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Will patient sue if you apologize? Evidence suggests opposite is true

Med-mal claims cut by more than half

Physicians often fear patients will sue if they apologize for errors that caused harm, but anecdotal evidence and published data contradict this belief.

The disclosure, apology, and compensation program used at University of Michigan Health System (UMHS) in Ann Arbor has dramatically reduced the number of malpractice claims, from 260 pre-suit claims and pending lawsuits in 2001 to 100 currently, and legal expenses and open-to-close time for claims were cut by half.[1,2] Current claims number only 63, with a very small percentage being actively litigated, reports **Richard C. Boothman**, JD, the organization's chief risk officer.

"Over the past 10 years, our clinical activity has risen considerably," adds Boothman. "So we've not only seen a reduction in overall claims numbers, but as a percentage of clinical activity, the drop is even more significant."

With nearly 20,000 incident reports in 2012, up from 2,400 in 2006, the organization is capturing many more incidents. "It is crystal clear that we've weeded out most of the groundless claims and isolated true mistakes. The vast majority of what we recognize as claims result from our own staff reporting," says Boothman. "We're not waiting for lawyers to bring these incidents to our attention."

> *"It is crystal clear that we've weeded out most of the groundless claims and isolated true mistakes."*

Boothman says patients typically sue caregivers because they don't get answers, because they want to be sure that medical mistakes don't happen to anyone else, because they want someone to take responsibility, and because when appropriate, patients expect an offer of compensation for the harm done. "Lawyers bring to the table their own priorities and interests in getting paid," says Boothman." Many patients who turn to the legal system report that they felt abandoned when they suffered a complication and everyone from the healthcare side ran for cover."

A "deny-and-defend" approach prevents physicians from admitting that patient safety problems exist and creates the impression that doctors are victims of a broken legal system, according to Boothman.

INSIDE

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"When unanticipated clinical outcomes happen, we not only deal with the claims threat on our own terms, but we also move forward directly on the safety issues," says Boothman. "Ultimately, this is the very best and most lasting antidote to malpractice."

Executive Summary

The number of pre-suit claims and pending lawsuits was cut from 260 to 100 after a disclosure, apology and compensation program was implemented at the University of Michigan Health System in Ann Arbor. Legal expenses and open-to-close time for claims were cut by half. Incident reports at the organization rose from 2,400 in 2006 to nearly 20,000 in 2012.

- ✦ Groundless claims are weeded out, and true mistakes are identified.
- ✦ Disclosure and apology programs mainly exist in self-insured large medical centers.
- ✦ Smaller physician practices can collaborate with insurers or larger organizations.

Patients just want answers

Physicians' inability to acknowledge problems with patient safety forces patients to sue to get answers, he explains. "Once the lawyers get involved, any effort to openly and honestly confront the safety problems is effectively chilled, out of fear of impairing the legal defenses," Boothman says.

He doesn't believe that lack of training accounts for the failure of doctors to be honest about their mistake. In fact, Boothman says, it is difficult for physicians who have devoted their lives to helping others through medicine to admit they've harmed someone through a mistake. "No matter how much training a caregiver gets, spending a day in a seminar is not adequate support when it happens to them, sometimes years later," he says.

Instead, physicians can obtain support 24 hours a day from the hospital's Office of Clinical Safety, which has several senior employees who have been specially trained in mediation techniques and evidence preservation. "These situations can be charged with emotion, and demand a grasp of facts that an individual cannot have on his or her own," Boothman explains. "Even the most apparently clear situation often turns out to be different from what it appeared at first."

UMHS' physicians are encouraged to take these steps:

- Always take care of the patient's and family's needs first and foremost.
- Always show empathy and work to suppress defensiveness.
- Pledge that "we will work to understand what happened" honestly.
- Call for help, if it even crosses their minds that they might need assistance.

"A badly-done disclosure is worse than a well-done one delayed by a day or two," warns Boothman. "I tell physicians all the time that you can't 'un-ring the bell' once they've told a patient something that turns out not to be accurate."

Collaboration needed

Robert M. Wachter, MD, professor and associate chairman of the Department of Medicine at University of California — San Francisco, says the

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trend toward disclosing errors "has been one of the most interesting developments in the patient safety field, and one of the most surprising."

"The orthodox thinking, until about five years ago, was that we had to go off in our corner, and patients and their lawyers would go off into another corner, and we'd all duke it out," he says. Many physicians were surprised by data from the Veterans Affairs (VA) Medical Center in Lexington, KY, showing liability claims costs that were the same or lower than those of a comparison group of similar VA hospitals, adds Wachter, but didn't believe it was relevant to more typical hospital systems.[3,4]

Even with compelling evidence from large academic hospital systems such as UMHS and University of Illinois Medical Center, some physicians in small groups or community hospitals remain skeptical that the findings would apply to their practices, Wachter says, "but the data are hard to refute. There is money on the line. Both the insurers, and in some ways, the insured, have a real financial incentive to do this well."[5]

Researchers found strong support for the Disclosure, Apology, and Offer model among key stakeholders at Massachusetts hospitals, who cited its benefits for the liability system and patient safety.[6] However, disclosure and apology programs have largely taken off in large medical centers and mainly in those that are self-insured, says **Peter B. Smulowitz**, MD, one of the study's authors and an emergency physician at Beth Israel Deaconess Medical Center in Boston.

"This is because they have the resources to manage the programs," he says. "It is much easier to operate this when you are the insurer as well and, thus, don't have to coordinate with an outside insurer."

Disclosure programs are much more challenging for physicians in smaller practices, he says, and "in many cases, they will need to collaborate with insurers or larger organizations."

Twenty percent of physicians surveyed in a 2012 study said they had not fully disclosed a medical error to a patient out of concern for malpractice lawsuits.[7]

This finding wasn't surprising, says study author **Eric G. Campbell**, PhD, director of research at Massachusetts General Hospital's Mongan Institute for Health Policy in Boston. Campbell adds that one obstacle to disclosure is that mistakes in healthcare are often multifactorial. "Often, there isn't a single person who can understand the whole thing without doing an investigation," he says.

What motivates insurers?

Insurers often discourage doctors from being honest with their patients, adds Boothman. "Most insurers are afraid of losing control over the claim," he says. "Increasingly however, we are understanding that the old ways of protecting the claim are really counterproductive, even from the insurance company perspective."

