Hot Topics in Risk Management in Neurologic Practice

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• Physician liability

Physicians practice medicine within a legal environment. Generally speaking, when judging the actions of physicians, the law uses the customs and values of the medical profession as reference points. Nevertheless, caring for patients with neurologic disease requires an understanding of certain aspects of civil law. This is especially true in selected types of interaction between physicians and neurologic patients, including obtaining informed consent, treatment of acute stroke with tissue plasminogen activator (tPA), reporting drivers with dementia, reporting drivers with epilepsy, and assessing the capacity to vote for those with dementia. This article provides a brief survey of these areas. In each instance, the neurologist is encouraged to become familiar with the laws in his or her own state.

INFORMED CONSENT

The concept of informed consent developed out of courts' respect for the principle of patient autonomy and the right to be free from nonconsensual interference with one's body.[1] The physician's duty to obtain informed consent notably extends beyond the acquisition of a patient's signature on a consent document. Physicians instead meet the terms of informed consent by ensuring that patients receive the appropriate amount of information before agreeing to treatment.

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In the United States, courts have historically used two standards to determine whether a physician has conveyed enough information to the patient for the consent to be informed. Under a physician-based standard, a court will seek to determine the information a similarly-situated physician would usually find necessary to convey to a patient in order for the patient to fully understand the issues in the decision at hand. Courts in other states measure informed consent against a reasonable patient standard by asking what information a similarly situated patient would want to know before treatment.[1]

The physician-based standard resembles the malpractice standard, asking what a similarly situated, reasonable practitioner would do. Under this standard, trial counsel will introduce expert testimony from other physicians (expert witnesses) to demonstrate the amount and kind of information reasonable physicians feel would be necessary before a patient could make a particular medical decision.

In contrast, the reasonable patient standard maintains that a patient's need for disclosure of information material to treatment should take precedence over medical expediency[2] and is a logical extension of the desire to protect patient autonomy. The reasonable patient standard asks physicians to take account of a patient's particular circumstances in assessing the information material to treatment, rather than deferring to standards set by the medical profession.[3] Not surprisingly, courts are moving away from the physician-based standard in favor of the reasonable patient standard.[1] Currently, approximately half of states endorse the reasonable patient standard.[1]

Elements of Informed Consent

Whereas two standards measure the adequacy of information conveyed for informed consent, courts across jurisdictions consider some types of information essential. In general, physicians should fully communicate the relevant diagnosis with each patient. If an evaluation is required before a diagnosis is rendered, physicians should discuss the tests they recommend, along with their associated risks.[1] Additionally, physicians should always discuss the nature and purpose of the treatment they propose, along with the possible risks and outcomes. Whether physicians must mention a possible outcome varies with its severity and probability of occurrence. That is, while physicians probably do not need to mention a 5% chance of treatable infection, they should certainly warn of a 1% chance of paralysis.[1] Physicians should further fully disclose alternatives to treatment, prognosis if treatment is accepted versus declined, and any existing conflicts of interest. Courts have not typically required physicians to provide their particular success rates with the proposed treatment or procedure, but physicians are required to answer patients truthfully if asked.[1]

Liability for the Failure to Inform

There are considerable legal ramifications for the failure to provide satisfactory information to a patient before treatment. In addition to malpractice lawsuits brought by the patient, some courts have allowed third parties to bring suit against physicians when a patient has harmed the third party as a result of insufficient information. For example, in *Coombes v Florio*,[4] Dr Florio did not inform his patient, Sacca, that the medications he prescribed might cause drowsiness, dizziness, fainting, or altered consciousness. Sacca therefore did not have reason to refrain from driving. While on medications prescribed by Dr Florio, Sacca drove over a sidewalk, killing Coombes' son and Coombes sued Dr Florio for failing to warn Sacca about driving while on the medications. The Massachusetts Supreme Court allowed Coombes to sue Dr Florio for negligently failing to provide appropriate information to Sacca about driving while taking the prescribed medications. The Court noted that the doctor's duty of reasonable

care, owed to a patient, includes the duty to provide appropriate warnings about side effects so a patient may make an informed decision about taking the prescribed medication and what activities to avoid when doing so. The Court then reasoned that because the foreseeable risk of injury is not limited to the patient, affected third parties may bring suit against the physician.[4]

