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The Essential Monthly Guide to Emergency Medicine Malpractice Prevention and Risk Management

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Medical Malpractice and Risk Management — Part I of II

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Part II will appear in December 2010 and will address risk management.

Most emergency physicians will be sued during their career.[1] Lawsuits can lead to interpersonal difficulties, loss of job satisfaction, and emotional distress.[1,2] An understanding of the malpractice process and ways to reduce risk can help emergency physicians deal with this ever present threat.

Malpractice Lawsuits

Medical malpractice lawsuits generally are brought against physicians under civil tort law. A tort is essentially harmful, wrong conduct by one entity against another. Patients can sue health care providers under various torts. These torts include medical malpractice, personal injury, product liability, defamation (libel or slander), infliction of emotional distress, invasion of privacy, and breach of confidentiality. Plaintiffs must establish four essential elements of the malpractice claim: duty, breach of that duty, causation, and damages. As cases work their way through the legal process, eventually they are dropped or dismissed, settled, or decided in court.

Types of Suits

The two most common types of suits brought against physicians are battery and negligence. Battery involves actions done to the patient that were not approved by the patient. This may occur when informed consent has been obtained but the patient believes the procedure performed is not the procedure agreed upon or was not done by the agreed upon provider.[3] Negligence is the most common type of suit against physicians. A physician can be sued for negligence for many reasons (*See Table 1.*)

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Who Can Be Named in a Lawsuit

In general, anyone whose name appears on the chart can be named in a lawsuit. This includes attending physicians, advanced practice nurses, physician assistants, residents, students, nurses, and anyone else on the health care team. A common misconception among residents is that they will not be named or involved in a lawsuit because they are under the direction of an attending physician. In one review of malpractice claims at a large teaching institution, residents and fellows represented 46% of physicians named in ED claims.[4]

Elements of a Tort

There are four elements of a tort that a plaintiff must establish.[5] First, that the defendant owed a duty to the patient. In the emergency department, particularly in light of the EMTALA regulations, it is safe to say that this element is relatively easy for the patient to establish. Second, it must be shown that the duty was not met by a failure to meet the standard of care. The standard of care can be defined as how a physician of ordinary skill, care, and diligence with similar training in a given situation would have evaluated and treated the patient.[6] It is important to understand that mistakes can be made without practicing below the standard of care. The key determinant of the standard of care is if the provider acted reasonably under the circumstances, not if a mistake was made.[7]

The standard of care in each case ultimately is determined by a judge or jury after hearing the testimony of expert witnesses. Each side will employ experts to testify as to the appropriateness and reasonableness of the treatment, or lack thereof, provided the patient based on their opinion of the standard of care for that condition or situation. Then the jury will decide which expert's version is best. In some states, the expert must be certified or practicing the same specialty as the defendant.[8] In other states, the expert may have to meet minimal requirements, usually licensure in the state where the case is being heard and some clinical practice requirement, to give testimony.[9] In recent years some specialty societies and medical groups have begun to call for action against or sanction members who provide misleading or inaccurate expert testimony.[8,10] In addition to the testimony of experts, hospital policies and written guidelines potentially may be used as evidence of the standard of care.[7] In rare cases the negligence may not require expert testimony to establish the standard of care. The exception to the requirement for expert testimony is the "doctrine of common knowledge," which is referred to as *res ipsa loquitur* or "the thing speaks for itself." Generally, this is applied to cases where a layperson can determine an error was made such as when instruments are left in a patient after surgery.[6]

The next element of a tort requires plaintiffs to show they suffered injury or damages, which may include loss of ability to earn income, loss of consortium with a significant other, future medical expenses, pain and suffering, and emotional distress.[11] Finally, the plaintiff must prove that the breach of the standard of care was the cause of the injury and damages. This means that the plaintiff must show a connection between the failure to meet the duty owed (standard of care) and the event (injury or damages) which occurred.[5] The law refers to this as "proximate cause." In

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Table 1. Types of Neglect

- Failure to diagnose
- Improper performance of procedure
- Improper management of treatment
- Delay in diagnosis
- Delay in treatment or procedure
- Failure to consult
- Acts or omissions that cause or aggravate a patient's illness or injury

Source: Jonathan Siff, MD, MBA, FACEP, Cleveland, OH.

most cases if the outcome would have been the same regardless of the actions of the defendant, there is no proximate cause. Another way to look at this concept is that if the adverse outcome would not have happened "but for" the actions of the provider then the provider may be liable. In evaluating proximate cause the jury must look at two scenarios: What should have happened with appropriate care as opposed to what did happen with the allegedly negligent care and the difference between them in terms of lost life, lost income, or other causally related damages.