Commercial insurers will be forced to move in this direction, says Boothman, "or be seen as anachronistic impediments to new expectations of professionalism and ethical conduct."

Independent doctors and groups can start by having an attorney review their policy of insurance to make sure there's no language that would somehow penalize the group for cultivating a culture of honesty within their practice, advises Boothman.

Next, physicians need to consciously think about how to react when something bad happens, including how information will be gathered and what to document.

"You cannot do this properly in the midst of a crisis, if you haven't planned for it ahead of time," Boothman says. *(See related story, p. 100, on how apologies could come up during a lawsuit.)*

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Apology could have unexpected effect in court

Worry over 'stray comments' overblown

"I'm Sorry" statutes are valuable, if they increase a physician's willingness to show empathy and maintain their connection with patients after an unintended clinical outcome, says **Richard C. Boothman**, JD, chief risk officer at University of Michigan Health System in Ann Arbor.

"Beyond that, the apology laws do not have a significant legal impact, in my opinion," he says. Most of the statutes, which 37 states have in place, say that expressions of empathy cannot be used against the physician in court, but a statement such as "I'm sorry for missing that cancer on the X-ray" could be considered a factual statement that can be used against a physician, Boothman explains.

"People hear and remember things very differently," he says. "The difference between an expression of sympathy and a true admission against interest may be more a matter of interpretation and recollection. The statutes do little to clarify those differences."

Boothman says that in more than 30 years representing doctors and hospitals, he cannot recall a single incident in which a case turned entirely on a physician's apology or misinterpreted expression of sympathy. "No case proceeds without medical experts who find a substantive breach of the standard of care that caused an injury," says Boothman. "The whole worry about the impact of a stray comment seems overblown to me."

Even if a physician's apology turns out to be admissible, Boothman says his organization's experience strongly suggests this apology would serve only to make the physician appear more credible.

"That being said, it is extremely important to understand that we advocate intelligent disclosure, not speculation, tantrums or uninformed mea culpas," says Boothman. "We urge our physicians to take care of the patient's medical needs first, before trying to answer complex questions and before they have all the information."

> *"It is generally understood that juries look favorably on apologies because it shows that physician defendants are taking responsibility for their actions."*

Peter B. Smulowitz, MD, an emergency physician at Beth Israel Deaconess Medical Center in Boston, says that apologies are "only a piece of the puzzle." The Michigan disclosure program is successful because it does the right thing for patients and providers from start to finish, Smulowitz says.

"It takes responsibility when things happen, communicates with patients throughout the process, apologizes when necessary, and provides compensation when appropriate," he says, adding that Massachusetts' new CARe (Communication, Apology, and Resolution) program will take the same approach. "These are the steps that are allowing for a reduction in lawsuits. Patients are made whole, and disputes get resolved early and outside the court system," says Smulowitz. "It's far more than just an apology."

How will the jury view you?

Physician defendants who don't disclose mistakes that harmed patients are likely to be viewed as outliers by juries, according to **Robert M. Wachter**, MD, professor and associate chairman of the Department of Medicine at University of California — San Francisco. "When everybody was covering errors up and lawyering up, the general expectation was, that is what you do," he says. "Now, many of your peer institutions and colleagues disclose, and there is an expectation of honesty. Their jurors' attitudes would be, 'What are they hiding?'"

It is generally understood that juries look favorably on apologies because it shows that physician defendants are taking responsibility for their actions, says Smulowitz. "This is good for patients and, it turns out, is probably a good thing in court," he says. "But the point to our programs is to resolve disputes without the patient ever having to resort to a lawsuit." ✦

Lawsuits stem from poor communication with transfers

After presenting to a Missouri emergency department and being diagnosed with pneumonia, a patient developed confusion and a headache. A CT scan revealed an epidural hematoma with a subarachnoid bleed. Because the on-call neurosurgeon was unavailable, the patient was transferred to a second facility.

"After reversing the anticoagulation effects of the [warfarin], the patient was taken to surgery for an emergency

craniotomy. The patient died two weeks later," says **Lizabeth Brott**, JD, regional vice president of risk management at ProAssurance Companies in Okemos, MI.

The plaintiffs filed a wrongful death claim against the neurosurgeon and the first hospital. They claimed the neurosurgeon was negligent in delegating his on-call duties to his associate, who did not have privileges at the hospital, and failing to notify the hospital he would be unavailable. The jury awarded the plaintiffs $400,800, attributing 50% of the fault to the neurosurgeon. The neurosurgeon appealed, but the appellate court upheld the verdict.[1]

When a patient is transferred, the primary liability risk is inadequate communication between the transferring physician and the receiving physician, according to Brott. "Failure by the transferring physician to provide relevant test results, or to make the receiving physician aware of test results that were posted to the patient's record following transfer, could pose significant risk to both the patient and the physicians," says Brott.

Be aware of legal obligations

A decision to transfer the care of a patient to a specialist, when appropriate, typically involves minimal risk on the part of the transferring physician, unless the transferring physician was aware of significant problems associated with the specialist's practice and made the referral anyway, says Brott.

"On the other hand, the decision to transfer a patient from a hospital emergency department to another facility can be fraught with risks," she warns.

The Emergency Medical Treatment and Active Labor Act (EMTALA) requires that when a patient presents to an emergency department with an emergency medical condition, the physician and/or the hospital shall provide necessary stabilizing treatment or an appropriate transfer to another facility where stabilization can occur, says Brott. "EMTALA further requires hospitals' policies and procedures to define the responsibilities of on-call physicians to respond and treat patients with emergency medical conditions," she says. "Hospital policies must also address steps to be taken if the on-call physician is unavailable."

In the Missouri case, the transferring hospital and/or the neurosurgeon also could have faced monetary penalties and exclusion from Medicare and Medicaid, in addition to the professional liability claim, she says. EMTALA also mandates that hospitals with specialized capabilities or facilities, such as burn units or neonatal intensive care units, cannot refuse to accept appropriate transfers of patients who require such capabilities or facilities if the hospital has the capacity to treat them, notes Brott.

