

PHYSICIAN *Risk* *Management*



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Surprising facts on diagnostic errors: Change practices to stop avoidable suits

It's the number one reason for successful malpractice suits

Diagnostic errors are the leading cause of successful medical malpractice claims, according to a recently published analysis of 350,706 paid claims occurring from 1986 to 2010 from the National Practitioner Data Bank.¹ Diagnostic errors represented 29% of the claims and accounted for 35% of total payments (\$38.8 billion). Payouts were higher for severe disability, such as quadriplegia or severe neurological injuries, than for death.

Diagnostic errors in outpatient and ambulatory care clinics more commonly resulted in malpractice suits than inpatient errors, but inpatient errors were more deadly. "That's in keeping with what you'd expect," says **David E. Newman-Toker**, MD, PhD, the study's senior author and associate professor in the Department of Neurology at Johns Hopkins Hospital in Baltimore, MD. "There are a lot more outpatients, so a lot more errors will happen. But the risk that

they are life-threatening is lower than in the hospital setting."

Diagnostic errors resulted in death more than other allegation groups (41% compared with 24%). The fact that serious morbidity was more common than mortality was somewhat surprising to the researchers. "We had good numbers before on deaths, but not good epidemiologic information on injuries short of death," says Newman-Toker. "We really didn't know a lot about morbidity associated with diagnostic error, in terms of its general prevalence in the population."

William R. Forstner, JD, an attorney in the Raleigh, NC office of Smith Moore Leatherwood, says, "We have seen a number of initial diagnostic determinations which turned out not to be correct. These arise often in radiology reads of head CT or spinal imaging, but also within traditional medicine." Here are items that Forstner says if documented, can make a misdiagnosis claim more defensible:

The fact that serious morbidity was more common than mortality was somewhat surprising to the researchers.

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- Information that shows the clinical team was focused on the patient's condition.

The record should reflect regular monitoring and attention, as well as timely treatment for the presumed diagnosis. "Documentation should show adequate attention was paid to the patient's symptoms and potential medical needs," says Forstner.

- The clinician's conclusion that additional or different treatments should be considered if the current care does not address the patient's condition.

For example, a physician might document, "If the patient's condition does not improve on antibiotics after 48 hours, consider X."

- Negative symptoms that help to rule out particular conditions.

For example, physicians might document "patient denies chest pain," "no evidence of redness/swelling," or "white blood cell count not elevated."

"Including multiple diagnoses in a differential diagnosis can cut both ways," adds Forstner. It shows that a physician is evaluating the patient's condition to determine possible causes,

Executive Summary

Diagnostic errors are the leading cause of successful medical malpractice claims, with claims higher for severe disability than for death. Many patients who are misdiagnosed in the primary care setting present with common symptoms. Providers should consider:

- ◆ using tools such as electronic decision support and diagnostic checklists to ensure an adequate differential diagnosis;
- ◆ taking a "diagnostic time out" for high-risk cases;
- ◆ expressing uncertainty upfront, and giving patients specific follow-up instructions.

and it helps avoid the argument that a physician is covering for a mistake after the fact by claiming to have believed the patient had a different illness or injury.

"However, not every possible diagnosis can be or is treated," Forstner says. "It can help or hurt a defendant if the ultimate diagnosis was considered, but not treated, earlier in the patient's course."

Area is "scientifically immature"

Creating strategies to reduce diagnostic errors is "an area that is still scientifically immature," says

Newman-Toker. "There are a number of things that people have developed or attempted."

None of these practices have been studied extensively in terms of their impact in reducing diagnostic error, he notes, though many have been studied for their immediate impact on simulated cases. Here are some practices for providers to consider, which might reduce liability risks of diagnostic errors:²

- Monitor your own natural tendencies to overestimate or underestimate the likelihood of a particular diagnosis based on bias, rather than sound reasoning.

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Editorial Questions
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• Use diagnostic checklists to make sure you have considered all the possibilities for a patient's symptoms, especially when there are red flags, such as the patient returning multiple times for the same complaint without a firm diagnosis.

• Take a "diagnostic timeout." "This is like a surgical timeout. Make sure you are taking a deliberate pause, if this is a patient you didn't give your full attention to, because you were distracted, or a high-risk case," Newman-Toker says.

EMRs "not there yet"

Better devices, better diagnostic tests, computer-based decision support, and improved diagnostic education are on the horizon, says Newman-Toker, but "the EMR is not yet there, in terms of doing good diagnostic decision support."

Some electronic medical records flag abnormal test results that never were followed up on, subsequent tests that never were ordered, refer-

als that never were made, and unexpected revisits to a hospital or provider. "Some organizations are working to use the EMR to identify problems not only after the fact, but also in real-time, when something has gone wrong with the diagnostic process," says Newman-Toker. "This is mostly being done around communication of test results."

Newman-Toker is unaware of any EMRs that are set up to help physicians make a diagnosis in a patient with a new symptom such as headache or dizziness.

"These sorts of decision support aren't yet accurate enough, efficient enough, or sufficiently well-tested for their impact on patient care to be incorporated right now," he says. "As for where the EMR could go in the future, the sky is the limit in terms of what it could help us with." (*See related story, below, on misdiagnosis in primary care settings.*)

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Common diseases are being missed — Insufficient time is risk in primary care

In the primary care setting, the most commonly missed diagnoses were pneumonia (6.7%), decompensated congestive heart failure (5.7%), acute renal failure (5.3%), and primary cancer (5.3%), according to an analysis of 190 primary care diagnostic errors that occurred in 2006 and 2007 at two large facilities.¹ Cough was the most common chief presenting symptom associated with a missed diagnosis.

"People tend to think that a lot of diagnoses being missed relate to rare, unusual, and hard-to-diagnose conditions. But our study found that many common diagnoses were being missed in primary care settings," says **Hardeep Singh, MD, MPH**, the study's lead author, chief of the health policy, quality and informatics program at the

Houston VA Health Services Research Center of Excellence and assistant professor of medicine at Baylor College of Medicine in Houston.

For example, an elderly male with lymphoma presented with headache, cough, green sputum, and fever. However, the provider did not order labs or X-ray to evaluate for pneumonia.

A "major finding"

Patients often presented with common symptoms, such as cough, shortness of breath, or abdominal pain. Most of the process breakdowns could be traced back to the history and physical exam. "That is a major finding," Singh says. "It suggests we are probably not spending enough time with the patient.

This is something in the patient/physician encounter that needs to be revitalized."