The Coombes decision does not change informed consent requirements for physicians, but does broaden the scope of who might be able to sue the physician for foreseeable injuries that result from a failure to inform a patient about the possible side effects of treatments or medications in the state of Massachusetts. At least two other states with cases on point have reached a similar conclusion.[5,6] It is too soon to say whether other states will adopt the rationale used in Coombes. No matter to whom the duty of informed consent extends, physicians should discuss the risks, benefits, and side effects of recommended treatments with their patients. The physician should provide the patient with adequate time to ask questions and document the discussion in the medical record.

LIABILITY FOR TPA DECISIONS IN ACUTE STROKE

In light of mixed opinions regarding the risks and benefits of intravenous thrombolysis with recombinant human tPA, many physicians have expressed concern that tPA use or non-use may expose them to legal liability.[7–9] The following presents two important elements of malpractice law that arise in tPA cases, standard of care and causation, and discusses how courts have analyzed those elements to reach a decision on physician liability for tPA decisions.

Standard of Care and Causation with Respect to tPA

In medical malpractice cases, the injured plaintiff has the burden of proving that the defendant physician's conduct violated the applicable standard of care. The standard of care in medical malpractice cases is generally thought to mean what most similarly situated physicians, practicing in the same specialty or subspecialty, would have done in similar circumstances.[10]

There are two clinical practice guidelines concerning tPA that may be used by expert witnesses to define the standard of care when they testify in malpractice cases. The American Academy of Neurology (AAN) Practice Advisory on Thrombolytic Therapy for Acute Ischemic Stroke[11] and the American Heart Association (AHA) Guidelines for the Early Management of Adults with Ischemic Stroke[12] support the use of intravenous tPA for acute ischemic stroke, with certain inclusion and exclusion criteria. However, the North American Emergency Medicine Physician organizations have issued position statements concluding that tPA should not be considered standard of care,[13] suggesting its use be restricted to medical centers with a specific stroke therapy infrastructure.[14]

If the guidelines can be used as evidence of the applicable standard of care in these cases, it seems reasonable to conclude that a neurologist would be expected to use the drug in the appropriate circumstances and that an emergency medicine physician would not be expected to use the drug—all things being equal. Thus, a plaintiff who is suing an emergency medicine physician for failing to use tPA might have a more difficult time proving that the doctor violated the standard of care than would a plaintiff who was suing a neurologist for the same reason.

This is not to say that a neurologist who does not give tPA to an otherwise qualified patient must be considered to have breached the standard of care. If that neurologist could show that a significant minority of neurologists would not have given tPA in the

same or similar circumstances, then his actions may be considered to have met the standard of care. This follows what is known as the respectable minority rule.[15] To prove this case, a neurologist would have to establish that there is reason to doubt the validity of the underlying data supporting the use of intravenous-tPA in acute stroke. This is becoming more difficult in light of a recent randomized, controlled trial confirming the drug's safety and efficacy[16] and population-based studies showing that the drug is as beneficial in community practice as it is in the research setting.[17,18]

The other pivotal element of malpractice claims regarding the administration of tPA is causation. If a jury were to find that a physician breached the standard of care by not offering tPA to the patient or plaintiff, the plaintiff must still prove that the failure to give tPA was the cause of the injuries.

In medical malpractice cases, a plaintiff traditionally demonstrates legal causation by showing that there is a greater than 50% chance that defendant's conduct was a substantial factor in producing the injury in question.[19] However, 20% to 38% of stroke patients will be asymptomatic, or almost so, at 3 months if they receive no treatment.[20] With treatment, 31% to 50% of patients will be asymptomatic, or almost so, at 3 months. Because there is a less than 51% chance of recovery with or without treatment, it would be very difficult in an individual case to say that the defendant's conduct caused the plaintiff's ultimate condition.