Brott suggests these practices to reduce legal risks involving transfers:

- When caring for a patient who was transferred to your hospital, don't rely exclusively on previous clinicians' documentation.
- When multiple physicians are involved in the care of the patient, confirm who is responsible for following up with laboratory test results and orders.
- Educate patients and families as to why a transfer is necessary, and document the conversation and the patient's agreement or refusal.
- Communicate relevant test results to subsequent treating clinicians, primary care physicians, and patients/family members.
- Ensure test results are clearly labeled as preliminary or final.

"Don't assume another clinician will reconcile preliminary and final results," says Brott.

- Don't rely exclusively on verbal reports without ensuring consistency with the written report.
- Transmit a copy of the discharge instructions and/or discharge summary to the patient's primary care physician.

If not available at discharge, consider providing an interim discharge summary clearly marked as preliminary with the diagnosis, pertinent medical history, and physical findings, says Brott.

Address any recommendations for subsequent treating specialists or sub-specialists, provide information on the patient's condition at discharge, and address medication reconciliation. Include details of follow-up arrangements and your name and contact information, she advises. "Confirm who will follow-up on test results posted to the patient's record after discharge," says Brott. "Lastly, physicians who transfer patients from emergency departments should understand their responsibilities under EMTALA."

Executive Summary

Inadequate communication between transferring and receiving physicians is the primary liability risk when a patient is transferred. Physicians transferring patients from an emergency department also have specific obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA).

✦ Don't rely exclusively on previous clinicians' documentation for transferred patients.
✦ Communicate relevant test results to subsequent treating clinicians, primary care physicians, and patients and family members.
✦ Confirm who will follow-up on test results posted to the patient's record after discharge.

Reference

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SOURCE

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Off-label prescribing? Know evidence base!

Physicians must not breach the standard of care

A patient given a medication "off-label" might allege that he or she was harmed by the prescribing physician as a result of negligent prescribing, says **Madelyn S. Quattrone**, Esq., senior risk management analyst at ECRI Institute in Plymouth Meeting, PA.

In 2008, several lawsuits were brought in numerous states for the off-label use of pain pumps, which were being placed directly in a patient's joint following orthopedic surgery. The plaintiffs argued the off-label use of the pumps destroyed the cartilage in their joints, necessitating joint replacement and causing permanent damage.

The off-label use of corticosteroids to treat brain edema following head trauma was halted after a randomized clinical trial of more than 10,000 adults with head injury revealed that this off-label use significantly increased the risk of patient death in the two weeks following the head injury.[1] "Similarly, off-label use of fenfluramine for weight loss was common, until it was shown that heart-valve damage occurred in thousands of patients who took the drug, resulting in lawsuits against providers and in class action litigation," says Quattrone.

Although the Food and Drug Administration (FDA) approves drugs for specific uses based on the data submitted during the approval process, it not only permits but expects off-label use, says **Leslie E. Wolf**, JD, a professor of law at Georgia State University College of Law's Center for Law, Health, & Society in Atlanta.

Off-label use isn't unlawful, and it doesn't necessarily constitute malpractice, says Quattrone. "The FDA does not regulate the practice of medicine. That function is reserved for state boards of medicine," she says.

Many common uses of FDA-approved drugs, including most pediatric uses, are off-label, says Wolf, but "physicians are at risk of liability if they breach the standard of care in their off-label prescribing."

Develop a policy and procedure for innovative off-label use of medication, with a multidisciplinary task force including medical staff, pharmacists, risk management, and the ethics committee, says Quattrone. "A facility might take several approaches to off-label use," she says. For example, it might not permit off-label prescribing at all, it might restrict off-label use to clinical research approved by an institutional review board, it might permit off-label use only if the use falls within the institution's therapeutic guidelines, or it might approve off-label prescribing based on clinical judgment of the provider that adequate evidence supports its use.

Physicians are less likely to be held liable for off-label prescribing if such use is considered standard of care among physicians in the same specialty and/or if there is evidence supporting the off-label use, says Wolf. *(See related stories on the standard of care, p. 103, and obtaining informed consent, below.)* "Accordingly, physicians should be familiar with the evidence concerning off-label uses before prescribing," she says.

Physicians are more likely to be held liable for injuries caused by off-label prescribing when the evidence base for the use is weak or non-existent, and when other physicians would not endorse the use, says Wolf.

"This risk can be compounded when physicians ignore FDA or manufacturers' warnings, or when they prescribe off-use without appropriate experience," says Wolf.

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Physicians must obtain consent for off-label use

Patients can successfully sue if you fail to properly obtain their consent when a drug or device is used in a manner that deviates from the purpose for which it was approved, warns **Claudia Dobbs**, loss prevention manager at MIEC, an Oakland, CA-based malpractice carrier.

When there is a potential for seri-

ous side effects due to off-label use of medications, Dobbs recommends considering these practices to reduce legal risks:

• Review scientific evidence that supports the off-label use of the drug with patients.

"Supplement your oral discussion with written information, video viewing, and Internet resources," recommends Dobbs. "Explain how the off-label drug will work better than the approved drug."

• Discuss with the patient the material risks and benefits of your recommendation for off-label use, which ensures your communication is at a health literacy level appropriate to the patient.

• With the patient's authorization, encourage family participation in the informed consent discussion.

• Answer all of the questions from the patient and family members, and document the patient's desire to proceed.

• Supplement the oral discussion by having the patient sign a consent form, and provide the patient with a copy.

• Clearly document your medical decision making.

"This will provide insight into your care and treatment of the patient and adherence with the standard of care," Dobbs says.

• Know whether or not the patient's health insurance plan will cover the cost of the off-label drug or device.

"Don't make your patients angry by failing to ensure that there is coverage," Dobbs says. "Should the patient experience an unexpected injury from the drug, anger over the uncovered medication will add to the patient's desire to seek the services of an attorney." ✦

Off-label use might be the standard of care

In a 2009 case, the plaintiff developed peripartum cardiomyaopathy pulmonary edema and congestive heart failure, which she claimed was caused by use of turbutaline as a tocolytic to stop contractions during pregnancy.[1] She also claimed the physician did not obtain her informed consent before prescribing the drug.

"The jury returned a $3.5 million verdict. The defendants appealed, and the court of appeals remanded the case due to procedural issues," says **Samantha L. Prokop**, Esq., an attorney with Brennan, Manna & Diamond, in Akron, OH.

