important in stroke neurology, given the range of treatments that are available during a stroke emergency and the limited time available to institute these treatments. For a physician facing a stroke emergency involving a patient not competent to provide informed consent, substitute consent may be obtained, that is, consent provided on behalf of the patient by a family member (next of kin) who is expected to act in the best interests of the patient. Note that under nonemergency circumstances, substitute consent may require a court order.³

During an emergency, a family member may be unavailable for a patient who is not competent, and so substitute consent is not an option. Under those circumstances, a physician may have the ability to proceed with treatment on the basis of an emergency consent or implied consent. Implied consent again relies on the reasonable person standard, that is, would a reasonable person consent to treatment under the circumstances? If there is (reasonably) sufficient evidence to support the treatment plan, the physician may proceed, even if the evidence is less than definitive.

Hypothetical No. 4

Patient E, presenting with acute basilar occlusion, arrives in the emergency department an hour after symptom onset and head computed tomography performed promptly shows no hemorrhage. The patient is comatose, and no family member is available. How should the physician proceed?

Answer

If the patient meets standard inclusion criteria for treatment with intravenous tPA, the physician may proceed

under the legal theory of implied consent. In other words, a reasonable person would be expected to provide informed consent for thrombolytic treatment under these circumstances given the evidence of the treatment's effectiveness in acute ischemic stroke. For treatments that are unproven, the situation is less clear. For a commonly used but unproven modality such as endovascular therapy, it is (arguably) reasonable to proceed under implied consent in these dire circumstances.

Medical Malpractice

Medical malpractice, sometimes termed *medical negligence*, is a powerful presence in the minds of many physicians. Nevertheless, most physicians may be unable to articulate exactly what constitutes medical malpractice. A simple definition of malpractice is a breach of a physician's duty that causes foreseeable injury to the patient. The terminology of this definition demands expansion and scrutiny.

There are 4 key terms in the definition of medical malpractice: *duty*, *breach*, *injury*, and *causation*. These are the terms that must be understood to fully understand medical malpractice. In legal terms, they constitute the 4-part test to determine whether malpractice liability may exist.

The duty referred to in medical malpractice typically refers to the *duty of care*, in which a physician's behavior is expected to be reasonable, prudent, and consistent with the standard of care.⁴ The *standard of care* refers to physician behavior (not knowledge) as a generalist, specialist, or subspecialist, as is typically determined by expert testimony in the course of litigation. Treatment guidelines, when widely used and originating from authoritative sources, are often used to define standard of care. However, guidelines may not carry much weight if they originate from less-than-authoritative sources, have not been widely incorporated, or remain controversial. Moreover, there may be times when adherence to clinical guidelines is not appropriate, and the clinician must always exercise sound judgment in deciding what treatment is appropriate for a patient in any given circumstance. (Note that if a physician chooses to depart from guidelines, it is prudent to discuss this with the patient and report it in the treatment record.)

The question of duty is usually the first and principal part of any malpractice action. Although duty of care is most commonly cited, there are other duties that can be incorporated into questions of malpractice. Specifically, the duty to obtain informed consent and the duty to consult can be significant parts of medical litigation. As previously noted, for a duty to be present, there must be a PPR.

The term breach refers to a physician's act or omission. If such an act or omission results in a failure of duty, then the consequence is, in general legal terms, negligence. The breach can be of any duty, for example, duty of acceptable treatment or duty to obtain informed consent. A breach of duty is thus the initial component of any medical malpractice action and the first concept that must be considered to determine whether true medical malpractice has occurred.⁴

For medical malpractice to be present, the patient must have sustained some injury. This is the injury that has occurred in

the course of the contested treatment. The injury typically is persistent and substantial. Minor and transient injuries generally do not form the basis of medical malpractice.

