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INSIDE

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Avoid the Common Mistakes That Encourage Patients to Sue

Much of risk management is focused on avoiding liability and discouraging lawsuits, but what really makes a patient or family decide to sue? Much of the motivation comes from how they feel after interactions with physicians and staff — or the lack thereof.

The biggest factor in a patient or family filing a medical malpractice lawsuit is the patient-physician relationship, says **Savera Sandhu**, JD, partner with Newmeyer Dillion in Las Vegas. A physician may have done everything right, but if he or she is not communicating efficiently, respectfully, and honestly with a patient, that patient tends to sue.

"I represented a pulmonologist in the defense of a medical malpractice case where the patient lost several limbs, including amputation of legs and various fingers after emergent cardiac surgery due to ischemia. The patient had comorbidities that prevented any functional recovery," Sandhu recalls. "She sued the entire hospital, from administration to nursing staff. My client, who provided subsequent care during her ICU stay, had nothing to do with her surgery or wound care."

> THE BIGGEST FACTOR IN A PATIENT OR FAMILY FILING A MEDICAL MALPRACTICE LAWSUIT IS THE PATIENT-PHYSICIAN RELATIONSHIP.

Sandhu asked the plaintiff to explain why her client was part of the lawsuit. "She explained that she did not even know my client but that the overall feeling was that the staff did not listen to her, nor cared about her condition," Sandhu says. "Luckily, I was able to get her to dismiss my client from the lawsuit altogether."

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In mediations, Sandhu says she consistently hears patients and their families say, "The doctor didn't seem to care about me and what I was saying," or "The hospital staff did not take care of me." Relationships are key to enhancing trust and encouraging correlated care for the well-being of the patient.

"Even if the patient or the family doesn't know the medicine, they just want to be heard. In return, they want the physician to keep them apprised of the situation," she says.

Patients Feel Rushed

Various actions, statements, or omissions can lead patients to the conclusion their doctor does not care. Sandhu says often it is the perception that care was not immediate, communication from the overseeing physician was delayed, or medical advice was short and without room for questions. The lack of dialogue makes patients feel unheard and uncared for.

"Medical schools and residency programs talk about bedside manner, but they should offer experience that is more practical. Unfortunately, the strain on healthcare resources and availability of physicians and medical staff as a whole prevents these professionals from hosting longer dialogues with patients," she says. "I always encourage my healthcare clients to ask the patient if they have any questions or concerns, and then listen intently with key words said back to the patient to acknowledge an understanding of their fear, concern, or hesitation."

In addition, always let the patient know the potential risks and harms of their overall condition and treatment, Sandhu advises. Do not hold back because the information is discouraging.

"Give room for the patients' families to communicate their concerns for their loved one, because ultimately they are searching for comfort," she says.

Sandhu notes most medical malpractice lawsuits that involve hospital staff are included under a vicarious liability theory requiring the hospital to show established policies and procedures to properly document patients' conditions and course of treatment, including any potential risk or harm.

In the same lawsuit and mediation Sandhu referenced, the hospital and staff were sued for failure to provide adequate postsurgical treatment. The plaintiff said they left her requests for new sheets, gown, food, and pain management unanswered, even

EXECUTIVE SUMMARY

A decision to file a medical malpractice lawsuit often is driven by how the patient and family feel they were treated by physicians and staff. Efforts to convey a sense of caring can reduce the likelihood of a lawsuit.

- Severity and permanency of injury are other significant factors in deciding to sue.
- Patients may conclude a physician does not care after overhearing comments about a busy schedule and other concerns.
- Thoroughly prepare for meetings with patients and family to answer questions effectively.

though the charts showed consistent care for her throughout her stay at the hospital, which amounted to several weeks.

"It was just her 'feeling' that they did not care," Sandhu says. Still, documentation of even the most routine care is essential.

Severity and Permanency of Injury

Each plaintiff's case is highly fact-specific, but the severity and permanency of the claimed injury are big factors in deciding to sue, says **Jeffrey Randolph Saxby**, JD, partner with Hall Booth Smith in Atlanta. *(See the story in this issue for more on how outcomes can affect the decision to sue.)* These factors can be used as a reasonable evaluator of whether a malpractice claim will be filed, regardless of whether the injury resulted from a known risk of the care or procedure.

