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INSIDE

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Informed Consent: Beyond Signing a Form

By Kevin Klauer, DO, EJD, Chief Medical Officer, TeamHealth, Knoxville, TN

Informed consent is critically important with respect to patient autonomy and individual choice. However, the purpose and intent often are lost and relegated to nothing more than signing a form. The informed discussion is critical to the informed consent process and meeting the applicable standard of care for obtaining informed consent. Thus, the content of that discussion is more important than a signature on a form, which frequently doesn't include enough details about the information shared with the patient. The concept of shared decision-making adds complexity to the idea of informed consent.

Shared decision-making and informed consent are related conceptually, but distinctly different in effect. They both address the necessary focus on patient autonomy and patient-centered care. However, merely including patients in the decision-making process (when appropriate) and conversing with a patient about treatment options is no surrogate for informed consent and its required elements. Ideally, shared decision-making is used when reasonable treatment options exist for a specific

> THE INFORMED DISCUSSION IS CRITICAL TO THE INFORMED CONSENT PROCESS AND MEETING THE APPLICABLE STANDARD OF CARE FOR OBTAINING INFORMED CONSENT.

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injury or disease entity. However, the need to obtain informed consent for the proposed treatment is an entirely different question.

History of Informed Consent

Historically, informed consent finds its roots in common law, emphasizing that, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[1] In this context, informed consent was applied in terms of battery, as opposed to the current (and more appropriate) context: the tort of negligence. In the 1960s, this doctrine evolved, including the addition of a requirement calling for information to be provided about the associated risks of the proposed treatment and any treatment alternatives that may be available.[2]

In 1972, *Canterbury v. Spence* brought new clarity to this concept by using the "reasonable patient" standard to define the scope of required disclosure. Although every possible detail, obscurity, or remote risk need not be disclosed, the practitioner must disclose what a reasonable patient would want to know about the proposed treatment or procedure.[3]

In this case, a laminectomy was performed. However, despite the physician's knowledge that the procedure may result in paralysis in 1% of patients, he did not disclose this risk. As we see frequently in claims, the unlikely becomes the unfortunate reality. The procedure was performed, and then the patient fell out of bed, resulting in paralysis.

Although we'll never know if the fall or the procedure was the cause of his paralysis (a question of causation), this case emphasized the patient's perspective, identifying that a material risk is one when a reasonable person would want to be informed about a potential risk. A physician must recognize the patient's position, identifying what a reasonable person would consider a risk and would need to know to make an informed decision.[3]

Case Law

Currently, state statutes are split between the reasonable professional standard/professional standard (what a physician under similar circumstances would consider necessary to inform the patient about) and the reasonable patient standard. Recognizing the need for patient autonomy and a focus on patient-centered care may have fueled momentum in favor of the more patient-centric approach.

A minority of states have adopted a hybrid approach, using the professional standard, but incorporating the requirement to include additional information that the practitioner knows the patient may want. Although the "reasonable professional" or "professional standard" is the historical approach, the *Canterbury* case has given ample notice to all physicians that considering the patient's position is critically important to obtaining informed consent.

Further emphasizing the "reasonable patient" standard is *Nixdorf v. Hicken*.[4] The surgeon left a needle in the patient and was determined to have a duty to disclose information about the patient's treatment, including the patient's condition after treatment. Additional case law has imposed more obligations on the clinician.

Gates v. Jenson held that specific interests (financial or personal) that may influence the physician's judg-

ment must be disclosed (i.e., consent for a research protocol in which a physician has a proprietary interest in the subject matter).[5]

Jandre v. Physicians Insurance Company of Wisconsin noted that all diagnostic tests that may rule out a possible condition be disclosed.[5] Of particular importance is the common requirement to inform a patient about risks that are specific to his or her situation.

For instance, if a patient is an aspiring pianist, risks to the hands may be greater to that person than they are to the average patient. It is wise to inquire about a patient's vocation to make certain such details are covered in the informed discussion.[5]

State Statutes

State statutes vary and are complex, including exceptions and jurisdiction-specific nuances. However, two exceptions are fairly standard. The first is implied (emergency) consent. If the patient is unconscious or rendered incapable of providing his or her informed consent and the benefits of treatment outweigh the potential risk of harm, informed consent is not required. However, the wise clinician will document the circumstances requiring implied consent. It is worth emphasizing that this exception does not include when a clinician is very committed to the treatment and believes it is the correct choice for the patient. The two elements of being incapable of providing informed consent and the benefits outweigh any potential harm from the associated risks are required for the use of emergency, implied consent.