The most complex component of the 4-part test for medical malpractice is causation, sometimes referred to as *legal* or *proximate cause*. For malpractice to be present, a causal link must be established between the breach of duty and the injury sustained. The concept of causation has 2 elements: *causation in fact* and *foreseeability*. Causation in fact provides specific linkage between the injury and the breach of duty. States have adopted different formulations for causation in fact, so that in California the breach of duty must be a substantial factor in the injury,⁵ whereas other states view the injury as something that would not have occurred but for (ie, in the absence of) the breach of duty. In addition, the injury must have been foreseeable by a reasonably prudent physician.⁴

In addition to the theoretical nexus between act and injury noted above, courts in most states generally require that error or omission be the cause of the injury to a *reasonable medical certainty* (ie, to a reasonable degree of medical certainty). For a medical certainty to be present, the nexus between event and injury must have been more likely than not, that is, greater than a 50% likelihood. In a substantial minority of jurisdictions, there is incorporation of a *loss of chance* doctrine, in which the injury to the patient is simply a reduction in the likelihood of a positive outcome⁶⁻⁹ (Table).

Table. Loss of Chance Jurisdictions

States Endorsing Loss of Chance	States Rejecting Loss of Chance
Arizona	California
District of Columbia	Florida
Illinois	Idaho
Indiana	Maryland
Iowa	Michigan
Kansas	Mississippi
Louisiana	New Hampshire
Massachusetts	Tennessee
Minnesota	Texas
Missouri	South Carolina
Montana	Vermont
Nevada	
New Jersey	
New Mexico	
Ohio	
Oklahoma	
Pennsylvania	
South Dakota	
Virginia	
Washington	
West Virginia	
Wisconsin	
Wyoming	

High courts of some states have either not directly addressed loss of chance or have deliberately left the issue open.⁶⁻⁹

Hypothetical No. 5

Patient F presents to the emergency room complaining of symptoms of acute onset chest pain and shortness of breath. He receives only a cursory examination, without chest x-ray or ECG, and storms out of the emergency room furious with the care he received. As a consequence, he is distracted while driving, loses control of his car, and sustains a neck injury producing carotid dissection and ischemic stroke. Is this medical malpractice?

Answer

Probably not. It appears that there was a breach of duty of care in the emergency room, and this eventually resulted in a carotid dissection and stroke. However, this sequence of events is arguably not reasonably foreseeable, and therefore malpractice would probably be considered absent. Note, however, that some states have expansive definitions of what is foreseeable, so that liability in this scenario may not be out of the question.

Hypothetical No. 6

Patient G, an 80-year-old woman, presents to her primary care physician with signs of atrial fibrillation. She has history of hypertension, diabetes mellitus, congestive heart failure, and has had a prior minor ischemic stroke. Despite absence of contraindications, she is not offered anticoagulation as treatment. She later sustains a major, disabling ischemic stroke. Is this medical malpractice?

Answer

The failure to offer anticoagulation to this patient with high stroke risk and no contraindications represents a breach of the duty of care. Her subsequent stroke is foreseeable and was preventable with anticoagulation, that is, but for the failure to provide anticoagulation, Patient G would not have sustained the stroke to a reasonable medical certainty. This is supported by the literature indicating reduction of stroke risk by $\approx 70\%$ with anticoagulation in atrial fibrillation.¹⁰ This scenario would qualify as medical malpractice.

The potential for liability for medical malpractice can be anxiety producing for the practicing physician. Examination of the facts of malpractice litigation is somewhat reassuring. As analyzed by Studdert et al,¹¹ in a review of nearly 1500 malpractice claims, 97% of malpractice claims involved an adverse outcome. Moreover, for most cases (73%) in which injuries occurred because of error, the plaintiff (the party bringing the lawsuit) received compensation. Nearly 80% of trial verdicts were won by the defense. Interestingly, in the presence of a medical error, there was a higher likelihood of no payment/compensation for plaintiff (16%), compared with the likelihood of payment in the absence of medical error (10%). Note that statutes of limitations for malpractice actions are jurisdiction dependent. In California, for example, malpractice actions need to be initiated within 1 year from the date that a person knew, or a reasonable person should have known, that an injury occurred, but no more than 3 years from the date of injury.¹²

Transient Ischemic Attack, Acute Stroke, and Medical Malpractice

The availability for tPA as an effective treatment for acute stroke has created an entirely new area for malpractice litigation involving use or nonuse of agents for acute stroke treatment, that is, intravenous tPA and intra-arterial interventions. During the often urgent discussions in the emergency room regarding treatment of a patient with acute stroke, the issue of litigation may be an implicit, unspoken part of the conversation. Litigation involving use of tPA has been the subject of several publications.^{13–16} In contrast, litigation issues involving the patient with transient ischemic attack (TIA) has received little attention.