Burden of Proof

To win their case, plaintiffs must meet the burden of proof that their reasoning and version of events is more plausible. This standard for civil cases, which is called a "preponderance of the evidence," means that if plaintiffs seem to be 51 percent correct the judgment would be for them.[8] This is unlike criminal trials where the proof must be "beyond a reasonable doubt." An exception in many states to the preponderance of the evidence rule is called the "loss of chance doctrine." This doctrine allows the recovery of damages for the destruction or reduction of prospects for achieving a more favorable outcome, even in cases where the patient would have had a 50 percent or lower chance of cure or more favorable outcome prior to the negligence.[12] Under the traditional rule if patients have a 50 percent or lower chance of survival or more favorable outcome even if no negligence occurred, then they would not be entitled to collect any damages since the negligence did not cause the majority of the damage. However, under loss of chance, if patients would have had a better chance to live with proper treatment, they can be compensated for the opportunity that was lost. For example, if a patient with a severe form of cancer who received "proper" treatment would have had a 30 percent chance to live but lost that chance due to a delayed diagnosis or other negligence, he or she may be able to collect 30 percent of the damages that might have been awarded if the negligence could have been proved to cause at least 51 percent of the damage. This greatly expands the legal risk to providers.

Statute of Limitations

The statute of limitations is the length of time after the injury was discovered or the doctor patient relationship was terminated that a lawsuit can be brought. This varies among the states but two years is a common length.[13] A suit may be bought long after the care was rendered in cases where the plaintiff did not discover the injury immediately, such as a retained foreign body. In the case of minors or other individuals who are unable to assert their rights due to disability, the statute of limitations may not start until the disability is removed. In many states this means when a child reaches the age of majority or the patient recovers.[11] Families are not barred from filing suit on behalf of these individuals at any time prior to the expiration of the statute of limitations. In cases where fraud or concealment exists on the part of the provider, such as altering the medical record, the time period to file a lawsuit may be extended.

Defense theories

Several defenses are used by physicians when defending a malpractice suit (*see Table 2)*.

The Legal Process

Once a physician is named in a lawsuit there are some actions that should and should not be taken (*see Table 3*). Some specialty societies, hospitals and medical associations offer non-legal guidance and counseling to providers during the long judicial process.[14]

The legal journey begins with a summons from the court, which is the official notice of a lawsuit. As soon as you receive this notice you should meet with your hospital or group lawyers or malpractice carrier. Your attorney will guide you through the discovery process. During discovery, information is gathered by both sides in support of their case. In some cases, the physician will be required to give a deposition, which is a discussion under oath in which the plaintiff's attorney asks questions to obtain information to use against the provider at

trial. Cases are never won, but can certainly be lost, at deposition. Finally, should the case not be dropped, dismissed, or settled (the majority of cases never go to trial), then the case would go to court for a trial. Data from the Physicians Insurers Association of America showed that 65 percent of claims were dropped, dismissed, or withdrawn, 25.7 percent were settled, 4.5 percent were finalized by an alternate dispute mechanism, and 5 percent were resolved by trial. In cases going to trial, the provider prevailed 90 percent of the time.[15]

This legal process can take several years to complete and cause great frustration and difficulty for providers.