Differential diagnoses were not documented up to 80% of the time. "To us, this finding suggests that there are some critical thinking processes that weren't being documented," Singh says. "Traditionally, when faced with uncertainty in the clinical encounter, we tend to think through the possibilities."

The providers might have done this, but there was no evidence of it in the chart. Singh thinks that documenting a differential diagnosis in the medical record itself helps physicians to consider other possibilities for a patient's symptoms. "We think it's a good exercise that people should do more of, but just don't have the time for," he says.

Primary care physicians are caring for more complex patients in a highly fragmented healthcare system, and many of them commented about the paper's findings. "They said they are so overwhelmed with the time crunch that they are not able to decipher the signal within the noise," Singh says. "One of the things that we need to be thinking about is how to best support the cognition of the primary care doc-

tor."

If physicians aren't certain of the patient's diagnosis, they should express that uncertainty upfront and give specific instructions such as, "It is very important that you call back if you are not better in two to three days because this could be something else," says Singh, instead of letting the patient decide what to do.

"Engage with patients more, and

let them know they are in charge," he advises. "Patients can play a pretty strong role in improving their own diagnosis."

Reference

1. Singh H, Giardina TD, Meyer AND, et al. Types and origins of diagnostic errors in primary care settings. *JAMA Intern Med* 2013; 173(6):418-425. ♦

Unpleasant office staff? It's one reason for suits — Many claims involve rudeness

When a patient called a pediatrician's office to ask for a same-day appointment because her child was not well, she received a curt response from the receptionist.

"The mother was known to call often and bring her 18-month-old child for even a minor cold," explains **Molly Farrell**, vice president of operations for MGIS Underwriting Managers in Salt Lake City, UT. "The receptionist, knowing the office was busy that day, told her there was no way she could be seen and made an appointment for two days later."

The receptionist didn't fully listen to the mother's complaints, however, and did not inform the nurse or doctor of the call. Within a few hours, the child got worse, and the mother drove her to a nearby hospital.

"Unfortunately, by that time the child had full-blown meningitis and as a result, suffered brain damage," says Farrell. "Eventually, much of the claim against the physician was dropped, but he still had to pay thousands in defense fees, and his practice suffered because of the negative publicity."

Rudeness is more than just a customer service issue. It can be the factor that pushes a dissatisfied patient into contacting a lawyer. "Many more claims involve rudeness than we want to accept," says Farrell.

If a patient has a great relationship with the doctor and the staff, even if

there is a bad outcome, chances are there will not be a suit, Farrell says. "However, if the patient has a good relationship with the physician and is unhappy with front office staff, and there is a bad outcome, there is still a higher risk of a lawsuit," she says.

Even good, caring doctors might not be able to overcome their office staffs' poor behavior. "It's as though two negatives and one positive still equal a negative," Farrell says.

Wrong impression

If front office staff respond curtly to a patient's request to see a physician, this response can give the patient the impression that they don't need an appointment. "When that impression is given, rightly or wrongly, and a negative outcome happens, there is the real potential for a malpractice issue," says Farrell.

During one lawsuit, a plaintiff testified that the receptionist told him he

didn't need an appointment, and the employee acknowledged this response during her deposition. "She said the patient came in all the time, and she figured this was just like all the other times," Farrell says. "The defense attorney started asking things like, 'And your medical training was conducted where?' I felt sorry for the woman by the time they were done with her."

Farrell recommends that practices have a place in the electronic medical record to document when a patient calls in to ask a medical question and the front office staff responds without first checking with the nurse or physician, or if the patient requests to speak with the physician or nurse about a condition or symptom and that message is not passed on.

Physicians need to understand that they are represented by their front office staff for better or for worse, she says. "The physician who is very involved with how the practice runs tends to get better outcomes and has a lower risk of

Executive Summary

Rude front office staff can be the precipitating factor in a patient's decision to file a malpractice lawsuit.

- ♦ Document conversations with office staff regarding patients.
- ♦ Call patients back to determine whether they need an appointment sooner.
- ♦ Use secret shoppers to request an immediate appointment.

being sued,” Farrell says. “The doctor is responsible for his office staff. Under vicarious liability, it falls back to him or her,” she says.

Most physicians are aware of their responsibilities to monitor the actions of staff, says Farrell. “The challenge is many physicians never consider the fact that their staff, who may have worked

at the office for many years, would ever behave in a manner that could cause legal action,” she says.

Members of the front office staff don’t always recognize the potential for an emergency. If a patient reports headaches, an ophthalmologist’s receptionist might not realize that this symptom could be the beginning of a retinal

detachment.

“They may just want the person off the phone as quickly as possible,” says Farrell. “A good practice will have the doctor call the patient back to determine whether they need an appointment sooner.” (See related story, below, on identifying problems with front office staff.) ♦

Learn how staff members really treat patients

Is a receptionist or nurse unfailingly polite to physicians, but rude and condescending to the patients who call or present for care? If so, the physician probably has no idea.

“Staff are generally deferential to the physician. Your first task is to find out if there is a problem,” says **Molly Farrell**, vice president of operations for MGIS Underwriting Managers in Salt Lake City, UT. Farrell says to take these steps:

- **Survey patients with a comment card to place in a box at the front desk, or conduct a short, private email survey.**

Farrell suggests asking these three questions:

- Does the office greet you in a pleasant and friendly manner?
- Does the office work to accommodate your scheduling needs?
- Does staff follow up with you as promised?

Open-ended questions will elicit more qualitative responses, Farrell adds,

such as “What was the one thing my staff did you did not like?” and “What one thing did my staff do that you really liked?”

- **If there is a problem, take it to the next level and invest in a professional survey.**

“I’m a big fan of secret shoppers. There are firms that provide this service, but you could also ask friends or family to act in that role,” she says. Farrell says to instruct individuals to forcefully request an immediate appointment to how difficult or easy it was and how the staff responded, and watch for these comments that should raise red flags:

- “There’s no way to see you today. We are too busy.”

- “Call us back in a few days if you still feel the same way.”

“It is not always specific comments. It could also be the overall tone or atmosphere created by the office staff,” says Farrell. Patients who feel their illness is not being treated seriously, or who are made to feel uncomfortable by

staff, are less likely to bring to medical issues to the office’s attention, she explains.

- **Over time, aggregate the data and post it on your website.**

Include the statement: “Your input matters to us. Here are three areas you want us to improve. Here is what we did.”