Cases such as this one should not deter clinicians from off-label prescribing, however, cautions Prokop. "In fact, failure to use a drug or product off-label could also be considered malpractice, if the standard of care required off-label use," she says.

Off-label prescribing is permitted if it meets the standard of care, explains Prokop, and in some cases, it might constitute the standard of care. **Madelyn S. Quattrone**, Esq., senior risk management analyst at ECRI Institute in Plymouth Meeting, PA, says, "To succeed in court on a claim of negligence, the plaintiff must prove that the off-label prescribing breached the standard of care, and that the drug, as prescribed, caused harm to the patient, or it was a substantial factor in causing harm to the patient."

The use of a drug "off-label" does not imply that the physician has acted below an accepted standard of care, and for some conditions, off-label use has become the standard of care, says Quattrone, "but when there is lack of valid clinical evidence and published peer-reviewed literature to support off-label use of a particular drug, the use of the drug involves some degree of uncertainty and risk about safety and efficacy."

Battle of experts

If a claim involving off-label use goes to trial, the jury will hear opposing expert opinion on whether the physician's prescribing breached the standard of care and whether the use of the drug was the proximate cause of harm to the patient, says Quattrone.

In one claim, a plaintiff alleged that the risk of the off-label use of a YAG laser had not been fully explained to him. "Corrective surgery went well, but the patient claimed impairment to near and intermediate distance vision, clouding in the center of the eye and general reduced vision quality," says **Janice M. Ginley**, assistant claims manager for MIEC, an Oakland, CA-based malpractice carrier.

The physician's documentation of the risks and alternatives to treatment was poor. "Despite review by multiple ophthalmic surgeons, we could not find any support on the standard of care for the use of YAG laser ablation in the treatment of vitreous floaters," adds Ginley.

In fact, several ophthalmologic surgery consultants explained that a YAG laser is too dangerous for treatment of vitreous floaters because there is too much risk of injury to the lens in this off-label application of the device, she explains.

"Although an independent medical examination demonstrated that the patient had a near-full recovery within months of the incident, because of the intentional acts, personal exposure and lack of expert support, the case was mediated and settled in the mid-six figure range," says Ginley.

Reference

1. Huss v. Gayden, M.D., 571 F.3d 442 (Fifth Cir. 2009) ✦

Does expert say your care was negligent?

Does an insurance company's expert say your care was negligent, but you disagree? Seek legal advice and evaluate whether a conflict of interest with the insurer exists, advises **Damian D. Capozzola,** JD, an attorney with Crowell & Moring in Los Angeles and co-author of Expert Witnesses in Civil Trials: Effective Preparation and Presentation.

"The physician may argue that he or she is entitled to insurer-funded independent counsel, with an implied right to an insurer-funded independent expert as well," says Capozzola.[1,2] He gives these recommendations:

• Consider retaining independent counsel and an independent expert privately, even if under the physician's particular circumstances or the law of the applicable jurisdiction the insurer is not obligated to fund such fees and costs.

"Such an expert could analyze the underlying facts, and hopefully reach a strong and independent conclusion that the care provided was not negligent," Capozzola says.

If physicians are unable to secure an independent expert who, after reviewing the facts, is willing to testify that the care was not negligent, they "should think seriously about trying to settle the matter quickly and quietly," he says.

• Work with attorneys to attack an expert's opinion based on his or her experience, data gathering and testing, and reasoning.

Communications with an expert might be discoverable by the other side in depositions, should the case progress that far, cautions Capozzola. However, he says to take an active role in ensuring your own expert has a full command of the relevant facts, good and bad.

"Even the most experienced expert is coming to the case cold, does not have a first-hand understanding of how the case progressed and can miss key facts," he says. "Indeed, some experts become complacent over time and are especially vulnerable to not gathering all the relevant materials or overlooking key details."

The expert's opinion should be based on a complete mastery of all the favorable evidence, with consideration of how any negative evidence might be reconciled with an overall opinion that remains favorable for the physician, he says.

Capozzola says that physician defendants can collaborate with their own expert and counsel to explore these questions:

— Does this particular insurance company expert really have the right experience in this particular area of medicine to have a qualified opinion? Or is this expert's experience such that he or she is essentially a paid "mouthpiece" for this particular insurance company and, therefore, is biased?

— Has the insurance company expert reviewed all of the necessary data and performed the right tests on that data?

— Even if the insurance company expert has the right experience and has analyzed the right data, has he or she employed the right reasoning?

— Is it possible that reasonable minds might disagree whether the care provided was negligent or not?

"These responses can lead to leverage the physician can use to extract concessions to support the argument that the care provided was not negligent," Capozzola says.

• Avoid delaying or stalling tactics, hoping the problem will simply go away.

"Get out in front of expert retention and analysis issues early," urges Capozzola. "Finding the right expert and working with that expert to develop a strong and credible analysis takes time." Involving an expert early will help direct the investigation or case, leaving ample time to obtain information that the expert needs to credibly and favorably bolster his or her analysis, he says.

"Delaying the retention of an expert until late in the proceedings may result in such opportunities being foreclosed, due to the passing of case deadlines or due to records that were previously available being lost or destroyed," Capozzola says.

Executive Summary

If an insurance company's expert says a physician's care was negligent, the physician should evaluate whether a conflict of interest exists.

✦ Physicians might be entitled to insurer-funded independent counsel and expert.

✦ Physicians might wish to retain independent counsel and an independent expert privately.

✦ An expert's opinion can be attacked based on experience, data-gathering and testing, and reasoning.

References

1. Cal. Civ. Code Section 2860(a).
2. San Diego Navy Fed. Credit Union v. Cumis Ins. Society, Inc., 162 Cal. App. 3d 358 (1984).

SOURCE

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Check policy now for 'consent-to-settle' clause

If physicians who were additional insured on a group practice policy leave their practices, and later are the only defendants in a medical professional liability action on that policy, they might find themselves unable to settle the claim.