When Payment Is Made to Plaintiff

The National Practitioner Data Bank (NPDB) was created in 1986 as a data repository for malpractice judgments. When a physician loses or settles a case, the insurer is required to report this to the NPDB. In addition, disciplinary actions related to provider competence and resignation or the surrender of privileges in return for the discontinuation of an investigation against the provider are reported.[18] Physicians may dispute the report and may write brief statements describing their side of the story, which will be seen by anyone accessing the information. The data currently are not open to the public. Among the groups able to access the database are hospitals, nursing homes, state medical boards, HMOs, and professional societies. Providers may review their own information.

Malpractice Insurance

Malpractice insurance should be carried by all ED physicians, and most will obtain coverage through their employer or contract company. There are two basic types of malpractice insurance; occurrence-based and claims-made.[19] Occurrence-based provides coverage for any act that occurs during the period of coverage regardless of when the lawsuit was brought. Claims-made polices cover the provider, for claims filed during the policy period, based on care that occurred after a specified past date and the end date of the policy. This specified past date is referred to as the "retroactive date" in malpractice policies.[19] When the policy ends the coverage ends as well. For physicians with a claims-made policy, it is imperative to obtain "tail coverage" which will cover claims on acts that occurred while the original policy was in effect that may be filed in the future. Another key element to malpractice insurance is the amount of coverage

Table 2. Malpractice Defenses

- Absence of one of the four required elements
- Statute of limitations has expired
- Contributory or comparative negligence—the patient was partially responsible for his/her own damages
- Injury worsened by a later negligent provider
- Assumption of risk—patient knew the risks and agreed to proceed and one of the known risks occurred

Source: Jonathan Siff, MD, MBA, FACEP, Cleveland, OH.

Table 3. Dos and Don'ts When Named in a Malpractice Suit

Do

- Call your attorney, hospital risk manager, or malpractice carrier immediately.
- Make a copy of the document and send the original to the appropriate person (in previous bullet)
- Remain calm—you are not alone
- Participate in the selection of expert witnesses
- Check to be certain your CV (which the plaintiff likely will request) is accurate, up-to-date, and contains no stretching of the truth
- Tell your attorney everything

Don't

- Discuss the case with anyone other than your attorney, spouse, or mental health counselor. Discussions with coworkers and friends are not privileged; these people could be called to testify in the case.
- Alter the medical record; however, you may make a clearly dated addendum with the advice of your attorney when appropriate.
- Contact the patient and "try to work it out."
- Speak to plaintiffs attorneys without your attorney present.
- Be impatient; the legal process is a slow one.

Source: Jonathan Siff, MD, MBA, FACEP, Cleveland, OH. Based on references 1, 16 and 17.

provided. Most policies have a lifetime limit and a per event limit. An example of a common policy is a "1:3" policy. This indicates a $1 million limit per claim and a $3 million limit for the provider's total coverage. Occurrence-based insurance is preferable but usually more costly and in some cases unavailable.

The information and suggestions in this article are general rules and not applicable to every patient or situation. These suggestions do not constitute a standard of care but are the opinion of the author.

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Unrealistic Expectations for tPA Can Lead to Litigation

Make your thought process clear

"It's too bad someone didn't give you thrombolytics, because you probably wouldn't be paralyzed now." Whether it's a nurse, doctor, or someone else making that statement to a stroke patient cared for in your ED, you could end up named in a lawsuit.

"There seems to be more and more litigation surrounding not giving thrombolytics," says **Matthew Rice**, MD, JD, FACEP, an ED physician with Northwest Emergency Physicians of TEAMHealth in Federal Way, WA. "People's expectation is that this is a magic drug. So, one of the risks for EDs is not giving it when people believe it should have been given."

Victoria L. Vance, JD, a health care attorney with Tucker, Ellis & West in Cleveland, OH, agrees that there is a public perception that tissue plasminogen activator (tPA) is a "magic bullet." Vance is former senior counsel and director of litigation for The Cleveland Clinic Foundation.

"The law lags science. Presently, the allure of the 'clot-busting' drug remains high," says Vance. "There are many reported settlements and verdicts arising out of the failure to give tPA to a stroke patient in the ED."

Evidence Against EDs

Jamison G. White, an attorney at Silverman, Thompson, Slutkin & White in Baltimore, says his firm has successfully handled several cases involving stroke patients who presented to the ED. Most of the lawsuits involved failing to administer tPA.