However, some jurisdictions do not employ the traditional method of assessing causation that requires a greater than 50% chance the physician substantially contributed to the outcome. Some jurisdictions have allowed a plaintiff to recover for the lost opportunity to achieve a better outcome. Under this loss-of-chance theory of causation, a plaintiff may recover for the reduction in his or her chances of achieving a better outcome, rather than for the outcome itself.[21]

Whether a plaintiff whose chances of a better outcome are slim will be able to recover for the lost opportunity occasioned by a defendant's negligent conduct is dependent in large part (but not exclusively) on whether that case arises in a jurisdiction that follows the traditional causation analysis or if it is brought in a jurisdiction that will allow the plaintiff to present evidence of, and recover for, the lost opportunity. In general, over half the states allow evidence of lost opportunity to be presented, while a smaller minority hews to the traditional causation analysis.[22]

Analysis of Trials and Appeals

A search of all state and federal court cases involving the use or non-use of tPA for acute ischemic stroke reveals 20 cases at the trial court level and 6 appellate cases that involved malpractice suits for failing to use tPA in stroke. No cases were found in which physicians were sued for injury allegedly caused by giving tPA.

Of the 20 trial court verdicts, 5 were for the plaintiff, 14 were for the defendant, and one case did not reach the verdict stage at the trial level. Three trials involved a neurologist; juries found for the neurologist in all three. Plaintiffs found the most success when they named the hospital as a defendant, with courts finding for the plaintiff in 5 of 12 such cases. State-level trial courts do not typically issue written opinions, meaning that it is difficult to discern how the analysis proceeded in each of the trial verdicts.

One appellate case from Texas, *Young v Memorial Hermann Hospital System*, exemplifies how causation traditionally plays out in tPA cases.[23] In that case, a 37-year-old male suffering from altered mental status was brought to the emergency room at 21:15 hours but was not diagnosed with stroke until 02:30 hours. The plaintiff sued, alleging the failure to timely diagnose his stroke precluded him from receiving tPA and experiencing a better outcome.[1] The court required the plaintiff to show

a 51% or greater chance of avoiding injury if tPA were administered in a timely manner.[1] In analyzing the plaintiff's evidence, the federal court noted that the absolute benefit of tPA in the National Institute of Neurological Disorders and Stroke trial was 11% to 13% and that a 1997 subgroup analysis found a 17% benefit of tPA in younger patients with lower National Institutes of Health stroke scale scores (in which group plaintiff would have been included). Because the plaintiff could not show that he had a better than 51% chance of avoiding his current condition with timely treatment, the defendants were entitled to a summary judgment in their favor (which precludes a jury from deciding the matter, among other consequences).[1] Of six total appellate tPA cases, three additional cases analyzed the causation requirement in a similar manner and held for the defendants.[24–26]

An appellate case from Kentucky illustrates one approach courts may take that increases the chances physicians will be found liable for failure to administer tPA. In *Lake Cumberland LLC v Dishman*, the plaintiff's expert witness testified that the plaintiff fell in a subgroup of persons that "within a reasonable degree of medical certainty" would have had a significantly better outcome had she been given tPA.[3,27] In effect, the expert witness performed an individualized assessment of the plaintiff's likelihood of improvement in relation to the published data in acute stroke cases to create a more-likely-than-not possibility that the plaintiff would have been better off with treatment. The plaintiff had undergone cerebral angiography for the complaint of worsening dizzy spells. She suffered a postprocedural stroke, which went undetected by the hospital staff for an undetermined length of time and for which tPA was not administered. At the outset, the appellate court noted that Kentucky follows the traditional view of causation. Thus, the issue on appeal was whether the jury could have reasonably concluded that there was a greater than 50% chance that the hospital's failure to administer tPA to the plaintiff was a substantial factor in causing her injuries. The appellate court viewed the expert witness' subgroup analysis as satisfying Kentucky's causation requirement. As a result, the Court held that a jury could have reasonably concluded that the plaintiff's injuries were caused by the defendant's negligence.[3]

Litigation regarding use of tPA highlights two intriguing issues in the law of medical malpractice: divergent practices in different medical specialties and the puzzle of deciding whether the physician's error caused harm in situations where a bad outcome would still have been the most likely result even if the physician had adhered to the standard of care. With respect to standard of care, at trial, neurologists may cite the AAN clinical guidelines in support of tPA as the standard of care in acute stroke. Neurologists who do not give tPA to a qualified patient, however, will need to establish a reason to question the validity of the underlying data supporting the use of tPA in acute stroke. It is noteworthy that our search returned no appellate cases in which a defendant neurologist or emergency medicine physician was sued for administering tPA.