In general, the following components should be included in the informed discussion for consent for a proposed treatment or procedure: an explanation of the proposed treatment, the risks and benefits associated with the proposed treatment, the anticipated outcomes, and any treatment alternatives (including non-treatment).[6]

Additionally, medical decision-making capacity should be verified and documented. Considering the required elements for a valid informed consent, the distinction between informed consent and shared decision-making becomes clearer. For instance, treating an ankle sprain with analgesics, ice, a stirrup splint, and crutches vs. ice, analgesics, and progressive weight bearing may be an appropriate shared decision-making discussion. However, neither of these two options or any of the proposed treatments would require informed consent.

The applicable standard of care for informed consent is misapplied frequently. Some institutions require informed consent for all procedures (i.e., laceration repairs), while others do not obtain informed consent routinely for the administration of tissue plasminogen activator (tPA) for ischemic stroke.

A reasonable approach to follow when considering which procedures or treatments require informed consent is whether the risks and benefits of the proposed treatment are intuitive to the reasonable patient. Thus, patients who present to the ED for a laceration repair generally understand that the wound will be examined, irrigated, and repaired in some way. The routine laceration does not require consent beyond the general consent for treatment. However, if the patient's laceration repair will include a technique with additional risk or staff will administer moderate sedation, consent would be required.

Regarding tPA, many institutions have used the "standard of care" argument for not obtaining informed consent. Whether a treatment option is considered *the* standard of care or simply *a* standard is not germane to the question, which is whether a reasonable patient or a reasonable professional (dependent on jurisdiction) would believe the risks and benefits should be disclosed. In other words, the risks and benefits of tPA are not intuitive and should be disclosed to the patient. The "standard of care" argument is illogical and without basis. Consider the standard of care for acute appendicitis as an illustration. Although non-surgical approaches (antibiotics alone) are under investigation, most would agree that the standard of care is appendectomy. Therefore, if the same logic applies to this scenario, consent no longer would be needed for appendectomy or the provision of general anesthesia.

Delegation and Documentation

Two important concepts that deserve adequate treatment with respect to informed consent or refusal are delegation and documentation. The consent process should be performed by the practitioner who will perform the procedure, and that consent is valid only for that specific practitioner to perform the procedure, unless otherwise disclosed and agreed to by the patient. It is not appropriate to delegate this process to another individual such as a hospital employee (e.g., a nurse).[3] However, once the informed discussion occurs, the act of signing applicable forms may be delegated.

Although standards for delegation may vary by jurisdiction, this approach is the safest and most risk-protective. In August 2017, the Pennsylvania Supreme Court issued a decision supporting this requirement. The justices ruled that surgeons are duty bound

to provide information about risks and benefits of a procedure, as well as information about alternatives, to obtain informed consent. Further, the court stressed that the surgeon must be the one who delivers the information personally to the patient.[7]

Detail the Conversation

The need for a consent form is debated frequently. Although obtaining and documenting informed consent is required, the means for documenting the patient's consent is not mandated. Generally, consent forms are preferred, as they are a universally accepted standard.[3] To deviate from that standard may call into question if informed consent actually was obtained. However, documentation of the informed consent process in the medical record may be an excellent alternative for a consent form. Many consent forms lack a description of the informed discussion. Although a patient may have signed the form, indicating he or she has agreed to a particular procedure or treatment, a signature alone does not verify that the standard of care for obtaining informed consent was met. Such incomplete documentation offers a false sense of confidence and actually may result in increased liability exposure as opposed to protection.

Ideally, both (documentation of the informed discussion and the signed consent form) would be entered into the medical record, but documentation of the informed discussion is much more risk-protective than an incomplete consent form without components of the informed discussion noted on that form or, alternatively, reflected in the medical record. Although not equivalent to informed consent, when shared decision-making occurs, documentation of that conversation may mitigate professional liability risk. ■

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Expanded tPA Criteria Means Many More Potential Plaintiffs

Attorneys paint ED visit as missed opportunity

Did a stroke patient experience a bad outcome in the ED? If tissue plasminogen activator (tPA) wasn't administered in the ED, without a good reason documented in the chart, a malpractice lawsuit is likely.