SOURCE/RESOURCE

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- A **web-based tool to measure patient satisfaction** is available from the American Medical Association (AMA) and Press Ganey Associates that provides patients with an outlet for feedback on their office experiences in an electronic survey. The price is \$100 setup per MD, plus \$55 a month for AMA members. Non-AMA members pay \$100 setup per MD plus \$85 a month. For information, go to www.ama-assn.org/go/patientexperience. Click on “RealTime: A Patient Satisfaction Solution.” ♦

Does insurer refuse to pay for referral? It won’t protect MD from liability

Physicians have the responsibility to refer a patient or consult with a specialist when they know that highly skilled treatment might thereby be obtained, says **Katherine A. Miller**, RN, CPHRM, a risk/claims consultant at SISCO, a subsidiary of RCM&D, a Baltimore-based provider of insurance consulting and risk

management services.

This step can be problematic for doctors working in HMOs, when the HMO tries to restrict their ability to make referrals and gives them monetary disincentives to make referrals, says Miller. “An HMO’s refusal to allow a referral does not protect a doctor in a medical malpractice case,” she

warns. “The doctor must at least try to make the referral.”¹

A physician who does not seek or recommend a specialist’s advice, when a reasonably prudent practitioner would do so and a specialist is available, could be held to the standard of care applicable to specialists in the particular area of medicine, says Miller.

(See related story on when referrals are required to meet the standard of care, p. 7.)

Thomas G. Gutheil, MD, co-founder of the Program in Psychiatry and Law at Beth Israel Deaconess Medical Center in Boston, says, “The physician gets no protection from an insurer’s refusal to pay for anything. He or she is left to ‘twist in the wind.’”

Members of juries generally do not want to hear about rationing of medicine and are not sympathetic to a physician who did not refer a patient to a consultant because a contract required pre-approval, according to Gutheil.

The fact that an insurer or a hospital policy might prohibit the referral does not provide a defense at trial, says **Russell X. Pollock, Esq.**, an attorney with Bergstresser & Pollock in Boston. “Quite often, the defense of these cases is that the failure to make the referral comported with the standard of care, rather than that the physician wanted to make the referral and the insurer or hospital policy forbade it,” adds Pollock.

Put patient first

When determining whether to refer a patient to a consultant, Gutheil says, “The best risk-reduction strategy is to put the care of the patient foremost. This creates an atmosphere antithetical to litigation.”

He advises physicians to obtain “economic informed consent” by discussing with the patient possible sources of payment or alternatives if the referral is not covered by insurance, such as the specialist supervising the treating physician at the patient’s expense.


Given the limited rates of reimbursement many insurers and hospitals are permitting, additional time spent with a patient can be costly. “However, research appears to indicate that physicians who spend more time communicating with a patient and taking extra time to meaning-

Executive Summary

An insurer’s or hospital’s refusal to allow a referral does not protect a doctor named in a medical malpractice case. To reduce legal risks involving referrals:

- ◆ Discuss possible alternatives with the patient.
- ◆ Obtain brief consultations by phone, email, or in person.
- ◆ Document attempts to convince the insurer to allow for the referral.

fully understand the patient’s condition, including from the patient’s own vantage point, are less likely to have a claim filed against them,” says Pollock.



“The best risk-reduction strategy is to put the care of the patient foremost. This creates an atmosphere antithetical to litigation.”

Thorough documentation identifying the examination that was conducted, testing requested, plan for follow up, and a note that the doctors spent ample time talking with the patient is usually helpful in defending these cases, “but only if the doctor is indeed practicing good medicine,” says Pollock. “Documenting substandard care is not going to be helpful to the physician.”

Refute plaintiff’s claims

Documenting attempts to have the insurer or hospital cover that referral, and the patient’s refusal to accept the referral because of cost, might provide a defense, but it will require the physician to admit that a referral was appropriate and perhaps necessary

for patient care, says Pollock. If that situation it is truly the case, the doctor must find a way to convince the insurer or the patient to allow for the referral.

“This, of course, creates a timely procedural morass for the doctor,” he acknowledges. “However, the physician will likely not regret the effort he or she expended on the patient’s behalf, but might regret the failure to do so.”

Brief consultations by phone, email, or in person provide risk management support for the approach being considered by the physician, and these do not require referral or approval, advises Gutheil.

“Every such consult is a ‘biopsy of the standard of care,’” he says. “The plaintiff’s claim that you did not get a consult is refuted by your crisp progress note about the consult.”

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Referral to specialist: Legal standard of care?

If so, failure to obtain it is negligent

A primary care physician failed to send a patient for a timely consultation with an otolaryngologist, and the patient had an undiagnosed nasal cancer for some time. An emergency department physician failed to call for a timely surgical consult, which allowed a patient's sepsis to progress.

These are two malpractice cases involving a physician who failed to refer a patient to a specialist for appropriate care handled by Russell X. Pollock, Esq., an attorney with Bergstresser & Pollock in Boston. "In both cases, we were able to establish that the physician departed from the standard of care," Pollock says. "Had the referral been made as it should pursuant to the standard of care, the patient would not have died or suffered as serious of an injury."

The physicians' defense in both cases was that they were reasonable and thereby not negligent in failing to make the referral, and even if the referral had been made, the patient's outcome would have been similar. "Nonetheless, we were able to obtain a significant recovery for the clients in settlement," Pollock says. "When viewed objectively, a referral was prudent and would have

helped the patient."

Referral sometimes required

Failure to refer, consult, or obtain supervision are three things that always can be claimed in malpractice litigation, whether the allegations are true or not, according to **Thomas G. Gutheil, MD**, co-founder of the Program in Psychiatry and Law at Beth Israel Deaconess Medical Center in Boston.

"While referral to a specialist is theoretically always an option, the situation that may well require it is when the treaters are 'in over their heads' or are called on to deal with a condition or type of patient they have never seen before and are unsure how to approach," he adds.

In deciding if the doctor was negligent, the jury will consider whether the failure of the physician to make the referral was a departure from the standard of care of the average qualified physician in the same specialty treating such a patient at that point in time. "If the jury finds that the average qualified physician would have

made the referral and the defendant physician did not, the physician was negligent," says Pollock.

Some factors that come into play when determining whether the referral is required pursuant to the standard of care is the patient's overall objective clinical picture and whether there is a condition on the differential that is potentially debilitating or life-threatening. "Reliance on the 'head in the sand' approach, or a single anomalous factor finding, is usually not well-received," says Pollock.

Pollock says plaintiff attorneys will look for the primary care physician's failure to refer when a patient complaint multiple times of the same or a similar issue, without any significant improvement by the physician's treatment.

"Experts defending the conduct will usually take the approach of claiming the conduct is reasonable by relying on isolated facts or arguing the condition could have been a benign process," he says. "However, such arguments are easy targets for what the patient's overall objective picture was." ♦

MD personally liable for huge jury verdict?