"It is well known that time is the enemy after any stroke," White says. "In our experience, one of the most powerful pieces of evidence in a case against an ED physician where the issue is failure to timely diagnose and treat a stroke patient, is the failure of the ED physician to order a stat blood draw and/or stat CT scan of the brain in a patient who presented within the 'golden window' of treatment with the recent onset of stroke symptoms."

This is particularly damaging when subsequent CT scans demonstrate that the patient suffered a non-hemorrhagic stroke. "In short, failing to treat a stroke patient with tPA within the golden window when no contraindications existed, runs contrary to the prevailing standard of care today," says White.

White says other strong evidence against EDs would be the failure of the ED staff to timely triage, and/or have a patient who presented with the acute onset of stroke symptoms be seen by a physician, within the golden window for treatment.

"Common errors that we see in this setting appear to be a failure of ED personnel to appreciate the true nature of a patient's complaints, a mix-up with one patient temporarily confused with another which delays treatment, and overall over-crowding in the ED," notes White.

The ED records may reveal the lag time between when a patient is triaged and when the appropriate stroke treatment is initiated has pushed a patient from inside to outside the treatment window.

"We have the ability to subpoena the ED's records to see how many patients were triaged and/or treated during the time period that the plaintiff was in the ED, to see if the ED was essentially overwhelmed and this particular patient fell through the cracks so to speak," says White. "What we allege in these lawsuits is a simple failure to timely diagnose and/or treat the patient."

John Burton, MD, chair of the Department of Emergency Medicine at Carilion Clinic in Roanoke, VA, notes that even with over-crowding, the ED must operate a successful triage function to identify patients with conditions that are "time dependent" with regards to therapy.

"Fortunately, there are not many truly time-dependent therapies. Acute myocardial infarction would of course be the classic example," says Burton. "Treatment of ischemic stroke with tPA has effectively evolved, and been represented, as another."

Don't Misuse tPA

Hartmut Gross, MD, a professor of emergency medicine at Medical College of Georgia in Augusta, says that the current legal atmosphere is clearly that you are more likely to be sued for failing to give tPA than giving the drug.

"This is much like after the cardiac tPA recommendations came out," says Gross. "The initial lawsuits were on losing the opportunity to treat, and are still the majority of cases—90% of so, based on what limited literature is out there."

A typical lawsuit involving damage after giving tPA might involve allegations that the patient's blood pressure was uncontrolled, the risks weren't explained, and there is a bad outcome.

Although a blood pressure documented in the patient's chart is difficult to dispute, medical decision making can be more of a grey area. "These cases always come up after several years and your memory is poor. You don't remember exactly what your thinking is," says Gross. "So if you don't give tPA, you need to describe very clearly why it's contraindicated."

In this legal climate, an ED physician may be tempted to err on the side of giving tPA, especially when family members or the patient are demanding it. "But there are risks with tPA treatment, to be sure," says Vance. "These can also have adverse legal, as well as medical, consequences."

For instance, if the stroke is caused by a hemorrhage, rather than a blood clot, tPA is generally contraindicated. "This is because of the high risk that it could cause internal bleeding into the brain, with devastating consequences," says Vance.

Likewise, patients with a history of intracranial hemorrhage or head trauma would be at risk for uncontrolled, and potentially fatal, bleeding if tPA is given, she adds. Pregnancy is a relative contraindication to using tPA because of the potential risks to mother and baby from placental abruption, retroplacental hemorrhage, abortion, or postpartum hemorrhage.

"Misuse of tPA in any of these scenarios is an invitation for claims and litigation," says Vance. She recommends the following to reduce risks:

Follow your ED's stroke and/or tPA protocol.

"Educate your staff on the protocol," says Vance. "Remember, protocols are not inflexible. These must be written as a guide to clinical judgment. Protocols should not be mandatory, or so

prescriptive as to foreclose case-by-case decision making."

Remember that even if tPA is given, lawsuits still can arise from the perceived failure to administer the drug quickly enough.