"The tPA question remains a prime opportunity for EPs to be second-guessed by plaintiff attorneys after an undesired outcome occurs," says **David S. Waxman**, JD, an attorney in the Chicago office of Arnstein & Lehr.

A recent statement from the American Heart Association/American Stroke Association outlines several scenarios in which the eligibility criteria for alteplase (a type of tPA) in acute ischemic stroke could be relaxed.[1]

"The new statement certainly anticipates increased utilization of tPA for patients over 80," Waxman notes. This could increase the number of patients who could benefit from the intervention significantly.

"It goes a long way toward challenging the orthodoxy of the three-hour post-symptom onset rule, with an eye toward extending treatment out to 4.5 hours," Waxman says. This gives plaintiff attorneys an expanded ability to argue that a particular patient should have received tPA, but didn't.

"When a damaging stroke occurs and tPA is not administered in the ED, counsel will immediately look for documented support for the decision not to intervene," Waxman warns.

The opposite also is true. If administering tPA results in a damaging bleed, even though it is a well-known complication, "the ED practitioner is immediately subject to criticism for being too aggressive," Waxman explains. There are now more patients for whom tPA is at least a potential

intervention. "Simply as a matter of statistics, even if all of the other risk factors remained constant, there is now a greater population of potential patients who were tPA-eligible but not offered tPA therapy," says **David J. Ryan**, JD, a partner at Lewis Brisbois in Portland, OR.

Additionally, there are now more higher-risk patients who potentially are eligible. These patients include the elderly; those suffering from diabetes, hyperglycemia, or hypoglycemia; and even those with prior intracranial hemorrhage as long as it wasn't recent. "On paper, these patients might be eligible, in the sense that they are no longer subject to an absolute exclusion," Ryan notes.

Nevertheless, EPs might conclude that the treatment is not justified by the risk-benefit analysis, or is contraindicated by the elevated risk of an adverse event. "A physician who uses discretion to withhold tPA under a risk-benefit analysis no longer can defend the decision by simply pointing to an 'absolute' exclusion," Ryan says. EPs must be able to explain and defend their clinical decision-making.

The same is true for claims alleging that tPA was offered improperly to a high-risk patient who suffered a bad outcome as a result. "These claims also could become more difficult to defend, for the same reason," Ryan says. The physician can no longer simply justify the decision by saying it complied with inclusion/exclusion criteria, but must explain the risk-benefit analysis. Ryan anticipates that the additional potential recipients will increase the number of potential plaintiffs. In addition, the relaxed eligibility for certain classifications of higher-risk patients could lead to an increase in patients who are not subject to absolute exclusion, but still may be subject to a discretionary exclusion based on the physicians' risk-benefit analysis. "This leads to more second-guessing," Ryan adds.

The fragility of the newly eligible population also could affect the potential damages. "In the event of an adverse outcome, the likelihood that the bad outcome could be of a catastrophic nature would seem to increase based on the overall poor health of the claimant," Ryan offers.

Loss of Chance

Nathaniel Schlicher, MD, JD, MBA, FACEP, says that for EPs, "additional hours of eligibility means more vigilance to consider tPA in a larger pool of patients."

Thus, EDs' liability exposure increases for the "failure-to-treat" patient population. "While the data [are] modest for this group, with current loss of chance doctrine litigation in many states, the need for ongoing consideration in this expanded population is real," says Schlicher, regional director of quality assurance and associate director of litigation support for TeamHealth in Tacoma, WA.

The loss of chance doctrine states that if the patient had already received a poor prognosis, the reduction in prognosis (such as a 15% reduction in survival going from stage 3 to stage 4 cancer) can be compensated for in the setting of negligence, Schlicher explains.

Additional jurisdictions recognize "loss of chance" theories of recovery. "This can be particularly daunting in the case of strokes, where proof of a particular outcome could be a difficult hurdle for a plaintiff," Ryan explains.

In some jurisdictions, the reduced chance of an optimal outcome (whatever that might look like for any individual patient) may be recoverable. This may be true even if the overall chance of achieving that outcome was less than 50%.

"With scientific literature backing the efficacy of tPA in improving the likelihood of an optimal outcome, even a small-to-moderate improvement of the odds can be legally significant," Ryan notes.