This much-feared scenario among physicians is not highly likely

If a jury verdict is returned for \$5 million against a physician whose policy limit is \$1 million, simple math indicates the physician would then be personally liable for \$4 million. This situation is highly unlikely, however, according to **Leonard Berlin, MD, FACR**, professor of radiology at Rush University and University of Illinois, both in Chicago, and author of *Malpractice Issues in Radiology*.

"Reputable plaintiff attorneys almost

never go after the physician's personal assets, though sometimes a very minor plaintiff attorney will do so," he says. "I have heard of only one or two cases of this, and in those cases, the physicians had almost no insurance coverage."

While \$100,000 of medical malpractice coverage is likely insufficient, \$1 million is probably adequate for most physicians, according to Berlin. If physician have additional millions in coverage, they could be setting them-

selves up as a "deep pocket" for plaintiff attorneys. Here, Berlin offers some factors that could protect physicians from being personally liable for a jury verdict that exceeds their policy limits:

• **It's rare for a physician to be the only defendant in the case.**

Usually, the hospital, group, referring physician, or consultant also is named. "Probably 95% of malpractice cases have multiple defendants. So whatever the jury verdict is, it's going to

be split,” says Berlin.

• **If the hospital is named in the suit, the plaintiff attorney is unlikely to go after an individual physician for the amount over the policy limits.**

“Even if there is an enormous verdict of say, \$15 million, which is highly unlikely, if the hospital, which has generally unlimited funds, is named, and a physician has \$1 million of coverage, no one is going to go after him for more than \$1 million,” Berlin says.

• **A “high/low” agreement is often reached during the trial.**

“The plaintiff’s attorney is worried that the jury may find the physician not guilty,” says Berlin. At the same time, the defense lawyer is worried the jury will come back with a multimillion dollar verdict against the physician.

In this scenario, the two sides often reach an agreement midtrial in which the plaintiff agrees to accept the physician’s maximum insurance coverage if the physician is found guilty, and the defendant agrees to pay a certain amount even if the jury’s verdict is not guilty.

“When the case is over, the news

Executive Summary

Physician defendants won’t necessarily be personally liable for a large jury verdict that exceeds their policy limits.

- ◆ Physicians might split the verdict with multiple defendants.
- ◆ A “high low” agreement might be reached midtrial.
- ◆ The plaintiff attorney might agree to accept the policy limit to avoid an appeal.

might report a \$3 million verdict. Most people don’t realize that in most cases, those amounts are never paid in full,” he says. “This is not uncommon and is never publicized.”

• **The plaintiff attorney might agree to accept the physician’s policy limits if the defense agrees not to appeal.**

If the jury returns a \$5 million verdict, and two named physicians each have \$1 million of coverage, for example, the defense attorney most likely will make a deal with the plaintiff attorney. “They will make this offer: ‘If you accept the \$2 million in insurance coverage as full payment, we’ll give you a check today. If you want to hold out for the \$5 million, we will appeal this case,’” says Berlin.

It will take several years for the appellate court to rule, and the court might reverse the verdict altogether, or if the verdict is sustained, the defense can appeal to the state supreme court. This appeal will take another several years to resolve, says Berlin.

“In 99% of cases, in this scenario, the plaintiff attorney will take the \$2 million and walk,” he says. “Only rarely will jury verdicts in excess of available insurance coverage be paid in full. That is the real world, and that is the way the system works.”

SOURCE

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News Briefs

Faster resolution of med/mal suits

A recent Supreme Court decision could mean faster resolutions for plaintiffs and doctors in cases involving patients receiving Medicaid-funded care.¹

U.S. Supreme Court justices ruled that federal Medicaid law preempts a North Carolina statute that allowed the state to recoup up to one-third of medical liability settlements and tort judgments received by Medicaid beneficiaries who required subsidized follow-up care, regardless of how much the state paid for the care of the beneficiary or how the settle-

ments were structured. The court said states are entitled to some reimbursement for their costs, but that the amounts must be reasonable.

“We’re very hopeful that this will lead to more settlements and less litigation in medical malpractice claims,” says **William B. Bystrynski, JD**, an attorney with Kirby & Holt in Raleigh, NC, who represented the original plaintiff in the case. “Fewer doctors will end up spending time in court instead of with their patients.”

In the past, states demanded so large a percentage of any settlement

that it became impossible for plaintiffs to settle cases and still receive enough money to compensate them for their injuries and pay for their future care, explains Bystrynski.

The Federation of Defense and Corporate Counsel argued in its amicus brief that allowing states to recover a disproportionate share of a settlement meant that they were asked to pay more to try to settle cases. “They said states were in essence calling on insurance companies, doctors, and hospitals to help fund the Medicaid program, and

that was unfair,” Bystrynski says. “Ultimately, this should mean that it will be easier to settle malpractice cases, so parties will

spend less time in litigation.”

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SOURCE

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Claims analysis identifies causes of OR fires

Electrocautery-induced fires during monitored anesthesia care were the most common cause of operating room (OR) fire claims, according to a recent study which analyzed closed malpractice claims in the American Society of Anesthesiologists Closed Claims Database since 1985.¹ Other key findings:

- Payments to patients were more often made in fire claims, but payment amounts were lower (median \$120,166) compared to nonfire surgical claims (median \$250,000).

- Electrocautery-induced fires increased over time to 4.4% of claims between 2000 and 2009.

- Most (85%) electrocautery fires occurred during head, neck, or upper chest procedures.

- Oxygen was administered via an open delivery system in all high-risk procedures during monitored anesthesia care. In contrast, alcohol-containing prep solutions and volatile compounds were present in only 15% of OR fires during monitored anesthesia care.

“Perhaps the most surprising finding is that the use of alcohol-based prep solutions was not the most com-

mon cause for these fires,” says **Sanjay M. Bhananker, MD, FRCA** associate professor in the Department of Anesthesiology and Pain Medicine at Harborview Medical Center in Seattle.

Recognition of the “fire triad” — oxidizer, fuel, and ignition source — and particularly the critical role of supplemental oxygen by an open delivery system during use of the electrocautery is crucial to prevent OR fires, concluded the researchers. To reduce liability, Bhananker says physicians should follow recommendations on evaluating fire risk and have an appropriate fire prevention plan for high-fire risk procedures. (See resources at end of article for more information.)

“Continuing education of OR personnel and development and implementation of fire prevention protocols is crucial,” he says. “This will likely lead to reduction in OR fires and associated liability.”