"Unfortunate medical care results that are correctable have little value in the eyes of plaintiffs' lawyers, particularly when a healthcare provider will cover the costs of additional care," Saxby explains. "Conversely, things like sensory injury, loss of appendage or limb, and inadvertent death are viewed as high-value claims to plaintiffs' lawyers, and they are more likely to take on the risks of pursuing such a claim, even when it's questionable whether a deviation from the standard of care occurred."

Generally, the current motivations usually are compensation for losses, pain, suffering, and future care; the need for an explanation as to how and why an injury occurred; recognition of the severity of the injury and trauma suffered; and a desire to hold someone accountable — be it staff or an organization — as a means of ensuring lessons have been learned and that future care will be improved.

"Sometimes, the facts of the case and the alleged injury make the motivating factors behind the litigation quite clear," Saxby says. "Other times, you can glean a great deal of insight from conversations with the patient or their family, frustrations they express, and things they say about how someone needs to pay for the mistakes they made."

While it is common for patients to claim their physicians did not care about them, Saxby says very few patients truly believe that a physician simply did not care.

"What is more common is that a physician says something in earshot of a patient, family member, or other healthcare provider that the patient might overhear. When other members of a medical team are deposed during litigation, that's often when things surface about inappropriate comments that were made about a patient's weight, age, health, or other procedures a physician has to perform next," he explains. "When a patient learns that their physician was concerned about his busy schedule while performing their own procedure, it is easy to conclude that the physician was not providing his full attention if an unfortunate result occurs."

Or perhaps a physician does not exhibit a good bedside manner, Saxby says, or simply does not take enough time to really listen to what the patient is saying or express enough empathy for how the person feels. When a patient is in pain or scared, the smallest perceived slight can turn into the perception that their doctor does not care enough.

"Make ample time to talk with a patient and/or their family before any non-acute procedure or treatment. That doesn't mean chatting with them for a few minutes immediately before a procedure," Saxby says. "That means making enough time to really talk with them about what's going to happen, why it's necessary, the potential risks or side effects, what recovery is going to be like, and what the long-term outcomes may be."

How to Explain Risks

The lack of informed consent often is raised not because a doctor did not explain a potential risk per se, but because the doctor did not take the time to explain the risks in a manner that a lay person would understand, Saxby notes.

For inpatients, a physician going above and beyond the usual once-a-day visit while in active care of a patient can go a long way toward showing the physician cares. A second visit by a doctor (not his or her nurse practitioner or other associate) to say, "I just wanted to check in on you and see how you're feeling," or, "We are still awaiting the results of ..." can greatly improve a patient's perception of the care they received, Saxby says.

Hospitals are increasingly subject to claims of corporate negligence in conjunction with many malpractice claims. Their roles in helping prevent malpractice claims and mitigate risk cannot be overemphasized. Hospitals must show they are fulfilling their responsibilities on peer review, credentialing, and privileging procedures, ensuring compliance with Joint Commission standards and procedures, updating hospital policies and procedures annually, and ensuring doctors do not perform new procedures without demonstrating the required training. These best practices can help prevent malpractice claims and strengthen the defense's case should litigation occur.

"One common issue we face in defending claims against doctors and nurses is when a hospital has a specific policy and procedure on a subject, and the doctor or nurse who is being sued has never seen the policy, or saw the policy years ago when they were hired but hadn't seen it since," Saxby says. "While policies and procedures are not standard of care, they are a major factor that jurors may consider in determining whether the standard of care has been met. Providing an annual review, continuing education, and other regular training on hospital policies and procedures with all care providers, including contract physicians, can be pivotal in litigation."

No single action by a hospital will ultimately persuade or dissuade a patient from deciding whether to commence a malpractice lawsuit, short of pre-suit settlement of a known claim, Saxby says. But there are a lot of things administrators can do to reduce the likelihood of litigation, particularly if an unfortunate outcome within the known risks of a procedure occurred.