An EP who determines that a modest chance of benefiting from tPA is outweighed by the inherent risks to justify that conclusion clinically on a standard-of-care basis, Ryan adds. "The 'no causation' defense might no longer be available."

Result: Delayed Diagnosis

Research suggests that EPs face higher risks for failure to administer tPA than if a bad outcome occurs as a result of giving it.[2]

Alan Lembitz, MD, chief medical officer at COPIC, a Denver-based medical professional liability insurance provider, agrees. "The data and our experience clearly show that litigation is now for failure to consider or to treat in acute neurologic compromise such as stroke."

Particularly problematic, because of their difficult presentations, are posterior circulation events and posterior circulation dissections. "Sagittal venous thrombosis is also rare, difficult to diagnose, and devastating," Lembitz notes. The lower threshold for advanced imaging studies such as MRI, magnetic resonance angiography, and magnetic resonance venography has made these diagnoses evident.

"This points to the original ED visit, or visits, as missed opportunities and resultant delayed diagnoses," Lembitz adds.

Telemedicine with trained stroke neurologists can aid in decision-making and, ultimately, the defense

of a malpractice claim against the EP. "Performance of, and documentation of, the neurologic examination is often a focal point in the litigated cases in which these diagnoses were delayed or missed," Lembitz explains.

In a classic case, an ED patient presents with dizziness. The EP's note states, "Neuro exam, non-focal," or "Alert, moves all four extremities," or something similar. The ED nurse's note mentions headache or neck ache, but somehow this piece of information is not conveyed to the EP.

"My own experience, in reviewing dozens of such cases, unfortunately, is that either a detailed neuro exam, including elements assessing posterior circulation, was either not done, not documented, or both," Lembitz says.

In the ED, suspected stroke patients generally don't undergo a CT of the head, notes Lembitz, "but even if they do, it misses posterior circulation events as high as 30% of the time, per the literature." Subsequent catastrophic dissection or enlargement of the posterior infarct and serious neurological compromise or death can occur as a result.

"We have been having a stroke neurologist do in-service training to emergency medicine physicians as to how to conduct and document a detailed ED neuro exam," Lembitz says. A thorough exam usually takes five to seven minutes.

"Some have reported that while they certainly recognize each element of the examination, their skills have atrophied over time," Lembitz adds.

EPs particularly appreciate the review on how to differentiate central vs. peripheral vertigo. "This is incredibly difficult, even in the most experienced clinician," Lembitz notes.

Only about 5% of patients with acute ischemic stroke in the United States receive tPA. "The most common exclusion is failure to arrive at the ED in time," Waxman says. Between 22-31% of patients arrive at an ED within three hours of symptom onset.

"In all instances, defensive charting can be of considerable assistance to the EP," Waxman offers.

The ED chart should show how the EP determined whether an acute stroke patient was a candidate for tPA. These are some factors that Waxman likes to see documented:

- whether the patient demonstrates clinical improvement;
- whether disqualifying comorbidities exist;
- the clarity of evidence on the timing of the onset of symptoms.

"Often times, there is no clear answer," Waxman notes. These two factors can help the ED defense:

1. Good documentation of the EP's thought process, supporting whichever decision he or she made.

"This can go a long way toward thwarting criticism of their decision," Waxman explains.

2. Consultation with a neurologist.

When a plaintiff's attorney is reviewing a post-stroke mishap, Waxman says "there is an enormous difference between a thinly documented decision by an EP faced with a difficult decision, and an EP charting their detailed consultation with a knowledgeable neurologist who was able to guide the EP on whether to pull the tPA trigger."

EPs often are frustrated when hospitals don't do more to ensure the availability of neurology consults within the tPA decision-making period. "EPs should be strongly encouraged to raise this issue through their administrative channels," Waxman underscores.

Not only is the expertise of a consulting neurologist a benefit to the patient, says Waxman, "it clearly has the potential to assist the EP and the hospital, should tPA second-guessing become an issue."

Patients and juries are more familiar with telemedicine, particularly telestroke consultations with vascular neurologists, Ryan notes. There is a growing expectation that EPs should have access to specialists via this technology.

"Physician documentation also should include a description of whether telestroke consult was considered and if not requested, an explanation for why not," Ryan adds.