Less commonly appreciated by physicians concerned about liability exposure is that the law accommodates differing views on what constitutes a sufficient link between a defendant's conduct and a plaintiff's injuries to warrant recovery. The traditional causation analysis would limit recovery in most cases involving stroke patients because the a priori probability of a better outcome with appropriate treatment is less than 51%. However, in some cases the loss-of-chance theory of causation allows plaintiffs to recover for the lost opportunity of a better outcome attributable to the defendant's negligence. A cogent approach to the quantification of lost chance in these cases is necessary to ensure that justice is served and that physicians are treated fairly.

Even in a jurisdiction using the traditional view of causation, a stroke patient may recover damages if the expert witness is able to credibly classify a particular plaintiff in a small group of similarly situated patients who would have benefited from tPA treatment, as was done in *Lake Cumberland LLC v Dishman*. The basis for the expert's assessment in that case is not mentioned in the court's opinion. However, whether based on personal experience or the published results of a subgroup analysis, such individualized assessments would be subject to vigorous exploration and critique by the defense attorney on the ground that the estimated probabilities lack a sufficient scientific foundation. Should the witness prove unable to substantiate his or her assessment, he or she would run a very real risk of losing credibility with the jury if the case were tried. Further, many courts have been unwilling to allow juries to speculate about whether a plaintiff fits into a group of people who may benefit from tPA treatment. However, the willingness of an expert witness to state that the failure to use tPA "more likely than not" prevented the plaintiff's recovery from the stroke would probably prevent a court from granting summary judgment for the defendant before the trial reached the jury, thereby making a favorable settlement for the plaintiff more likely.

DRIVERS WITH DEMENTIA

Some patients with dementia who operate a motor vehicle pose a significant risk to themselves and others. Physicians are frequently in a position to observe symptoms that indicate the danger a patient poses before an accident occurs. The resulting conundrum for physicians is how to mitigate the danger by effectively ensuring the patient does not continue to drive or drive more often than appropriate while respecting the confidentiality of the physician-patient relationship. A loss of driving ability can have considerable impact on a person's autonomy and personal liberty, especially among elderly patients. Physicians confronted with this dilemma must balance the need for public safety with the real likelihood that the patient may not seek medical care or reveal the full extent of her or his symptoms knowing the physician will share that information with state authorities. In addition, a decision by the state to suspend the patient's driving privileges may have a significant impact on the patient's health. Studies have shown that driving cessation is a strong predictor of increased depressive symptoms.[28] In most states, the physician has the option to report the patient to the state authorities. In other states, physicians are required to do so. The American Medical Association has compiled a brief summary of state reporting laws.[29]

Reporting is Governed by State Law

Most states have laws governing driving-related reports of patients with dementia. These laws vary widely. When faced with the issue for the first time, physicians should consult an attorney or their risk management department regarding the laws of their state.

In general, a physician reports his or her concerns to a state department of motor vehicles (DMV). An official with the DMV will then contact the patient to arrange a formal evaluation of the patient's driving ability to determine if they may retain their license to drive. In most cases, the state, not the physician, determines whether a patient can operate a vehicle safely enough to retain the right to drive.

In a majority of states, physician reporting to the DMV is optional. Optional reporting provides the physician and the patient with the most flexibility in terms of resolving conflicts about driving and the greatest chance of preserving their relationship in those

instances in which the patient is not safe to drive. In these states, physicians may encourage a patient to voluntarily stop driving or self-report to the DMV when the patient's cognitive function makes driving dangerous. Optional reporting also takes advantage of the physician's unique position to observe the danger a patient poses on the road, and the ability to weigh the danger to the public against the individual circumstances of a particular case. Thus, where a patient has little family or external support, and the danger on the road is low, a physician may decide that the patient should retain the mobility associated with the ability to drive and choose not to report that patient to the DMV.