Reference

1. Mehta S, Bhananker S, Posner KL, et al. Operating room fires: A closed claims analysis. *Anesthesiology* 2013; 118(5):1133–1139.

SOURCE/RESOURCES

- **Sanjay M. Bhananker, MD, FRCA**, Department of Anesthesiology and Pain Medicine, Harborview Medical Center, Seattle. Phone: (206) 744-3059. Fax: (206) 744-8090. Email: sbhanank@u.washington.edu.

- The American Society of Anesthesiologists’ (ASA) updated **Practice Advisory for the Prevention and Management of Operating Room Fires**, which gives recommendations to identify the situations conducive to fire, prevent the occurrence of OR fires, and reduce adverse outcomes associated with OR fires, is available at <http://bit.ly/19KRwim>. To view an ASA closed claim analysis, “On-Patient Fires: Prevention during Monitored Anesthesia Care,” go to <http://bit.ly/YQllhvi>.

- Educational videos for preventing surgical fires from the U.S. Food and Drug Administration, titled **Surgical Fires: How They Start and How to Prevent Them, Prevention of Surgical Fires, Prevention and Management of Operating Room Fires, and FDA Patient Safety News: Preventing Fires in the Operating Room** are available at <http://1.usa.gov/16vCjp3>.

- The Anesthesia Patient Safety Foundation’s 18-minute video, **Prevention and Management of Operating Room Fires**, can be viewed at <http://bit.ly/k3KseQ>. To request a free copy of the DVD, fill out an online form at <http://bit.ly/ewOGfP>. To request multiple copies, send an email to stoelting@apsf.org. ♦

Off-label use ruling might help sued docs — Decision could affect med/mal suits

Pharmaceutical companies could become more forthcoming with information provided to physicians on off-label usage of medications as a result of a recent decision from the U.S. Court of Appeals for the Second Circuit. The ruling vacated the criminal conviction of a pharmaceutical sales representative who was found guilty of conspiracy to introduce a mis-

branded drug under the Food, Drug & Cosmetic Act, because he spoke about off-label uses of a particular drug.¹

The decision could diminish the Food & Drug Administration (FDA)’s ability to rein in dissemination of truthful information on off-label uses, says **Joseph P. McMenamin, MD, JD, FCLM**, a Richmond, VA-based healthcare attorney and former practic-

ing emergency physician.

“It wasn’t as though there was a complete embargo against it, but the doctor and the company had to jump through a bunch of hoops for the information to be provided to the physician,” he explains.

Drug reps are not allowed to initiate or even to prompt discussion of off-label uses. If asked directly by a

physician about off-label uses, the rep can do no more than to refer the doctor to someone at the company with additional training, often called a medical science liaison, and usually someone with a clinical background, such as a nurse, a pharmacist, or even a physician.

In the recent Caronia case, the drug rep broke these rules. He promoted the drug for off-label uses to a physician who was a government informant. The Caronia court noted that, if information on off-label uses is withheld from physicians, the public could be harmed. FDA elected not to appeal the case.

“In the wake of Caronia, companies will probably proceed cautiously. FDA law remains substantially intact,” says McMenam. “Caronia is good law only in the Second Circuit: New York, Connecticut, and Vermont.”

FDA rules stand

Even there, untruthful or misleading information is not protected, and FDA’s rules on labeling, misbranding, and adulteration still stand. Nevertheless, the decision eventually could help physicians who prescribe medications off-label because, at least in the Second Circuit, drug companies might believe they face a lower risk of prosecution for making information on off-label uses more readily available.

“That information that could help physicians make better judgments about therapy,” says McMenam.

While the decision involves commu-

Executive Summary

Physicians might find it easier to prove that off-label use of medications wasn’t a breach of the standard of care, due to a recent court ruling. Defense lawyers can point out the following:

- ◆ In some cases, off-label use is required by the standard of care.
- ◆ The approval process is slow and cumbersome.
- ◆ Medicare pays for off-label uses of medications.

nication between regulated industry and the medical profession, it also has some potential implications for malpractice litigation, says McMenam.

“I can imagine some confusion in the minds of jurors, if they hear about the seemingly inconsistent rule that although the doctor is at liberty to write for the product for whatever reason he thinks appropriate, the company is not allowed to promote it except for government-approved indications,” he says.

The ruling could make it easier for physician defendants to convince jurors that that off-label use isn’t necessarily a breach of the standard of care, says McMenam. “Doctors write off label all the time, and in fact, in certain situations doing so may be required by the standard of care,” he says.

If a drug’s off-label use is admissible, the plaintiff’s attorney likely would emphasize the demonstration of safety and efficacy that the FDA insists on before it allows a drug to be marketed in the United States, says McMenam. “The expert would say, ‘The indication is not on the label for a reason. No one has ever satisfied FDA that it is any

good for Condition X, yet this maverick doctor over there wrote this script, and my client came to harm,’” he says.

The defense then would need to explain that many times, off-label use is not only appropriate but required, and that the FDA approval process is slow and cumbersome, says McMenam. The defense also could point out to jurors that Medicare pays for off-label uses of medications, he says.

“So it’s not only accepted by the profession as the standard of care, it’s accepted by a third party payer — even though another branch of the U.S. government is telling pharmaceutical houses that they are not allowed to advertise this information,” says McMenam.

Reference

1. United States v. Caronia, 703 F.3d 149 (2d Cir. December 3, 2012)

SOURCE

- Joseph P. McMenam, MD, JD, FCLM, Richmond, VA. Phone: (804) 828-5460. Email: joe.mcmenamin@venebio.com. ◆

Parent removing child AMA? Know legal risks! MD protecting child is easier to defend

(Editor’s Note: This is a part one of a two-part series on legal risks involving parents refusing medical care for a child. This month, we cover how to document. Next month, we cover reporting obligations.)

Was a physician attempting to protect a child from harm due to

a parent’s refusal of care? This scenario is much more defensible, from the point of view of malpractice insurers and defense attorneys, than defending a medical negligence case against the physician when a child suffers as a result of the naïve decision of the parent, says **John W. Miller II**, a malpractice insurance broker and principal

at Sterling Risk Advisors in Marietta, GA.

“The struggle between parental autonomy and child welfare occasionally falls in the lap of physicians,” says Miller. “Physicians should not be fearful of the legal repercussions of advocacy for their pediatric patients.”

Executive Summary

Physicians should not fear legal repercussions of advocacy for their pediatric patients when protecting a child from harm by a parent's refusal of care. Physicians should consider:

- ◆ documenting the parent's responses;
- ◆ documenting a parent's awareness of risks and ability to communicate;
- ◆ writing 'against medical advice' discharges at a sixth-grade literacy level.