Three Important Things

Schlicher says documenting these three events can be particularly helpful to the ED defense team:

1. Onset of symptoms.

"Failure to document time of onset of symptoms leaves it to recollection and factual arguments that are unlikely to go in the provider's favor," Schlicher warns.

Clearly documenting that symptoms started 10 hours prior to arrival at the ED effectively shuts down the plaintiff attorney's ability to argue tPA should have been administered. "In the opening line of your history of present illness, it indicates that the patient does not qualify," Schlicher explains.

2. The reason that a patient did not receive tPA.

"Documenting in the medical decision-making with a clear statement of exclusion or in a protocolized checklist can further secure your defense," Schlicher says.

3. A National Institutes of Health (NIH) Stroke Scale.

Failure to document an NIH Stroke Scale on all patients with possible stroke makes it "pretty easy" for the plaintiff's counsel to prevail,

Schlicher notes. "It's all in the name. Far too many providers still do not do it, and this is a shame."

The NIH Stroke Scale helps communicate the extent of the patient's injury. "It can help defend you in low- and high-score cases where tPA is contraindicated," Schlicher notes.

Schlicher says that in his experience, a merely catastrophic outcome generally will not result in a settlement, if these items are documented properly.

"These three steps make it harder for a plaintiff's attorney to want to accept a case where a clinician considered the diagnosis and made a clinical judgment on appropriate treatment," he adds.

Negotiating Tool

In Ryan's experience, most "failure to give tPA" cases eventually settle. "In fact, cases with defensible care but catastrophic injuries and potentially significant damage awards are sometimes the best candidates for settlement," he notes. This is because each side faces massive risks if the case proceeds to trial.

"In such circumstances, one of the important but sometimes forgotten roles of good documentation is to position the case for a favorable settlement," Ryan offers.

Strong documentation in these cases is a powerful tool for the EP defendant. "It allows defense counsel, a mediator, or the court to create pressure on plaintiff's counsel to negotiate reasonably because of the risk of a defense verdict at trial," Ryan adds. ■

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Do State Damage Caps Apply to EMTALA?

Latest ruling shows area of law still not settled

Courts are split on whether state medical malpractice damage caps apply to Emergency Medical Treatment and Labor Act (EMTALA) claims. A recent pending case in the 5th U.S. Circuit Court of Appeals is under scrutiny.[1]

The case involves a young girl who was paralyzed after a hospital allegedly failed to properly diagnose an injury to her spinal cord. The judge ruled that the damages payable for their EMTALA claims could be capped by the state law, because the failure to diagnose was included in Louisiana's definition of malpractice.[2] This contrasted with a previous ruling in the state, in which damage caps were found not to apply to an EMTALA claim.[3]

"As the *Scott* [decision] points out, EMTALA explicitly incorporates state law for the determination of damages available in EMTALA claims," notes **Timothy C. Gutwald**, JD, a healthcare attorney in the Grand Rapids, MI, office of Miller Johnson.

Most courts have interpreted that language to mean damage caps apply

EXECUTIVE SUMMARY

Courts remain divided on whether state medical malpractice damage caps apply to EMTALA claims.

- EMTALA explicitly incorporates state law for the determination of damages available in EMTALA claims.
- Most courts have interpreted that damage caps apply to EMTALA claims.
- Delays in implementing orders expose EDs to EMTALA and medical malpractice claims.

to EMTALA claims. "However, by granting an interlocutory appeal, the *Scott* [decision] acknowledges that this area of law is not settled," Gutwald notes.

The case is a good example of how a delay in implementing an order can expose EDs to EMTALA and medical malpractice claims. "Here, it took a long time to get the MRI done," Gutwald says. Even if the delay in performing the MRI was not a breach of the standard of care, it still may be a viable EMTALA claim.

"This case presents another good example of how emergency physicians face an additional level of liability that other physicians simply do not face," Gutwald adds.

Inconsistent Rulings

The *Scott* case is the latest in a long series of cases dating back to the early EMTALA cases, says **Stephen A. Frew**, JD, vice president of risk consulting at Johnson Insurance Services and a Rockford, IL-based attorney.

"Courts have taken a state-by-state analysis approach to whether or not EMTALA incorporates state malpractice caps," Frew explains. This results in an inconsistent pattern of rulings across the country. Rulings focus on different aspects of the state damage caps rule.