In a handful of states, it is critical to note, a physician has the legal duty to report a patient to the DMV for retesting and possible termination of driving privilege. Thus, even in a case in which a patient obeys a physician's direction to stop driving, the physician may still be obliged to report the patient.

State legislation often describes the conditions for which a physician should report a patient. For example, Pennsylvania law allows physicians the discretion to report based on a host of conditions and symptoms, including seizure disorders, unstable diabetes or hypoglycemia, periodic loss of consciousness, mental or emotional disorders, or any other condition that, in the opinion of the physician, could interfere with the ability to control and safely operate a motor vehicle.[30] In comparison, Montana law provides only that a physician may voluntarily report a person whose medical condition will significantly impair a person's ability to safely operate a motor vehicle.[31]

Physicians face potential liability in the reporting process. First, where physicians are not permitted or mandated to report, they may face lawsuits or professional penalties for violating physician-patient confidentiality.[32] For example, in Hawaii, generally doctors may not disclose to any person any information pertaining to a patient's diagnosis, treatment, or health,[33] and doing so may result in fine or license revocation.[34,35] Despite the fact that courts have been reluctant in imposing liability on physicians for failure to report,[36] a handful of states in which physicians help assess driving safety permit liability to be imposed on physicians for their assessments.[29] However, most states with discretionary reporting also provide physicians specific legal protections for doing so. These states generally immunize physicians against lawsuits arising out of the physician's decision to report. Some states also prohibit the DMV from disclosing the name of the reporting physician to the patient.[36]

Though the federal Health Insurance Portability and Accountability Act (HIPAA) regulates disclosing patient information, HIPAA's regulations have provisions recognizing the requirements of state law and the need to manage risks to public safety. HIPAA allows physicians to report patients to the DMV when required by state law and discretionarily when the patient poses a serious threat to public safety behind the wheel.[37] However, where state law does not allow physicians to report, HIPAA does not absolve them of the liability or professional consequences of reporting created by state law.

Physician Guidelines Regarding Reporting

The American Medical Association and AAN encourage reporting patients who pose a safety risk to themselves and the public.[32,38] Both organizations favor reporting only when a patient has not self-reported to the DMV or if the patient has ignored the physician's advice to discontinue driving. Until state laws are changed, physicians who practice in states without immunity for reporting will have to choose between their obligation to protect the health of their patients and the public, on the one hand, with the potential legal liability associated with the ethically questionable act of violating physician-patient confidentiality on the other. In these circumstances, neurologists

can avoid the ethical dilemma if the patient freely agrees not to drive. Neurologists should create an environment within the physician-patient relationship wherein the patients can make such a choice by engaging in honest and repeated discussions with the patient and the caregivers about risks that the patient poses to himself and others by continuing to drive.

DRIVERS WITH EPILEPSY

Epileptic seizures are the most common cause of accidents associated with acute driver incapacity.[39] Approximately 700,000 of 180 million licensed drivers in America have epilepsy.[40] Generally, state laws governing the physician's ability or requirement to report drivers with dementia also apply to reporting drivers with epilepsy. For physicians, the similar rights, obligations, liabilities, and legal protections are implicated when reporting those with epilepsy as reporting those with dementia. A minority of states mandate physician reporting, but it is voluntary in the majority of states.[40] However, unlike state laws governing driving and dementia, states laws governing driving and epilepsy reflect the fact that epilepsy may result in only intermittent impairment of driving ability. Rather than prohibiting driving completely for patients with seizures, a slight majority of states require patients with epilepsy to be free of seizures for a fixed period of time before they may resume driving. As of 2001, the median restriction among state laws was 6 months, with a range between 3 and 12 months.[40] On the other hand, a substantial number of states employ more flexible approaches to driving restriction. These flexible approaches commonly employ individual clinical factors to assess when an epileptic patient may resume driving.[40] For example, some state laws outline that driving can resume in a shorter period if the seizure occurred during a physician-directed reduction of antiepileptic medication.[40] Conversely, repetitive seizures in a short time frame after a certain seizure-free period can mean the patient will need to wait a longer time before resuming driving.