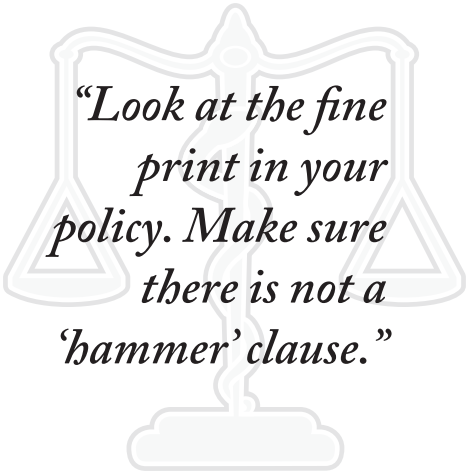
"The former practice might not consent to the settlement, in order to prevent a payment impacting its premium," says **Stephanie A. Sheps**, Esq., director of claims at Coverys, a Boston-based provider of medical professional liability insurance.

In some scenarios, consent might rest with entities who are not a party to the action or entities from which the physician defendant is estranged, Sheps explains. "In this instance, there are few, if any, remedies to the physician, other than to appeal to the policyholder's logic and reason," she says.

Too often, physicians are unaware of "consent to settle" or "hammer" clauses included in their professional liability insurance contracts — until litigation occurs, warns **Jonathan Katz**, president of Oros Risk Solutions, an Orlando, FL-based insurance and consulting agency specializing in selling medical professional liability insurance.

Consent to settle clauses provide that the insurer will not settle any claim without the insured's consent, as long as consent is not withheld unreasonably, explains Sheps. "These types of clauses are often found in professional liability policies so that the insured maintains an additional measure of control over his professional reputation and potential impact on future employment and licensure," she says.

Though professional liability insurers typically involve the policyholder in decision-making for case disposition regardless of the presence of such a clause, they serve to ensure that the policyholder's position on settling a case is considered and followed in the event there are opposing views on the matter, says Sheps.



"Look at the fine print in your policy. Make sure there is not a 'hammer' clause."

Katz says, "There are different variations of consent to settle, and there are different state-specific legal requirements that have allowed for it or not." In Florida, to the benefit of plaintiff attorneys, consent to settle clauses were against public policy to be included in policies for physicians for many years, but this legislation recently was overturned, he reports. "Plaintiffs may invest $200,000 or more on these cases, and as they are typically on a contingency fee, risk getting nothing in return if they don't win," says Katz. "If they can get the insurance company to settle with them, they don't have to take as much risk or invest as much work hours and money, and they don't have to wait for the reward."

Regardless of whether a policy includes a consent to settle clause, the liability insurer should be mindful of the physician's feelings about settlement, says Sheps.

"Claims professionals and defense counsel are aware of the professional and personal ramifications of paying a claim and give them due consideration when determining case disposition," she says.

Look for "hammer" clauses

Katz advises, "Look at the fine print in your policy. Make sure there is not a 'hammer' clause. We see this quite often in the excess and surplus lines insurance market or with lower-quality risk retention groups or start-up companies." *(See related story, p. 106, on what physicians should consider before purchasing medical malpractice insurance.)*

"Hammer" clauses shift the risk back to the policyholder in the event of an adverse verdict if they withhold consent after the insurer has recommended settlement, says Sheps. "A 'hammer' clause is designed to compel the insured to consent to settlement by providing financial consequences to the decision," she explains.

For example, if the insured refuses consent to a settlement or compromise that is acceptable to the claimant and elects to take the matter to trial, a hammer clause might provide that the insurer's liability will be capped at the amount for which the claim might have been settled plus expenses, regardless of whether the available

Executive Summary

Physicians should be aware of whether their professional liability insurance contract contains a "consent-to-settle" clause, stating that the insurer won't settle a claim without the physician's written consent.

- ✦ State-specific legal requirements vary.
- ✦ A "hammer" clause makes the physician responsible for any additional costs incurred if he or she chooses to go to court rather than settle the case.
- ✦ Physicians should consider insurers' approaches to handling claims.

policy limit was higher than that amount.

"The insured would be responsible to pay the balance of this judgment," says Sheps. "Physicians should read these clauses carefully and understand their potential exposure in the event of an adverse verdict."

Physicians should also consider who has the right to consent when their policies contain a consent to settle provision, and this is especially important when a physician is an additional insured on a hospital or group policy, she says.

Usually, the right of consent will be given to the "named insured" on the policy, which is often the hospital or group, says Sheps. "It is critical for physicians to read and understand the policy's definition of "named insured" in those instances," she says. "Have a clear understanding of the hospital or group's interpretation of the policy."

SOURCES

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Buying policy? Money isn't the only factor

Physicians often can be short-sighted when buying malpractice insurance

The cost of your premium and your policy limit aren't the only things to consider when purchasing medical malpractice insurance.

"Often, whoever comes in with the lowest price is what the doctors want," says **Jonathan Katz**, president of Oros Risk Solutions, an Orlando, FL-based insurance and consulting agency specializing in selling medical professional liability insurance. "But that is a very short-sighted approach."

Here are some often-overlooked factors to consider when buying malpractice insurance:

• Whether the company has a legitimate rating of A or better.

"Just as in medicine, where there are legitimate board certifications and there are certifications that are not recognized as valid that you can just take a weekend course to obtain, the same thing is true with financial rating companies. Some rating companies will give out an 'A' rating that we don't believe is legitimate," Katz cautions. He adds that Oros recommends a company rated "A" or better by A.M. Best Co.

• The amount of money the insurance company has put away to pay claims.

"You want to be with an insurer that is financially secure, which can invest in the best defense and best expert witnesses," says Katz. "Some start-up insurance companies writing medical malpractice policies have a very small surplus."

In meetings with medical groups, Katz has sometimes determined that the combined net worth of the physicians in the group was more than the surplus of the insurer they were considering. "When you have more money to pay claims than your insurance company, that's a problem," he says. "You have to look at the financial backing of the company. What happens to you if the company goes under because it's poorly capitalized?"

"When you have more money to pay claims than your insurance company, that's a problem."

• The way the insurer handles claims.

Some insurance companies just want to deal with claims the cheapest way possible and will try to use every angle in the policy to get out of a paying a claim, says Katz. "Others are physician-centric and take a long-term approach. They like to go to court and send a message that they are not an easy target," he says. "Look at the company's culture around how they handle claims."

• The availability of patient safety and risk management resources.

"Most of the major companies have risk management and patient safety departments, but some do a better job than others," says Katz. "Maybe there are no claims currently, but the group wants to get better in certain areas."

Physicians often fail to take advantage of the resources available to them at no cost, such as site assessments and training, though. "They may have been with a company for ten years and extracted zero resources," says Katz. "We see that all the time."