For a stroke specialist to understand litigation risk inherent in a given clinical situation, it is essential to methodically analyze a case using the 4-part system described above: Is there a duty? Is there a breach (of duty)? Is there injury? Is there proximate causation? By doing so, the situation and risk can be understood with some precision.

Although it may seem counterintuitive, malpractice risk will probably be higher for the patient with TIA, compared with the patient with acute ischemic stroke. For a patient with TIA, a physician's duty of care is understood to consist of rapid evaluation and institution of treatment. If failure to do so is followed by a stroke, the causal link will be relatively easy to show. Stroke is a foreseeable consequence of failure to promptly institute treatment of TIA, and this causal link will be of relatively high likelihood. Given a literature reporting that promptly instituted TIA treatment reduces stroke risk by as much as 80%,¹⁷ the requirement that causation be to a reasonable medical certainty (ie, $>50\%$) is met in a relatively straightforward manner. Failure to properly initiate the necessary treatments to prevent stroke, when the standard of care is relatively clear-cut, will result in high physician risk for being a defendant in a successful action of medical malpractice.

For the patient with acute ischemic stroke, the issues are less clear. Malpractice risk associated with tPA treatment has received multiple reviews during the past decade. Weintraub¹³ reported 9 cases involving tPA use that went to trial during the first decade after the initial report of tPA's effectiveness,¹⁸ with trial outcomes evenly split between plaintiff and defense (4 each). An overarching issue for these cases was uncertainty regarding standard of care, not surprising given the relative novelty of acute stroke treatment with tPA at the time. It is noteworthy, however, that none of cases resulted in liability for a treating neurologist. Rather, plaintiff verdicts involved liability for emergency physicians, internists, and an expert witness.

Bambauer et al¹⁴ briefly alluded to 7 tPA cases that went to trial and eventually received appellate decisions, with 6 of the 7 cases resulting in a defense verdict. Liang and Zivin¹⁵ systematically reviewed the legal literature and identified 33 cases between 1999 and 2007, 30 of which had trial verdicts. Verdicts were for the defense in 64% of the cases. Notably, failure to provide tPA (88% of cases) and delay or failure to diagnose stroke (67%) were the most common claims by plaintiff, and only 6 cases (18%) involved a neurologist as defendant. Moreover, 10 of the 12 cases decided for plaintiff were based on failure to treat with tPA, whereas only 2 cases had claims of injury attributable to tPA treatment. The authors

concluded that litigation risk in acute stroke cases involving tPA was typically attributable to a delay or failure to make the correct diagnosis of stroke and failure to treat with tPA.¹⁵

Bhatt et al¹⁶ also conducted a systematic review of the legal literature, identifying 40 cases involving tPA use in patients with stroke between 1999 and 2010; verdicts were available on 38 of these cases. Remarkably, 95% of these cases involved either a failure to treat with tPA (28/40; 70%) or delay in diagnosis of stroke resulting in a loss of opportunity to treat with tPA (10/40; 25%). Approximately two thirds (26/40; 65%) of cases resulted in verdicts for the defense, 90% (36/40) of cases involved the hospitals as defendants, and 63% (25/40) had emergency room physicians as defendants. Only 20% (8/40) of cases had neurologists as defendants, and 6 of those 8 cases were defense verdicts. Thus, in only 5% of the cases was a neurologist liable for medical malpractice in an acute stroke case involving tPA treatment.¹⁶

From these analyses of tPA case litigation emerge a picture in which claims are typically based on failure to treat with tPA, with the defense prevailing approximately two thirds of the time. When physician liability does occur, it is usually in the absence of a neurologist defendant. This is occurring in a legal climate in which medical malpractice claims, when they are decided at trial, are usually defense verdicts.