The window of opportunity to administer tPA recently has been expanded from 3 hours to 4.5 hours. Guidelines state that "delays in evaluation and initiation of therapy should be avoided, because the opportunity for improvement is greater with earlier treatment."[1] A recent analysis of pooled data from eight clinical trials showed significantly elevated mortality risk among patients who received tPA from 4.5-6 hours after stroke.[2]

"In a tPA-related claim, the legal retrospective will focus on time," says Vance. "It is advisable to document the timeline of your workup."

Vance says to note the time when the neurologist consult was called, when labs were drawn and results returned, when the patient was sent for and received CT imaging, all nursing interventions, and all physician orders and actions.

Gross notes that while some institutions wait for all laboratory results to come back before giving tPA, this is not his practice. "Unless I suspect an abnormality, I don't wait for the lab results—we just move on to tPA," he says. "The big emergency medicine policymakers generally suggest leaving it up to the individual institutions. However they make their protocols, that will be the standard they'll be held to."

Retain your ED's census records, trauma logs, and duty rosters.

"If a patient-plaintiff ever asks about staffing and acuity levels while questioning the speed of treatment of a particular patient, you will be prepared to respond," says Vance.

Obtain and document an accurate history as to the time of onset of symptoms, to determine if the therapeutic window is still available.

A patient may tell you upon arrival at 3:00 p.m. that their symptoms began at noon, which is carefully documented in the chart. Minutes later, an ED staff member finds out from a family member that the patient's symptoms in fact began hours earlier, so tPA cannot be given. If the time of onset is not corrected in the chart, says Gross, you might later have a hard time defending your decision not to offer the drug.

"Seek out family members, knowledgeable witnesses, or a foreign language translator, as necessary, to get the most accurate and complete history and timeline of pertinent events," says Vance. These may include onset and progression of symptoms, recent head injuries, bleeding problems, bleeding ulcers, trauma, hypertension, and pregnancy.

Carefully document the patient's clinical course in the emergency department.

"If patients are improving, they often do not qualify for tPA," adds Vance.

However, this is not always the case. "Some folks will make the argument 'the symptoms are improving,' so tPA was not given, but that is kind of a vague point," says Gross. "If you have a patient who is rapidly improving, but still seems to park at a fairly high number, most of those folks we will continue to treat. If the patient still has a pretty bad deficit, I would proceed on giving it, and document exactly that."

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Cover This Ground with Patients to Avoid tPA-Related Suits

If you aren't going to give tPA and would like to avoid a lawsuit, you'll want to be very clear in your documentation as to why the patient didn't meet treatment criteria. "And if you do give it, you should be very clear why the patient did meet the criteria," says **John Burton**, MD, chair of the Department of Emergency Medicine at Carilion Clinic in Roanoke, VA.

Plaintiff attorneys are aware there is a window of opportunity for treatment options for stroke patients. "If a patient presents within that, the failure to provide that treatment is sometimes met with litigation," says **Robert B. Takla**, MD, MBA, FACEP, chief of the Emergency Center at St. John Hospital and Medical Center in Detroit, MI. "But there are plenty of ways around that litigation. It is an issue of documentation, or lack thereof."

Takla recently was an expert witness in a case where a patient sued because thrombolytics were

not given. In this case, he does not believe it was appropriate to treat the patient with thrombolytics.

The patient's National Institutes of Health Stroke Scale (NIHSS) score was two, and symptoms were very minor. "He later had worsening of his symptoms and the stroke score increased, but the allegation was he should have received tPA on presentation, which is incorrect," says Takla.

Some additional documentation would have made it lot easier to defend the case. The ED physician did not document the decision-making process, nor did he provide the option to the patient and his wife, explaining that the NIHSS score was only two, and the risks usually outweigh the benefits of treatment with such minor strokes.

"Then any rational person would decline the tPA, and that should be documented," says Takla. "A lot of times, what ED physicians fail to do well is document the thought process in the medical decision-making portion of the chart. Explaining this in a deposition is much different than explaining it the first time in the chart itself."

In the case of a stroke patient, that includes documenting that you talked with the patient about giving, or not giving, thrombolytics, and whether the patient agreed with your decision.