• Experience and success rates.

Consider the insurer's win ratio at trial, how long they have operated in your state, and whether they handle claims themselves or hire a third party to do so, advises Katz.

"When you have a claim, you want to make sure they have the experience and the financial strength to go fight it and win," he says. ✦

Time limit of 4 years for med-mal suits upheld

Should a patient be allowed to sue a physician for malpractice that occurred many years or even decades earlier? No, according to a recent Ohio Supreme Court ruling that upheld the constitutionality of a state law that prevents medical liability cases from being filed more than four years after the date of an alleged incident.[1]

The ruling provides a reasonable amount of time for a person injured by negligence to determine they were injured and bring legal action, while at the same time holding the physician or other medical provider legally responsible for a reasonable time, according to **Rick Sites**, Esq., legal counsel for the Ohio Hospital Association.

Thirty-two states and one territory have enacted medical malpractice statutes of repose, and at least 16 states have upheld those statutes against constitutional challenges, adds Sites. (*A list of states upholding statutes of repose can be viewed on p. 14 of a legal brief at http://bit.ly/Wle7Pf.)* "Only one state, Kentucky, found its statute of repose unconstitutional, and that was a 1990 ruling that might be decided differently today," he says.

Generally speaking, a statute of limitation is the time a person has to file a lawsuit following an injury of which the injured person is aware, whereas a statute of repose addresses situations where a person is not aware of the injury, such as an object left in the person during surgery, and gives a period of time for the person to discover the injury and then file a lawsuit, explains Sites.

Without statutes of limitation and repose, past events would forever adversely affect important medical business operations such as medical record keeping, liability insurance purchases, purchase and financing of new technology, expansion, and mergers and acquisitions, says Sites. "Additionally, the medical provider would forever be haunted by the fear that someone in the distant past could suddenly file a legal action and do so when memories of the event were impaired, medical records destroyed, and witnesses unavailable due to relocation or death," he says.

The decision means a medical provider has more certainty that events in the past will not adversely affect future medical business operations, according to Sites. "Opportunities to benefit society would be frozen, or at least impeded, by fear of events — forgotten or unknown — lurking in the past," he says.

Reference

1. Ruther v. Kaiser, 2011-Ohio-1723. ✦

COMING IN future MONths

✦ New treatments that are now standard of care

✦ Stop risk-prone practices involving obese patients

✦ Avoid lawsuits alleging prescribing errors

✦ Keep online reviews from becoming lawsuits

CME OBJECTIVES

After reading *Physician Risk Management*, the participant will be able to:

- describe the legal, clinical, financial, and managerial issues pertinent to physician risk management;
- explain the impact of risk management issues on patients, physicians, legal counsel, and management;
- identify solutions to risk management problems for physicians, administrators, risk managers, and insurers to use in overcoming the challenges they face in daily practice.

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.

2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.

5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ✦

CME Questions

1. Which is recommended regarding disclosure, apology, and compensation programs, according to Richard C. Boothman, JD, chief risk officer at the University of Michigan Health System?

A. Smaller physician practices should not collaborate with insurers or larger organizations to develop disclosure programs.

B. Physicians should always disclose errors in real-time, even if they don't yet understand what occurred.

C. Physicians should call for help if it even crosses their minds that they might need assistance.

D. Physicians should apologize to patients only if they are certain the apology will not be admissible as evidence in the event a lawsuit is filed.

2. Which is true regarding legal risks involving transferred patients, according to Lizabeth Brott, JD, regional vice president of risk management at ProAssurance Companies?

A. Inadequate communication between the transferring physician and the receiving physician is the primary liability risk when a patient is transferred.

B. Receiving physicians can legally rely exclusively on previous clinicians' documentation for transferred patients.

C. Transferring physicians face significant legal risks even when the decision to transfer the care of a patient to a specialist is appropriate.

D. The transferring physician is not legally responsible for making the receiving physician aware of test results that were posted to the patient's record following transfer.

3. Which is true regarding liability risks involving off-label prescribing, according to Madelyn S. Quattrone, Esq., senior risk management analyst at ECRI Institute?

A. Physicians are less likely to be held liable for off-label prescribing if such use is considered standard of care among physicians in the same specialty and/or if there is evidence supporting the off-label use.

B. Physicians cannot be held liable for injuries caused by off-label prescribing even when the evidence-base for the use is weak or non-existent.

C. Patients who are treated using medications for "off-label" indications cannot allege they were harmed by the prescribing physician as a result of negligent prescribing.

D. Off-label prescribing cannot be considered as the legal standard of care under any circumstances.

4. Which is recommended if an insurance company's expert says a physician's care was negligent, according to Damian D. Capozzola, JD, an attorney with Crowell & Moring?

A. It is not advisable for physicians to retain independent counsel and an independent expert privately.

B. Physicians should evaluate whether a conflict of interest exists.

C. Physicians should retain an independent expert only if the insurer is obligated to fund this under the law of the applicable jurisdiction.

D. If physicians are unable to quickly secure an independent expert who after reviewing the facts is willing to testify that the care was not negligent, this situation should not factor into the decision as to whether to settle the claim.

Physician Legal Review & Commentary

A Monthly Supplement to PHYSICAN RISK MANAGEMENT

Court awards $5 million against radiologist for failure to diagnose an impending stroke

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News: A couple was awarded $5 million against a radiologist who failed to properly diagnose and prevent a stroke that resulted in brain damage. Plaintiff presented to the emergency department with complaints of a severe headache that lasted several days. A few hours later, she developed slurred speech, restlessness, giggling, paralysis to her right arm, and low blood pressure. She underwent a CT scan, which plaintiff's counsel alleged was misread. The plaintiff subsequently suffered a seizure and brain hemorrhage resulting in brain damage.

Background: On Aug. 9, 2007, the plaintiff, a 25-year-old female, presented to the emergency department at a 100-bed community-based hospital at approximately 8:30 a.m. with complaints of a severe headache that developed three days earlier. She also reported seeing occasional flashes of light. Over-the-counter medications did not provide any relief. She was initially treated at the hospital for a migraine. She was given intravenous fluids and pain medication. At approximately 11:30 a.m., she developed slurred speech, restlessness, giggling, paralysis to her right arm, and low blood pressure. At 12:20 p.m., a CT scan was ordered.