For tPA cases in particular, there are other considerations that favor the defense. Specifically, as described earlier, causation standards usually require that injury be proven to a reasonable medical certainty or >50% likelihood. In other words, these cases are usually based on a claim that failure to treat the acute stroke patient with tPA caused injury to the patient to a reasonable medical certainty. This causation standard is difficult to reach, given a medical literature that emphasizes that only a minority of patients will actually benefit from tPA treatment. For example, a widely quoted recent meta-analysis reports that for patients with acute stroke treated within 3 hours, benefit for tPA in the form of the patient being alive and independent was demonstrable in 90 of 1000 patients treated, or 40.7% of patients treated versus 31.7% of patients untreated.¹⁹ For the more rigorous outcome of modified Rankin Scale of 0 to 1, the benefit was for 87 of 1000 patients treated, or 31.6% versus 22.9%. Although these are impressive figures from the perspective of clinical trials, they are less persuasive in courtroom litigation targeting physicians who did not treat acute stroke patients with tPA. Litigation involving failure to treat the patient with TIA seems more likely to create vulnerability for the physician defendant, given the high efficiency of stroke prevention efforts in this population.¹⁷

This legal climate favoring physician defendants may be changing, particularly given what appears to be a generalized increase in litigation involving tPA treatment in acute stroke.^{15,16} More states are relying on the relatively relaxed causation standard of loss of chance,⁶⁻⁹ which is likely to substantially impact outcome in tPA cases. Here, the stroke literature is more supportive of the notion that failure to treat the patient with acute stroke resulted in injury because the patient was deprived of an opportunity to obtain a good outcome from the treatment, regardless of whether the likelihood was <50%.

The relative paucity of neurology defendants in tPA cases is also consistent with the notion that what drives this litigation is a loss of chance for a good outcome, with loss of chance based on failure to treat with tPA as well as failure to engage the proper expert (ie, a neurologist) in the care of the patient with acute stroke.

Hypothetical No. 7

Patient H is brought to his local emergency room with stroke symptoms beginning 1 hour earlier, and head computed tomography is normal. A hospital neurologist is not available, and the emergency physician attempts but is unable to contact a neurologist at a nearby university hospital. The patient meets all inclusion criteria for treatment but does not receive tPA and has a poor outcome. Is this medical malpractice?

Answer

The legal question will revolve around whether the failure to treat with tPA caused the poor clinical outcome. To a large extent, the legal outcome may depend on where the case occurred and its causation standard. If there is reliance on causation to a reasonable medical certainty, the standard requirements for determining malpractice would not be met because the breach of duty of care (ie, failure to treat with tPA) cannot be shown to legally cause the injury. However, if the case occurred in a loss of chance jurisdiction, the 4-part requirements for malpractice would be met and the physician would be at considerable risk for liability.

Conclusions

Legal aspects of stroke are based on simple principles involving competency, PPR, and informed consent. These principles form the basis of physician duty to the patient. Ultimately, it is the failure of physician duty that creates the basis for medical malpractice.

For the physician, medical malpractice is the most feared legal issue in stroke neurology. The risk for malpractice is largely seen from the perspective of treatment with tPA for acute stroke. Review of acute stroke cases that have gone to trial indicate that it is failure to treat with tPA, rather than hemorrhage as a consequence of tPA treatment, that is the basis of most litigation. These cases, when they do go to trial, are typically decided for the defense, and neurologists are implicated relatively rarely.

Litigation risks in acute stroke treatment may substantially depend on where they occur. States that rely on a loss of chance causation standard will have an environment in which risk for litigation may be higher than those states relying on the more traditional to a reasonable medical certainty standard. Perhaps ironically, for the stroke neurologist, it is the patient with TIA who creates a greater litigation threat than does the patient with acute ischemic stroke.

Disclosures

The views expressed herein are those of the authors and not those of the Regents of the University of California. Dr Fisher has served as expert witness in medical malpractice cases. Dr Schneider reports no conflicts.

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