Many times, parents project guilt over a bad outcome that occurred due to their leaving against medical advice (AMA) onto physicians and decide to file a malpractice suit, says Miller. "The defense 'I tried to warn them and they ignored my advice' often works to sway juries in adult AMA cases," says Miller. "The same juries may hold the physician responsible in a pediatric case, because he or she should have been an ardent advocate for the pediatric patient that cannot protect him or herself."

Miller says that generally, physicians dealing with parents who wish to sign their children out AMA should go through this list of questions and document the parent's responses just as they would if faced with a patient refusing treatment:

- Does the parent understand and appreciate the diagnosis, prognosis, and the likelihood of risks and benefits of leaving the hospital?
 - Is the parent aware of the alternatives to treatment in the hospital and the risks and benefits associated with these?
 - Can the parent make and communicate a choice?
 - Can the parent articulate a reason for the refusal that is consistent with his or her values?²
- "Positive responses to these ques-

tions make the claim more defensible," says Miller. "Any negative answers to these questions raises the stakes for defending a physician's inaction." He adds that physicians should be mindful of the literacy level of parents signing their children out AMA. "Many of the malpractice insurers now encourage physicians to write their AMA discharges at the sixth-grade level," says Miller.

Medical Mutual Insurance Company of North Carolina partnered with Health Literacy Innovations after a 2007 North Carolina Institute of Medicine report challenged malpractice carriers to incorporate health literacy education and effective communication skills into their risk management training.

"They've found that tailoring AMA documents to the appropriate reading level has assisted their physicians in providing effective communication to a population of patients who need the education of the risks and benefits posed by an AMA discharge the most," says Miller. ◆

Reference

1. Lo B. *Resolving Ethical Dilemmas: A Guide for Clinicians*, Second ed. New York, NY: Lippincott; 2005. ◆

COMING IN f u t u r e M O N t h s

- ◆ Why handoffs are coming up in malpractice claims
- ◆ Factors make it likely MD will be dismissed from suit
- ◆ Little-known legal risks of hearing-impaired patients
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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.

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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%.
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CME QUESTIONS

1. Which is true regarding malpractice claims involving diagnostic errors, according to a study in BMJ Quality and Safety?

- A. Payouts were much higher for death than severe disability.
- B. Payouts were higher for severe disability than for death.
- C. Inpatient diagnostic errors resulted in more malpractice suits than diagnostic errors occurring in outpatient and ambulatory care clinics.
- D. Diagnostic errors in outpatient areas were more deadly than diagnostic errors occurring in inpatient areas.

2. Which was the most common chief presenting symptom associated with missed diagnosis in the primary care setting, according to a study in JAMA Internal Medicine?

- A. Shortness of breath
- B. Fever
- C. Cough
- D. Headache

3. Which is true regarding malpractice litigation alleging failure to obtain a referral, according to Russell X. Pollock, Esq.?

- A. An insurer's refusal to allow a referral always protects a physician defendant in a malpractice case.
- B. A physician who fails to consult with or refer to a specialist when necessary cannot be held to the standard of care applicable to specialists in the particular area of medicine.
- C. Physicians should not obtain brief consultations by phone, email, or in person in the event a patient refuses to accept a referral because of cost.

D. The fact that an insurer or a hospital policy prohibited the referral does not provide a defense at trial.

4. Which is recommended for physicians to document when a parent refuses care for a child, according to John W. Miller II, a malpractice insurance broker and principal at Sterling Risk Advisors?

- A. Whether the parent understands and appreciates the diagnosis, prognosis, and the likelihood of risks and benefits of leaving the hospital.
- B. Whether the parent is aware of the alternatives to treatment in the hospital and the risks and benefits associated with these.
- C. Whether the parent can articulate a reason for the refusal that is consistent with his or her values.
- D. All of the above.

Physician Legal Review & Commentary



A Monthly Supplement to PHYSICIAN RISK MANAGEMENT

\$388,000 awarded to family of patient who died after failure to monitor administration of Coumadin

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News: A San Francisco jury awarded \$388,000 to the family of a deceased patient of a prominent local cardiologist for failure to monitor the patient's blood levels during administration of the drug Coumadin. After the administration of the drug, the patient complained to the cardiologist of side effects, but the cardiologist failed to perform repeat blood tests during the few days following her initial discharge from a hospital for heart surgery. A jury concluded that the cardiologist's failure to monitor her blood for abnormal thinning (which can lead to internal bleeding) caused her to bleed out and die. An initial award of \$1 million for emotional

pain and suffering later was reduced due to California medical malpractice caps.

Background: A San Francisco jury awarded \$388,000 to the family of a deceased patient of a prominent local cardiologist. The patient was a

... the cardiologist failed to perform blood tests on the patient to monitor whether her blood was thinning at an abnormal rate.

59-year old woman who had heart surgery performed at a local hospital in July 2009. She presented to her cardiologist three days postoperatively. The cardiologist prescribed Coumadin, a popular anticoagulant, to thin her blood and prevent post-surgical clotting.

The cardiologist tested the patient's blood three days after she

was released from the hospital and found it to be in normal range. One week later, the patient presented to the cardiologist's office with complaints of a skin rash, a known complication and potentially dangerous side effect of the drug that may indicate internal bleeding. However, the cardiologist failed to perform a blood test at this office visit. Another week lapsed, and the patient's family contacted the cardiologist with complaints of lethargy and loss of appetite. Nonetheless, the cardiologist failed to perform blood tests on the patient to monitor whether her blood was thinning at an abnormal rate. Research shows that any of these side effects should be treated seriously and medical attention should be sought immediately to prevent internal bleeding.

On Aug. 26, 2009, one week after her family's complaints to the cardiologist, the patient was found unconscious and bleeding. She died the next morning. At trial, the patient's attorney argued that the cardiologist's failure to perform subsequent blood tests during the administration of Coumadin would have prevented the abnormal thinning, which led to a fatal onset of

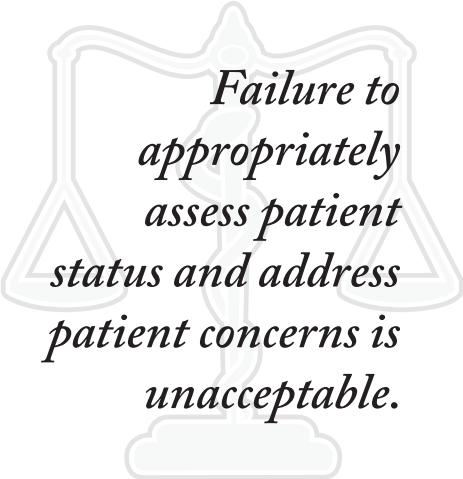
internal bleeding. Defense counsel argued that the cardiologist had provided appropriate care and presented an expert witness who testified that although Coumadin is a powerful drug and its side effects should be closely monitored, the drug did not cause the patient's death and has been administered to patients with cardiology conditions for more than 20 years.