...if the CT scan had been properly read, the plaintiff could have been given heparin, a blood thinner, to prevent the stroke.

The defendant, who was a member of a radiology group under contract with the hospital's radiology department, reviewed the CT scan and gave the following diagnosis: "[T]there is no evidence of acute hemorrhage, mass lesion, mass effect, acute ischemia or extra axial fluid or collections." The defendant noticed that two veins in the plaintiff's brain were "mildly prominent," but reported that they were of "doubtful clinical significance."

At 5:35 p.m., the plaintiff suffered a seizure and hemorrhage. She was placed on a ventilator and transferred to a hospital in a large metropolitan area. A CT scan performed at that hospital revealed that the plaintiff had suffered intra-cranial hemorrhages. She underwent brain surgery. The plaintiff remained on a breathing machine for 11 days and was in a medically induced coma for a portion of the time. She remains partially paralyzed in her right arm and right hand. She developed epilepsy and suffers from seizures.

The plaintiff's counsel alleged that the CT scan showed significant abnormalities and if the CT scan had been properly read, the plaintiff could have been given heparin, a blood thinner, to prevent the stroke.

A jury found the radiologist negligent and awarded the plaintiff and her husband $5 million, which was the amount requested from the jury.

What this means to you: Here we have a 25-year-old married woman who suffered a significant lifelong

Financial Disclosure: Co-Authors **Jonathan D. Rubin**, Esq., **Heather Laschewer, Leilani Kicklighter**, **Christopher U. Warren**, and Executive Editor **Joy Dickinson** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

neurological untoward outcome. By today's standards, she has the majority of her life ahead of her.

This patient presented to the emergency department with a headache of "several" days duration that initially was diagnosed as a migraine. However, we don't know the basis of this diagnosis and whether she had a history of migraines. If so, how were prior migraines treated, and what was the efficacy of that treatment? Had she been to a neurologist for the diagnosis and treatment of migraines if this were not the first episode? If so, was that neurologist called by the emergency department staff? Was any neurologist called to consult on this patient?

Many hospitals have created Stroke Centers of Excellence. Many such centers are accredited as stroke centers, meeting accrediting standards and medical practice standards. We do not know if this hospital was/is a Stroke Center of Excellence. However, there are accepted evidence-based standards of practice regarding treatment of suspected stroke in any setting.

The timeline is as follows: admission to the emergency department at 8:30 a.m. with changes in speech and sensorium, and weakness of her right arm at 11:30 a.m., three hours later. The CT was ordered 50 minutes later, but we do not know when the CT was read by the radiologist and if the radiologist who viewed the films was on site. We don't know if the film was ordered stat, when it was finally read, or when the results were conveyed to the treating physician. To whom and when were the results of the CT scan conveyed? Was the reading of this CT scan considered critical laboratory/test results and conveyed in that manner? Did the radiologist contact the patient's physician directly or just send the preliminary report to the emergency department? Was the radiologist made aware of the patient's significant neurological changes as the clinical indication for the CT scan and to convey the significance of the situation? Only the chart documentation and a detailed timeline would provide us with some of this critical information.

At this point, we don't know if a neurologist had been called in to consult and if the patient had been admitted or was still in the emergency department. If a neurologist was not called to consult, then why not? What are the standards in this facility regarding when to call in a neurologist or neurosurgeon? If she were still in the emergency department, how often and by whom was she being monitored? Emergency departments are not intended nor are they staffed to monitor patients to the extent patients are monitored in an intensive care unit or an inpatient nursing unit.

The time between when the CT scan was ordered and the patient suffered a seizure and hemorrhage and put on a ventilator was 5 hours and 15 minutes, at which time she was transferred to a hospital in a large metropolitan area. Again, this raises the question of when the CT scan was read, when were the results conveyed, and to whom? We still don't know if and when a neurologist or neurosurgeon was called or if called when he/she came to the emergency department. Another CT scan was done at the subsequent hospital that showed an intra-cranial hemorrhage. When compared to the films taken at the first hospital, significant abnormalities were evident.

When a situation such as this one arises, the risk manager at the first hospital should conduct a detailed investigation into the timeline and facts of this patient's stay before transfer to the city hospital. The risk manager, on behalf of the hospital, should notify the hospital liability insurance carrier. The doctors involved should notify their individual carriers. The radiologist was part of the radiology group contracted with the hospital to provide radiology services. The risk manager should review the contract to determine whether the radiologist in this matter acted in concert with the terms of the contract.

Does this hospital have a quality control program in the radiology department that entails rereads of an established sample of different types of tests and reads by different radiologists throughout the year, the re-reads done by a different radiologist than the original reading radiologist? Where are those studies reported? Does the risk manager involved have input into trends or patterns of differences in readings? This particular case should be sent for medical peer review. Is this a part of the contract?

This unfortunate adverse untoward outcome meets The Joint Commission standard for a disclosure meeting. More than 25 states have statutes requiring disclosure of adverse events, in addition to The Joint Commission standard. Physicians and risk managers should be familiar with their state's statutes regarding disclosure and apology. In this situation the risk manager should facilitate a root cause analysis into this situation. In addition, the risk manager should facilitate a disclosure meeting with this patient's husband, the physician's involved, and nurses.

The risk manager should facilitate a collaborative review of the protocol for dealing with sustained headaches, including neuroradiology, emergency department physicians, neurologists, and neurosurgeons with a focus on validating or modifying the current practice protocol.

Reference

Rockingham County (NH) Superior Court. Civil Action No. 218-2010-CV-00670. ✦

Failure to diagnose meningitis leads to stroke, subsequent brain damage, and a $28.5M verdict

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News: A 10-month old infant presented to defendant hospital with complaints of a persistent fever. He was treated by two doctors, who were also co-defendants. The doctors ordered a spinal tap, but misdiagnosed the presence of bacterial meningitis. As a result, the infant suffered a stroke, which caused severe brain injuries. A jury awarded the infant and his mother $28.5 million, which included a $12 million award for non-economic damages. Florida law places a limit on non-economic damages, thus the $12 million award may be reduced to $1 million. Additionally, the doctor who the jury found mostly liable did not have medical malpractice insurance. Under Florida law, this doctor may be liable to pay only $250,000 of her share of the verdict.