"If I were to attempt to draw a set of rules from what I have seen in cases so far, it would be a generalization that state procedural rules that require administrative hearings before a court case may be brought are not applicable to federal court cases," Frew offers. This is because state court procedure generally does not limit federal courts.

The question of damages is more difficult. "EMTALA language appears to incorporate the elements of damages allowed by the state where the hospital is located," Frew explains. Where damage caps are applicable to all tort actions in the state, courts have split on whether that means that caps apply to EMTALA, which might be argued to be a tort law. Other cases have argued that the elements of damages apply to EMTALA, but the caps do not.

"This inconsistent palette of rulings probably has only one direct impact on ED physicians," Frew says. How a state views the applicability of caps to EMTALA will influence how much EPs pay for professional liability insurance.

"Most major professional liability insurance carriers have built the caps issues into their general pricing, but may adjust premiums based on changes in state cap rulings," Frew explains. ■

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Missed Compartment Syndrome in the ED Often Leads to Litigation

Recent review shed more light on who brings these claims and why

Compartment syndrome is one of the few true orthopedic emergencies seen in the ED, and the consequences can be dire.

"Thus, it presents a high risk for litigation," says **J. Mason DePasse**, MD, an orthopaedic surgery fellow at Brown University's Warren Alpert Medical School in Providence, RI. Researchers reviewed 139 malpractice claims involving missed acute compartment syndrome.[1] Of this group, 37 were settled, 33 resulted in a plaintiff ruling, and the rest resulted in a defendant ruling.

"We wanted to better characterize the factors that affect the outcomes of malpractice claims related to compartment syndrome," says DePasse, the study's lead author. Key findings:

• Women and children were more likely to win suits, but indemnity payments were not affected.

"These findings are likely the result of the jury reactions," DePasse offers. "Juries may be more sympathetic to women and children."

• Seventy-two percent of cases involved the lower extremity.

• Plaintiffs who developed compartment syndrome because of an elective surgical procedure, such as

calf enhancement or total joint replacement, were more likely to win suits when compared to plaintiffs who were diagnosed with compartment syndrome after trauma.

Jurors may be less likely to assign blame to a physician in cases of compartment syndrome caused by trauma, DePasse suggests.

• There was no difference in litigation outcome for plaintiffs who required amputation compared to plaintiffs who did not.

This was an unexpected finding for the researchers. "It could be that adverse neurologic outcome is perceived as equal in severity to amputation, which may be true in many cases," DePasse offers.

• Plaintiffs who developed compartment syndrome as a surgical complication were more likely to win suits.

However, the most common etiology of compartment syndrome across all malpractice claims was acute trauma.

• Delay in diagnosis was present in almost 90% of cases.

Surprisingly, delay in diagnosis did not affect the outcome of litigation. DePasse says this might be because almost every ED malpractice claim involves delay in diagnosis.

"The few that do not involve factors that juries find equally compelling, such as compartment syndrome as a result of erroneous intravenous catheter placement," he says.

DePasse says that the most important thing emergency physicians can do to limit legal risk is to be aware of risk factors and injury patterns associated with compartment syndrome, as well as signs and symptoms suggestive of compartment syndrome.

Although compartment syndrome can occur in the thigh and foot, it is far more likely to occur in the lower leg. "It is usually associated with high-energy trauma or crush injuries," says DePasse, adding that high-energy, bicondylar tibial plateau fractures and segmental tibial shaft fractures are particularly worrisome.

"While measuring compartment pressures is a useful adjunct to diagnosis, it is important to remember that compartment syndrome is a clinical diagnosis and is made based on exam," DePasse stresses.

Physicians should be very suspicious when the patient is in pain that seems out of proportion to the injury, and when there is pain with gentle, passive stretching of the toes or fingers. "Furthermore, if the leg or forearm feels very firm or 'rock hard,' compartment syndrome is likely developing," DePasse warns.

The classically taught "Ps" — pain, paresthesia, pallor, paralysis, pulselessness, and poikilothermia — often are not as helpful as EPs might assume. Most of these symptoms, especially loss of pulse, occur after significant damage has occurred, according to DePasse.

Compartment syndrome in children may be difficult to recognize, DePasse notes. "Keeping the three 'As' [agitation, anxiety, and increasing analgesic requirement] in mind is useful."