Patient May Insist

What if you tell the patient, "On your CT scan it looks like you had some bleeding, and because of that it's contraindicated to give tPA," and the patient says, "I don't care, I want it anyway"?

"Document the contraindication," says **Matthew Rice**, MD, JD, FACEP, an ED physician with Northwest Emergency Physicians of TEAMHealth in Federal Way, WA. "If later there is a complication and the patient is angry, it is clear why you did not give it for medical reasons even though the patient wanted it."

Takla says that one of the first things he tells residents is to involve the patient and family in the decision process for everything, whenever possible. "Our job is to inform. It's not necessarily to decide for. We provide information and recommendations, but it's ultimately the patient's decision," says Takla. "That does not mean you must do what the patient says, you just cannot do something to the patient without their consent, including giving tPA."

Takla says that if he felt tPA was not appropriate, he would explain his reasons to the patient. "They typically make the right decision," he says. "Just document that."

You need to explain the risks that IV tPA carries with it. Takla says that he presents this option to patients with an NIHSS of above four and below 24. After explaining the risks and the benefits, he explains that the patient needs to make the decision right away. He documents that the patient is alert and oriented, capable of making an informed decision, that alternatives have been discussed, and that the patient either decided to proceed or does not want the treatment.

"That's what I document in my chart, and that's how I stay out of court," says Takla.

Though it doesn't happen often, Takla says that occasionally a patient will insist on treatment even if it's contraindicated. "They can insist all they want, but if I feel it's contraindicated it's my obligation to do what I think is best," he says.

In this case, Takla tells the patient, "If you were my family member, I wouldn't make this available to you because it's not appropriate."

Be Clear About Risks

Although some contraindications are absolute, such as evidence of bleeding on the CT scan, active internal bleeding, or history of intracranial hemorrhage or aneurysm, other contraindications are

Sources

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not as clear-cut. The patient may have had major surgery two-and-a-half weeks ago, a myocardial infarction a few months ago, a seizure with the stroke, or a spinal tap within a week.

The chart always should reflect the appropriate care that's been rendered to the patient, and the rationale behind it. "If you do the right thing, it also serves secondarily as a medical legal document. But the intent is to document the facts. Hopefully from that, your thought process and logic comes through," says Takla.

Correcting a patient's unrealistic expectations for tPA could avoid a later lawsuit.

"Patients may believe that it will just bring them back to normal again," says **Hartmut Gross**, MD, a professor of emergency medicine at Medical College of Georgia in Augusta. "You need to explain that the goal is to alleviate or minimize some of the stroke symptoms, but there is a possibility that this is not going to happen. Also, there is a risk of intracranial hemorrhage and other bleeding complications and death. Nobody wants to hear that, but everybody has to hear that. And make sure that is documented."

Gross says that it's not enough to simply give the patient his or her options. "There is no way they can properly process all that and come to an informed decision. A lot of times they will look to the physician and ask, 'Well, what do you recommend?' I say here's what I have to offer and the risks that come along with that, these would be my recommendations unless you have a disagreement.' That shifts that burden over to me, which I think is where it should be," Gross says.

Document your informed consent discussion with the patient, if he or she is able to participate, and with family or other legal representatives.

"Be very clear about the risks, benefits, and alternatives to proposed tPA therapy," says **Victoria L. Vance**, JD, a health care attorney with Tucker, Ellis & West in Cleveland, OH. "It is not a guarantee of success, and is not for every patient, regardless of what the television medical shows portray."

Standard of Care for tPA for Stroke Has Evolved

Although some ED physicians remain opposed to the idea of using tPA, the consideration of the use of thrombolytics such as tPA for stroke patients who are eligible candidates has become the public expectation.

"Two years ago, you could argue whether this is the right or wrong thing to do, but now that argument is pretty much behind us," says **John Burton**, MD, chair of the Department of Emergency Medicine at Carilion Clinic in Roanoke, VA. "People will be held to a standard that pretty much dictates that if the patient meets the treatment criteria, considering this is the right thing to do."