A jury voted 11-1 that the cardiologist's negligence was a substantial factor in causing the patient's death and awarded \$138,000 in medical costs and funeral expenses and \$1 million in emotional distress. However, the emotional distress award was later lowered to \$250,000 due to a California state cap on medical malpractice awards for emotional harm.

What this means to you: We live in an era of regulatory requirements and consumer expectations that encourage and require the development and implementation of a culture of safety for patients. Failure to appropriately assess patient status and address patient concerns is unacceptable. To do so increases the potential for a litigious event based on negligent behavior for healthcare providers. In this case, in which adverse reactions to a medication were noted and reported by the patient and her family, failure on the part of the prescribing physician to respond within the standard of care led to a jury award for the plaintiff. Complacency and an unwarranted comfort level with the use of a commonly used anti-coagulant medication might have been contributing factors that increased the risk of negative outcomes for and ultimately the death of a 59-year-old patient.

Although defense counsel presented an expert witness who opined the physician, a prominent cardiologist, performed within the standard of care, 11 of the 12 jurors

disagreed. Perhaps this disagreement is due to the fact the commonly used anticoagulant warfarin, with the brand name Coumadin, is commonly understood to require diligent monitoring for therapeutic levels and adverse reactions. It is known and understood by health-care providers that Coumadin has the potential to be affected by food, over-the-counter supplements, and other prescription/medication



*Failure to
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interactions. Hence, patients must be carefully instructed on administration of the medication, food or drug interactions, and signs and symptoms of side effects that require immediate medical attention. Some of the side effects requiring immediate medical attention include, but are not limited to, swelling of the face, throat, mouth, legs, feet, or hands; hives, rash, or itching; numbness or tingling in any part of the body; difficulty moving; chest pain or pressure; respiratory or gastrointestinal disorders (including taste perversion); or chills.

Pharmaceutical instructions for Coumadin also indicate that the full anticoagulant effect of the drug is not achieved for several days; therefore anticoagulation must be carefully monitored during Coumadin therapy. The appropriate initial dosing varies widely for different patients. The initial dose might be

influenced by clinical factors such as body weight, age, race, sex, comorbidities, and concomitant medications. It is known that Coumadin can cause major or fatal bleeding and that bleeding is more likely to occur within the first month. History of heart or cerebrovascular disease, anemia, genetic factors, hypertension, and other comorbidities are risk factors for bleeding.

In this case as presented, the patient's initial drug therapy level was monitored by the cardiologist on Aug. 4, three days after the patient's hospital discharge with a history of heart surgery. The International Normalized Ratio (INR) results were within normal limits, and the cardiologist planned to re-test in three to four weeks. However, on Aug. 12, the patient returned to the cardiologist with the complaint of a rash, but no blood tests were ordered to determine INR level. On Aug. 19, the patient's family contacted the cardiologist to report the patient was lethargic and had no appetite. Still, no blood tests for Coumadin monitoring were ordered. On Aug. 26, the patient was found to be hemorrhaging and unresponsive. She died Aug. 27.

It is difficult to comprehend why the cardiologist chose, first and foremost, not to minimize or eliminate the risk of harm for his patient, and subsequently reduce the risk of litigation for himself, by monitoring her INR and other blood levels to ascertain for a potential adverse reaction to Coumadin. This was a newly prescribed drug for the patient, and it would have been prudent to monitor her ongoing response to the drug, especially after potential side effects were reported. Perhaps the red flag of complacency was a factor. It might be true, as testified by the defense expert witness, that prescribing of the "powerful" drug did not cause the patient's death; failure to monitor the effects of the drug in this patient and act

accordingly, however, was clearly deemed to be a contributory, negligent cause.

It is critical to develop a relationship with patients to open up lines of communication to better understand a patient's history, risk factors,

and changes in their health status. It is important to be alert to risk factors, such as adverse drug reactions, and work to reduce or eliminate such risk factors to provide a culture of safety for patients and put an end to complacency in healthcare. It may

be no easy task, but it is possible through lessons learned in cases such as this.

REFERENCE

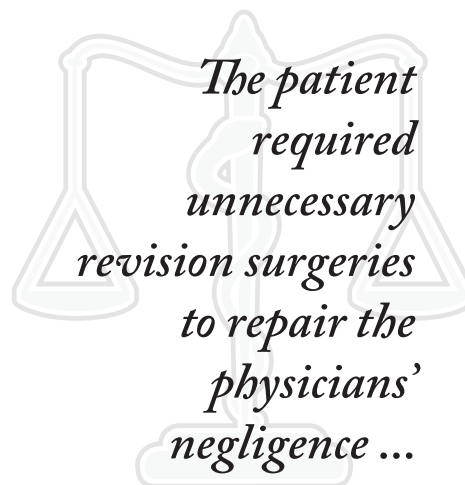
CGC-10-502053 (San Francisco County Sup. Ct. 2013). ♦

Jury awards \$1.5 million to patient who received negligent colonoscopy and subsequent laparoscopic surgery

News: A jury awarded a patient \$1.5 million against a gastroenterologist and laparoscopic surgeon for their respective failure to perform a colonoscopy and subsequent laparoscopic surgery repair to the colon. The gastroenterologist perforated the patient's colon during the colonoscopy through his use of a heater probe, which a jury found to be unnecessary and extremely risky, given the patient's prior gastrointestinal history. The patient presented to the laparoscopic surgeon to repair three holes caused by the gastroenterologist, but the surgeon failed to detect the proper perforations intraoperatively and, thus, failed to correct the condition from which the patient suffered. The patient required unnecessary revision surgeries to repair the physicians' negligence and endured pain and suffering and hospitalizations.