If the EP is concerned about the possibility of developing compartment syndrome, DePasse says "ensure the involved extremity is iced, elevated, and immobilized, and seek prompt surgical consultation." ■

EXECUTIVE SUMMARY

Missed compartment syndrome presents a high risk for ED litigation. To reduce risks:

- remember that compartment syndrome is a clinical diagnosis, and is made based on exam;
- be very suspicious when the patient is in pain that seems out of proportion to the injury;
- ensure the involved extremity is iced, elevated, and immobilized and seek prompt surgical consultation.

REFERENCE

1. DePasse JM, Sargent R, Fantry AJ, et al. Assessment of malpractice claims associated with acute compartment syndrome. *J Am Acad Orthop Surg* 2017;25:e109-e113.

SOURCE

- **J. Mason DePasse**, MD, Orthopaedic Surgery Fellow, Department of Orthopaedic Surgery, Warren Alpert Medical School, Brown University, Providence, RI. Email: jmdepasse@gmail.com.

COMING IN FUTURE MONTHS

- What to expect for ED liability reform in the near future
- Record EMTALA fine shows risks of ED "boarding"
- Cursory psychiatric exams forcing settlement of ED claims
- ED staffing practices cause malpractice litigation

EP Defendants Need Forensic IT Experts to Explain EMRs

Plaintiff and defense both need help interpreting ED chart

A recent malpractice lawsuit against an EP alleged that a patient coded and spent two weeks in an ICU because he received a medication to which he was allergic. Since the electronic medical record (EMR) clearly documented the patient's allergy to the medication, at first glance, it looked as though the EP had made a colossal mistake. However, this was not the case.

"The printed chart made it appear that the physician had ordered the medication in spite of the allergy information in the chart," says **Jill M. Steinberg**, JD, a shareholder at Baker Donelson in Memphis, TN.

When the EMR was produced to the plaintiff, it showed the allergy, and the fact that the patient was given the medication. However, it did not show the date and time when the allergy was reported.

A forensic IT expert came to the EP's rescue and revealed the EMR had "back populated" the allergy information to the ED chart. ED nurses had added the allergy to the patient's chart *after* the reaction.

"We had to have forensic experts review the electronic record with the plaintiff's own expert," Steinberg recalls. The forensic experts showed that the allergy information was not a part of the history that had been given upon admission.

"Eventually, the lawsuit was dropped, but not until we went through several months of litigation," Steinberg notes.

Educate Defense

Increasingly, both defense and plaintiff attorneys are turning to forensic computer experts for help interpreting EMR documentation of ED care.

Katharine C. Koob, Esq., an associate at Post & Schell in Philadelphia, says, "The use of IT experts changes the landscape of malpractice litigation from the time a case is filed through how it is presented to a jury."

At deposition, defendants or witnesses are asked specifics on how their ED's EMR works. Typical questions center around what information can be accessed in the EMR, and whether providers can make changes to their chart entries.

"This may require retention of a consulting IT expert to educate the lawyer regarding EMR software, enabling the lawyer to competently and diligently represent his or her client," Koob says.

EMR audit trails are perplexing attorneys trying to decipher exactly what happened during the ED visit. **John Tafuri**, MD, FAAEM, regional director of emergency medicine at Cleveland (OH) Clinic and chief of staff at Fairview Hospital in Cleveland, says, "They are becoming increasingly aware that sometimes they need to take a really deep dive in this."

Plaintiff attorneys sometimes think they have a strong case, until an IT expert reveals that the EMR audit trail is misleading. For instance, a timestamp for a lab test result might refer to the collection time — or the time results were returned. This can make or break the outcome of an ED malpractice claim.

Steinberg explains, "It is not always clear who entered the information or when it was put in the chart. It just becomes a part of the ED physician summary."

Plaintiff attorneys can't tell what choices the EP had from the drop-down boxes used for assessment, such as pain or orientation. "Thus, they do not know what was excluded when the nurse or physician checked a certain assessment parameter," Steinberg notes.

'Buried' Evidence

Typically, the ED staff members are asked to produce the entire medical record to the plaintiff's attorney. "This can be difficult for hospitals,

EXECUTIVE SUMMARY

Increasingly, forensic IT experts are called on to explain the complexities of electronic medical records (EMRs) in ED malpractice litigation. These EMR-related issues commonly confound attorneys:

- Some "back populate" the record with the patient's medical history;
- Time stamps don't always indicate the time an event occurred;
- All information within the record doesn't print.

in the age of electronic charting," Steinberg says.