However, **Robert B. Takla**, MD, MBA, FACEP, chief of the Emergency Center at St. John Hospital and Medical Center in Detroit, MI, says, "As ED doctors, we don't see the long-term benefit—we see the immediate catastrophic effect. A lot of us will question the studies, but the current standard of care is to provide the lytic therapy option for a subset of patients who present with a stroke."

Whether science supports this practice—and some ED physicians strongly feel that it does not—is a separate issue. "For ten years we have argued that the science just doesn't support treatment with tPA. But it is increasingly becoming the standard of care that you consider therapy," says Burton. "Protocols for CTs and stroke assessments and evaluations are old hat. EDs have moved beyond that."

The evolution of ED stroke care is very different from the "time is muscle" approach now taken with heart attack patients in the ED, adds Burton. "With heart attack, ED physicians could at least see that there was science and evidence that this is something that would make a difference every single time," he says.

In contrast, some ED physicians are very disappointed at the evidence that tPA translates into scientifically proven differences in outcomes. "It's easy for them to get caught up in that disappointment, but they should not," says Burton. "We all need to realize that there is a certain standard of care and processes that have evolved."

Matthew Rice, MD, JD, FACEP, an ED physician with Northwest Emergency Physicians of TEAMHealth in Federal Way, WA, says that the best way to approach this dilemma, medicolegally, is for ED physicians to think through how they are going to evaluate stroke patients. Then, patients must be informed of their options to either receive, or not receive, the drug.

"Have the patient and family participate as to whether they want to accept the risk," says Rice. "Then, document in the chart the decision-making process and what the patient and family have chosen to do. "

While tPA is still not universally considered as

standard of care, says **Hartmut Gross**, MD, a professor of emergency medicine at Medical College of Georgia in Augusta, if your hospital has protocols in place you have now made it standard of care in your institution and will have to comply with those guidelines.

"It used to be that standard of care was determined on the local level, but now with access to information on the Internet, there is no reason to limit it to locality anymore," says Gross. "By the same token, if you don't have certain resources or certain levels of expertise available, you shouldn't be held to the same standard as another facility with a whole stroke team in place to expedite care."

Having a neurologist at the bedside in the ED as one would do at a stroke center, is just not realistic or even possible in a small, community ED. "However, even the small community ED would be held to a standard of having an assessment and treatment protocol/process in place for the stroke patient," says Burton. "This would include consideration for the timely administration of tPA."

In a stroke center, the protocol may well dictate that the decision will be made by a neurologist, either in direct consultation or physically present. "In the latter, the community ED, the decision will more often than not rest with the emergency physician at the bedside, unless there has been some prearranged process for neurology consultation at a distance," says Burton.

Neuro Involved in tPA Decision?

Protect yourself legally

"Why didn't my grandmother see a neurologist immediately in the ED?" is a question that may arise in the event of a malpractice lawsuit involving stroke care.

In addition to the inclusion and exclusion criteria for which patients are eligible for consideration for treatment with thrombolytics, a consultant also may play a role in the decision-making process. If this isn't carefully documented, it could mean increased legal risks for ED physicians.

"The role of consultants, particularly neurologists, in immediate care and evaluation of the patient, is something that EDs should be very sensitive to," says **John Burton**, MD, chair of the Department of Emergency Medicine at Carilion Clinic in Roanoke, VA. "Many patients believe that they are going to see a neurologist in the ED, and the reality is the vast majority will not. The process for involving the neurologist should be carefully considered."

An example of this would be an institution where there are two different neurologists who take call for the ED.

"Neurologist one 'believes in tPA,' while neurologist two is 'less than impressed by the data,'" says Burton. The ED treatment plan for stroke care in this ED might rely heavily upon the neurologist consultation and advisement. This could result in a scenario where virtually identical patients, presenting on different days, might receive different therapies due to the neurologist on-call for that day.

"If the involvement of the neurologist is not clear in the record, then the record would represent to an external observer—the plaintiff's attorney—that the ED physician is making different choices with the same stroke patient scenarios," says Burton. "In reality, the ED physician is simply responding to divergent opinions by his or her consultant."