Background: In 2006, a 10-month old infant was presented to defendant hospital with complaints of a persistent fever. He was treated by two doctors, who ordered a spinal tap. The doctors did not initially diagnose the meningitis after they reviewed the spinal tap, and therefore no treatment for it was provided. The infant subsequently suffered a stroke, which destroyed three of the five lobes on the left side of his brain.

The infant, who is now a 7-year-old boy, has the mental capacity of an 18-month-old, and will probably remain that way for the remainder of his life. He wears diapers and is unable to talk. He also suffers behavioral disabilities, which include punching his head and banging it against the wall.

The infant's mother, individually and on behalf of the infant, sued the hospital and both doctors. She alleged the defendants failed to diagnose the bacterial meningitis on the spinal tap's results and failed to give her son the treatment that could have cured him. As a result, her son suffered a stroke and subsequent brain damage, she claimed.

The infant, who is now a 7-year-old boy, has the mental capacity of an 18-month-old, and will probably remain that way for the remainder of his life.

At trial, the plaintiff's expert opined that prompt treatment with antibiotics would have successfully treated the infant. The doctors alleged that they eventually diagnosed and treated the meningitis. And the doctors alleged that the infant was "beginning to respond well" to the treatment and that the stroke was a "surprise."

The plaintiff sought recovery for medical expenses, and past and future pain and suffering. The jury found that the doctors departed from the standard of care and returned a verdict for $28.5 million against them. It found one doctor 75% liable and the other doctor 25% liable. This split means the doctors would be responsible to pay roughly $21.3 million and $7.1 million each, respectively. The hospital reached a tentative settlement with the plaintiff for a nominal amount.

The jury's verdict included a $12 million award for non-economic damages. While current Florida law places a cap of $1 million for such non-economic damages in medical malpractice cases, the constitutionality of this law is before the Florida Supreme Court. As such, the plaintiff may be entitled to recover the full non-economic damage award. The doctor who was found 75% responsible, however, had no medical malpractice insurance. Under Florida law, she may only be responsible for $250,000 of her portion of the verdict.

What this means to you: Any time an untoward outcome involves a child, there is a lot of emotion in response, regardless of the etiology. This outcome is tragic and affects more than just the child/patient.

Working with the facts we are given here, there are many questions raised that might give us a more complete picture. The facts we are given here indicate the two physicians who attended to this infant focused appropriately on ruling out meningitis, as the presenting sign and symptom was a persistent elevated temperature (fever). The appropriate meningitis diagnostic test, a cerebrospinal tap, was done. We are told the doctors reviewed the spinal tap and made a decision that meningitis was not the diagnosis.

What was documented in the record to support their diagnostic decision?

Here is where some of our questions arise. First, why were there two physicians? Were both caring for the child at the same time, or did one call in the other for assistance? Second, what were the specialties of these two physicians? Was one the child's pediatrician or the pediatrician on call, and/or was one the emergency department physician. If so, was he/she a pediatric emergency department physician? Is the emergency department medical care provided through a contracted group? Does this hospital have a designated pediatric emergency department and pediatric trained medical and nursing staff? Are either of these two physicians employees of this hospital?

Another question is, what does it mean that the two doctors reviewed the spinal tap? Did they rely on the absence of cloudy spinal fluid to determine whether it was meningitis? Was a gram stain done? Did the laboratory do a stat review of the specimen? What was the final laboratory report? What was being done to reduce this child's fever while in the emergency department? What were the other physical signs or symptoms exhibited by this child, and how were they evaluated by these two physicians? What was the jury's reasoning for the 75/25% distribution of liability?

At this point we are discussing a diagnosis of meningitis, based on the facts and information we are given here, that allegedly eventually lead to a significant, unexpected stoke. However, we are told this meningitis diagnosis eventually was made. If so, by whom? When? And was it bacterial or viral? If it was viral, we know antibiotics would not have been effective and might have been detrimental in some situations. Much literature has been distributed to educate the public and the medical community about the result of prescribing antibiotics for viral infections or other conditions. This literature states that the symptoms of viral infections treated with antibiotics will recede on their own. These prescription might have contributed to the increasing antibiotic resistance of many bacterial organisms, thereby reducing the "weapons" we have to fight some infections.

We are told that the child was treated for meningitis, but the timeline does not tell us what the treatment was or when the treatment began. We are told the child was "beginning to respond well," but we are not told the relationship of these events to the untoward, unexpected massive stroke this child experienced. Without this information, we cannot opine whether the treatment would have been effective in preventing this outcome if it had been initiated earlier. Additionally, the lack of diagnosis, bacterial or viral, is a critical omission from this discussion. However, even with these many unanswered questions, there are many steps that could or should be taken to prevent recurrences of such events in the future.

What were the other physical signs or symptoms exhibited by this child, and how were they evaluated by these two physicians?

The untoward outcome would have been promptly reported to the hospital risk manager, who should have responded rapidly, and the physicians should have notified their insurance carrier. In this case, we are told that only one of the two physicians carried medical malpractice insurance. It is suggested that, even when a physician/surgeon carries no or low limits of medical malpractice insurance, they have identified a medical malpractice defense attorney to contact in instances such as this one with substantial untoward outcome. In Florida, in addition to The Joint Commission standard, there are statutory requirements governing disclosure of untoward events to patients. This is such a case in which a disclosure meeting with the family of this infant should be coordinated by the hospital risk manager. The meeting should include the family, the two physicians and an emergency department nursing representative. However we do not know where this child was located when the stroke occurred, so the nursing representative or bedside nurse, if not in the emergency department, also should be included.

This case should be thoroughly investigated by the hospital risk manager and the case should be referred to the medical staff for a peer review and proper action based on those findings. In addition, a root cause analysis should be undertaken, coordinated and facilitated by the hospital risk manager. The results of this root cause process should be shared with the medical staff. Steps also should be taken to implement findings that "tighten" the current processes that may prevent recurrences. In addition, the emergency department, pediatric, neurology, and infectious disease medial staff should collaborate in reviewing the process of evaluation, diagnostic steps, and tests and treatment of pediatric potential meningitis diagnoses. All emergency department, pediatric, and neurology physicians should be educated to the revised or confirmed critical pathways developed as a result of this collaborative review.

Reference

Palm Beach County (Florida) Civil Court, Action No. 502008CA026517XXXXMB. ✦