First, EMRs look very different printed on paper than they do in their electronic state. "Providers participating in the litigation process as defendants or witnesses may need to familiarize themselves with the records in an unfamiliar format," Koob cautions.

The problem is that EMRs weren't designed to be printed, which causes much confusion during litigation when the ED has to produce the "entire" medical record. "All of the information that is in the electronic chart does not print when the chart is to be produced," Steinberg explains.

Steinberg also asks clients to consider language in the custodian affidavit that indicates that:

• some electronic data and metadata relating to the patient's clinical course cannot be reproduced through the mechanism of printing the records;

• the records printed and produced consist of all data reasonably accessible for scanning and printing, as established by the third-party software vendor and the hospital's IT department.

"There is always the potential that some portion of the documentation is in the EMR but doesn't come out easily, unless you specifically look for it," Tafuri offers.

Callbacks to patients are just one example. Understandably, EPs would assume that once these are documented in the EMR, they'd be clearly visible to anyone looking at the record. In fact, the callbacks conducted by EPs might be surprisingly hard to find.

"If you are not specifically looking for it, you might not be able to find it. If somebody subpoenaed the records, would they see it? I don't know," Tafuri laments.

That's where IT experts come into play. "Having a forensic specialist go into the record and find every note and every detail, including the times logged, will become increasingly important in the future," Tafuri predicts.

Evidence that could help the plaintiff sometimes is buried in reams of electronic data. "This is particularly effective when they discover more embedded information later that was not produced when initially requested," Steinberg says.

One solution is to offer plaintiff's counsel supervised access to the electronic records system. "This avoids counsel arguing that the medical provider was hiding something," Steinberg notes.

IT experts sometimes find a surprise "smoking gun" in the EMR. Although medical issues can be complex and nuanced, most EMR issues are black and white, such as "Was the note put in after the patient experienced a bad outcome, or not?"

"Either a note is there, or it's not," Tafuri says. "It just might take a forensics expert to find it." ■

SOURCES

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CME/CE 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.

ED LEGAL LETTER™

CME/CE QUESTIONS

1. **How are updated eligibility criteria for the use of tissue plasminogen activator (tPA) in acute ischemic stroke expected to affect ED malpractice litigation?**

   a. The defense will find it easier to get cases dismissed if patients present more than three hours after symptom onset.
   b. Patients older than 80 years of age no longer can allege tPA should have been administered because of new exclusion criteria.
   c. Patients with diabetes are subject to an absolute exclusion from tPA, barring them from recovery.
   d. Expanded timeframes for the use of tPA widen the pool of potential plaintiffs.

2. **Which is true regarding the defense of a claim alleging the EP failed to administer tPA?**

   a. An EP who uses discretion to withhold tPA under a risk-benefit analysis no longer can defend the decision by pointing to an "absolute" exclusion, but has to be able to defend the thought process.
   b. The newly eligible population decreases the likelihood of a catastrophic bad outcome, making cases less likely to settle.
   c. Increasingly, courts bar "loss of chance" theories from recovery in the case of strokes.
   d. Even in jurisdictions recognizing "loss of chance," recovery of damages requires at least a 50% reduction in the likelihood of optimal outcome (i.e., as a result of the doctor's actions, the optimal outcome became unlikely to occur).

3. **Which is true regarding state damage caps and EMTALA?**

   a. Courts have taken a state-by-state analysis approach to whether EMTALA incorporates state malpractice caps.
   b. State procedural rules that require administrative hearings before a court case that may be brought also are applicable to federal court cases.
   c. The elements of damages do not apply to EMTALA, but the caps do.
   d. Professional liability coverage costs cannot be tied to a state's damage caps for an EMTALA claim.

4. **Which is true regarding malpractice litigation involving missed compartment syndrome?**

   a. Indemnity payments for women and children were significantly higher.
   b. There was no difference in litigation outcome for plaintiffs who required amputation compared to plaintiffs who did not.
   c. Few cases involved the lower extremities.
   d. Jurors were more likely to assign blame to a physician in cases caused by trauma, as opposed to an elective surgical procedure.