Background: A patient had visited a gastroenterologist for a routine screening colonoscopy as recommended for adults over 50. Despite having no complaints of pain or signs or symptoms of gastrointestinal distress, the gastroenterologist used a heater probe, a device that is inserted through the colonoscope that applies heat directly to the tissue to stop bleeding. The device was used to cauterize the patient's blood vessels, as the gastroenterologist noted some

bleeding during the colonoscopy. Postoperatively, the plaintiff complained of burning abdominal pain, but the gastroenterologist dismissed his complaints and assured him that



they would resolve on their own. However, the patient's symptoms failed to subside, and he visited the gastroenterologist in his office the following day with further complaints. The gastroenterologist diagnosed the patient with a probable perforation of the cecum, a part of the colon near the appendix, and referred the patient to a laparoscopic surgeon.

Subsequently, the patient presented to the laparoscopic surgeon for repair of three holes in his colon that had been punctured by the heater probe cauterization by the gastroenterologist. The surgery

appeared to have no complications, and the patient was discharged to home after a few days. However, a day and a half later, the patient returned to the hospital with complaints of severe abdominal pain. He underwent subsequent laparoscopic surgery in which a perforation of the small intestine was found in a different area than the heater probe injuries by the gastroenterologist.

At trial, the patient presented expert testimony that a heater probe carries a risk of perforation of the bowel which is 30 times greater (1 in 40) than the risk of perforation in a regular screening colonoscopy (1 in 1,200). In addition, as the patient had a normal gastrointestinal history that did not include any gastrointestinal bleeding, the patient argued that this heater probe was unnecessary and risky. Furthermore, the patient also presented evidence that the laparoscopic surgeon failed to properly inspect the small intestine during his surgery, which caused additional problems and the need for subsequent surgeries.

The jury concluded that the gastroenterologist was 60% liable for the patient's injuries and the laparoscopic surgeon was 40% liable for the same. It awarded \$1.5 million to the patient for his injuries.

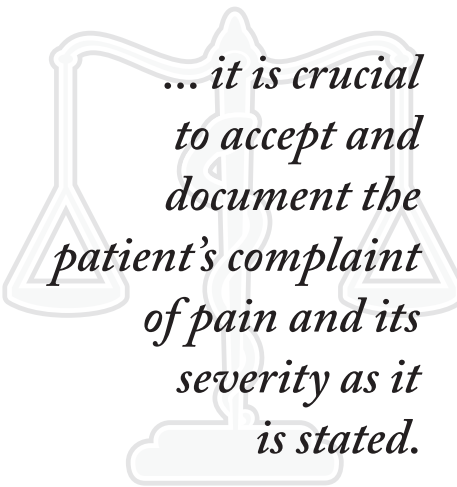
What this means to you: The root of this case might be similar to that of the first case presented in

this supplement: complacency on the part of the gastroenterologist who performed the colonoscopy and the surgeon who was tasked with the ultimate perforation repair. Following eight weeks of evidence, testimony, and deliberation, both physicians were held accountable for their actions, which resulted in the plaintiff's award of \$1.5 million.

Although bowel perforation is a known potential risk to the patient as a result of the procedure, it cannot be discounted, taken lightly, or rendered in a complacent manner, regardless of the number of times a physician has successfully performed the procedure without incident. Such a risk factor must be included in the verbiage of the procedure consent form by stating the purpose, benefits, risks, and alternatives to the colonoscopy. The consent form must include clear, rational statements in a language and content that is easy for the patient to understand to ensure that the patient has the knowledge and comprehension to give consent without undue influence or duress. Most importantly, signed consent should be obtained by the person who will perform the procedure. Not only does this process meet the definition and requirements of informed consent, but it also provides the opportunity to develop and/or enhance the patient-physician relationship prior to the procedure. A solid, trustworthy patient-physician relationship reduces the risk of litigation in the event of an adverse outcome related to a procedure.

Alleged indiscriminate use of a heater probe, with acknowledgment of its significantly higher risk of bowel perforation, called for awareness and sensitivity on the part of the gastroenterologist as to the increased potential for harm to the patient during the procedure. In this case, when the patient

complained of "burning abdominal pain" following the procedure, the gastroenterologist failed to consider a complication might have arisen and thus intervened, but instead assured the patient the burning pain would resolve without further intervention. Subsequently, the patient returned to the gastroenterologist within 24 hours with unresolved pain. The patient then was referred to a surgeon. Treatment time delay in the event of a bowel perforation leads to a greater potential of the risk of life-threatening complications.



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Bowel perforation, the traumatic breach of bowel integrity, requires a detailed history and careful physical evaluation of the post-procedure symptoms and duration. Procedural information, patient symptoms, and the severity of same, plus timing of the procedure compared with the onset and duration of the symptoms, all serve to provide the surgeon with information necessary to determine the best intervention for the patient. CT scanning provides an accurate view of perforation, and blood tests serve to indicate bleeding. What is difficult to understand in this case is the reported history or diagnosis of not one but three identified perforation sites that should have placed the surgeon on alert for due diligence in examining the bowel for evidence

of additional trauma. Use of CTs preoperatively, perioperatively, and/or postoperatively is one means that would prove beneficial in making certain all areas of injury had been properly identified and repaired or treated as appropriate and necessary. Unfortunately for the patient, his initial surgery resulted in additional surgery and hospitalization for missed repair of yet another site of perforation, perhaps due to the medical-surgical assumption or complacency that injury occurred in only one side or area of the bowel. Abdominal exploration to eliminate the possibility of other injury or injuries would have been wise and prudent in ensuring a positive outcome for the patient and reducing litigation risk for the surgeon. The jury held the gastroenterologist responsible for the initial procedural injuries, but also held the surgeon accountable for incomplete repair and additional pain and suffering as well.

It can be easy to become complacent and lose sight of the validity of complaints of pain or discomfort when such concerns are frequently expressed by patients to their physicians on a daily basis. To minimize the risks of complacency, misdiagnosis or failure to intervene, however, it is crucial to accept and document the patient's complaint of pain and its severity as it is stated. In doing so, such recorded complaints form the basis for appropriate medical and/or surgical evaluation and mode of treatment. Thorough and accurate documentation of statements, evaluations, recommendations for treatment, follow-up, and outcomes is a key risk reduction strategy that might help to eliminate the red flag of complacency and focus attention on the patient and their safe care.

REFERENCE

Index No, 3584/2009, New York (2013). ♦

Dear *Physician Risk Management* Subscriber:

This issue of your newsletter marks the start of a new continuing education semester.

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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.

If you have any questions about the process, please call us at (800) 688-2421, or outside the U.S. at (404) 262-5476. You can also fax us at (800) 284-3291, or outside the U.S. at (404) 262-5560. You can also email us at: customerservice@ahcmedia.com.

On behalf of AHC Media, we thank you for your trust.

Sincerely,



Lee Landenberger
Continuing Education Director
AHC Media