VOTING WITH DEMENTIA

In an environment where political groups battle over the validity of each and every vote by counting chads and dimples, one issue drawing national concern in recent years has been voting by persons with cognitive disabilities. Although federal law protects the right to vote generally, whether cognitively impaired individuals may be disenfranchised based on their condition is determined by state law and there is considerable disparity among states with regard to this issue. Often, state standards for capacity to vote are only vaguely defined, with little case law to provide clarity. If any generalization can be made, though, it is that many states prohibit voting by persons declared incompetent by a court.

Laws Addressing the Right to Vote

Only nine states currently focus their standard specifically on the person's capacity to vote: Connecticut, Florida, Ohio, Massachusetts, Iowa, New Mexico, Wisconsin, Delaware, and Oregon; and none of them provide a standard to assess that capacity.[41] About two thirds of states and the District of Columbia have laws which prevent persons from registering to vote on the basis of certain legal classifications not specifically related to the capacity to vote.[41] For example, states may disenfranchise someone if that person has been judged insane, if he or she is under the care of a court-appointed guardian, or if a court has found him or her generally incompetent. This approach treats mental capacity as an all-or-nothing matter: diminished capacity as to some matters is treated as having diminished capacity for all matters and is

clearly incompatible with current principles of mental health law. However, this may be changing. In states where legal classifications determine voting rights, some courts are beginning to take measures that restore voting rights to those with cognitive disorders. For example, guardianship courts are beginning to tailor their judgments to specific matters, meaning individuals may retain the right to vote where they previously would not.[42] In an escalating number of states, guardianship orders are now required to specify which rights a person retains.[42]

Assessment of Voting Capacity

In general, a court must determine whether an individual has the capacity to vote, if such an assessment is to be made.[41] With the exception of Wisconsin, voting registration officials may not assess the capacity to vote. Wisconsin is the only state that has a formal judicial procedure whereby an election official may challenge someone's capacity to vote. The final determination is still made by a court.[43]

Federal courts have rarely spoken about the appropriate standard for capacity in voting. However, in 2001, a federal District Court in Maine offered some clarification for the capacity to vote. In *Doe v Roe*, three persons challenged the Maine constitution which disenfranchised those "under guardianship for reasons of mental illness."[44] The District Court found that a person has the capacity to vote if he or she understands the nature and effect of voting and has the capacity to choose among the candidates and questions on the ballot.[44] Because it is a trial-level decision, the *Doe v Roe* standard does not have the force of law across the country. However, it is highly relevant as a beginning point for understanding the fundamental aspects of the capacity to vote in the United States, and as the beginning of potential reforms to come.

Executing the Right to Vote

There are several points at which individuals with dementia might face barriers to voting.[40] First, registration forms may ask if a person has a legal guardian or has been declared incompetent by a court. These questions are appropriate and anticipated, assuming the particular state law defines capacity to vote using such classifications. Second, voter registration staff may suspect a person is not competent to vote and refuse to give out an application for registration. As mentioned, Wisconsin is the only state in which registration officials may question the capacity of a potential voter. Third, there is a paucity of voting technologies tailored to individuals with cognitive impairment.

Finally, family or long-term care staff might not believe an individual competent to vote and as a result may not assist him or her in the process of voting. In practice, the decision of whether an individual is competent to vote often falls to family and long-term care staff who are in daily contact with the cognitively-impaired person. Although they serve an important screening role in voting[40]—because some cognitively impaired patients who clearly lack capacity to vote end up casting ballots—there is a risk that they may make unwarranted assumptions about an individual's capacity to vote and, as a consequence, fail to help the individual exercise the right to the franchise. If the patient does not express an independent desire to go to the polls, his or her ability to vote often goes unutilized as caregivers may simply fail to broach the subject with the patient.

Neurologists may play a meaningful role in this process by raising the subject of voting in discussions with their cognitively impaired patients and their caregivers to ascertain the patient's interest in voting and to uncover any tacit assumptions being made by those taking care of the patient. If the patient expresses a desire to vote, the neurologist should consider performing an evaluation to determine whether the

patient understands the nature and effect of voting and has the capacity to choose among the candidates and questions on the ballot.

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