If tPA is not given, will the ED physician or neurologist be held legally responsible? **Hartmut Gross**, MD, a professor of emergency medicine at Medical College of Georgia in Augusta, says this largely depends on your hospital's policies. "If the policy is that it is the neurology physician who makes the determination, then it would seem like the burden is going to be shouldered by that person," he says. "They are being put in the position of being the expert to make that decision. The ED physician is only tasked with 'call early and get him in here,' not making the decision."

What if a neurologist will not give tPA under any circumstances? "There are some neurologists that are not proponents of tPA. They are out there," says Gross. "If you have one at your hospital, then probably the time to find that out is before your stroke patient arrives."

If this is the case, or a neurologist won't come to the ED and refuses to give you a recommendation, Gross says to document this and transfer the patient to another facility. "Or you may be able to talk to a neurologist at another facility. Maybe they are comfortable making that recommendation over the phone, as you are working on the transfer," says Gross. "If you have lack of support by specialist groups, then today is a good day to find out, 'What am I going to do when it happens?' Because a stroke patient is going to come. It's not a matter of if, it's when."

Document Advice

In some cases, neurologists may disagree as to the efficacy of thrombolytics. "You may have one who says, 'We should give tPA to anybody who meets treatment indications,' and another who says, 'I don't believe in this, we should never do it,'" says Burton.

If during a consult with a neurologist, he or she says to either give the treatment or not to give it, this should always be documented.

"This is especially important if the patient meets the criteria for tPA and the neurologist says not to give it," says Burton. "Ask them, 'Why is it that you don't want to treat the patient? We understand they do meet enrollment criteria.' They will give you an answer, and that answer ought to be documented. I'm not a neurologist, so I'm not going to stick my head out to treat a patient if a neurologist says don't do it," says Burton. "At the same time, I'm going to document in my record that the neurologist said not to do it and why, because that was a critical piece of information in my decision making."

The goal is not to be inflammatory toward colleagues, but rather, to document in objective language what you were directed to do and why, adds Burton.

CNE/CME OBJECTIVES

After completing this activity, participants will be able to:

1. Identify legal issues related to emergency medicine practice;
2. Explain how the legal issues related to emergency medicine practice affect nurses, physicians, legal counsel, management and patients; and
3. Integrate practical solutions to reduce risk into daily practice. ■

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CNE/CME QUESTIONS

18. Which is true regarding litigation involving ED care of stroke patients?
    A. ED physicians are much more likely to be sued for giving tissue plasminogen activator (tPA) when it is contraindicated, than for failing to offer this option to patients.
    B. ED physicians will not be held legally responsible for failing to order a STAT blood draw or CT scan of the brain.
    C. Most lawsuits against EDs involve failing to give thrombolytics
    D. If tPA is given, there is no basis for a lawsuit alleging failure to administer the drug quickly enough.

19. Which is recommended to reduce risks when thrombolytics are not given?
    A. Avoid involving the patient and family in the decision making process.
    B. Other than documenting contraindications, it is not necessary to document additional aspects of your decision making process.
    C. Protocols should be mandatory
    D. Carefully document the patient's clinical course in the emergency department.

20. Which is true regarding standard of care for stroke?
    A. Failing to treat a stroke patient with tPA when no contraindications exist is contrary to the prevailing standard of care.
    B. A strong legal argument can be made as to whether science supports treatment with tPA.
    C. Even if your hospital has tPA protocols in place, the treatment is still not considered standard of care.
    D. What is considered as standard of care does not ever vary, regardless of what resources or levels of expertise are available at a given facility.

21. Which is recommended to reduce risks regarding neurologist consultations for stroke?
    A. .Inform all stroke patients that they will see a neurologist in the ED
    B. Always document any recommendation for treatment given by a neurologist
    C. Avoid documenting a neurologist's statements that he or she does not believe tPA is appropriate for any patient.
    D. If the neurologist will not give a recommendation on tPA, it is not advisable to consult a second neurologist.

Answers: 18. C, 19. D, 20. A, 21. B.

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