Consider Meeting with Patient and Family

Determine whether a meeting with the patient and family and the hospital's risk management and legal teams is the best course of action. Often, it can be beneficial in demonstrating the hospital cares about what transpired and helps the patient feel heard.

"It's an opportunity to answer their questions objectively and matter-of-factly while referring back to the patient record about medications, dosage, details of a procedure, and other factors," Saxby says. "Sometimes, meetings with the patient and family should be avoided because it may lead them to believe that a hospital is worried about possible litigation or trying to talk them out of certain choices. Carefully consider the facts of each situation before deciding."

Patients sue because their feelings were ignored or attitudes they perceive from the staff, but if a patient feels as though their concerns were directly acknowledged and addressed, they are less likely to resort to litigation, says **William H. Chamblee**, JD, managing partner of Chamblee Ryan in Dallas.

"Patients are also less likely to sue a long-time care provider if they have an established rapport and strong physician-patient relationship," he says. "Being forthcoming and honest with patients can go a long way."

Obviously, an adverse event or missed diagnosis contribute the most to patients filing a malpractice lawsuit, Chamblee says. But the already negative feelings are fueled by anger or resentment over perceived failures in communication, lack of empathy, or lack of follow-up from a physician or the office.

"From the beginning, a patient's interaction with front desk and office personnel can lead to this perception that the doctor doesn't care before the doctor has even seen the patient. There may be difficulty in scheduling, or the staff may fail to follow up or return calls," Chamblee says. "This can lead to medical board complaints, or even a lawsuit, given the right fact scenario. Following a visit, there may be billing issues that are entirely an issue with the patient's insurance provider, but since the physician and the office visit are the basis for the charge, the blame usually falls on them."

Physician Blamed for Negative Encounters

When a patient leaves the physician's office after a negative interaction, he or she is much more likely to scrutinize the visit and conclude the negative encounter is attributable to the physician or a lack of supervision of the staff, Chamblee says.

In addition, patients want to feel heard and understood. If a patient asks a question regarding a medication option that has worked well in the past, directing a physician

to take the time to explain the risks, benefits, and then actually listening is all the patient needs to feel assured. That approach works much better than simply ignoring their request and prescribing a different medication.

Another issue is follow-up with test results. This can fall to the physician or the staff. "If a patient undergoes a procedure to treat or diagnose a particular longstanding problem, they will likely want a face-to-face visit to discuss the results, not just a generic upload of the results to the electronic chart," Chamblee says. "While most of these items are more likely to result in a formal complaint because they are smaller issues, if amplified in the wrong scenario, they could result in a lawsuit. For example, what if the delay in discussing results of a test [causes] a delayed diagnosis and worsening of disease?"

Patients want to feel heard and understood. Sometimes, asking patients about their lives lends a bit more to diagnosing their condition. For example, certain careers are prone to more stress, or perhaps the headaches are caused by a lack of sleep or negative trigger in the patient's personal life.

"Discussing those kinds of issues can improve the diagnostic outcome of the visit, and can improve the physician-patient relationship," Chamblee explains. "Basic etiquette, such as responsiveness, maintaining eye contact, speaking directly to the patient, and including patients in basic decisions, such as scheduling, have been shown to influence positive perceptions."

Unrealistic Expectations

Medical malpractice lawsuits often are caused by a combination of poor communications and unrealistic expectations, says **Janice L. Merrill**, JD, shareholder with Marshall Dennehey Warner Coleman & Goggin in Orlando. Timely communication with the patient and family after an adverse or unexpected outcome can prevent a malpractice claim.

Relentless advertising by plaintiffs' attorneys has caused an uptick in medical malpractice claims. But by addressing the family's concerns in a timely and sensitive manner, lawsuits often can be avoided.

Medical negligence claims are expensive for plaintiffs to prosecute and for the healthcare provider to defend. As a result, most cases involve a death or serious injury. In those cases, but perhaps more frequently in the unexpected death cases, even the best relationship with the patient can quickly deteriorate and result in a lawsuit.

In medical malpractice cases, the quality and timeliness of the documentation can make all the difference. The electronic medical record can be both a blessing and a curse.

"The volume of the record has increased dramatically, and a healthcare provider's note is now populated with repetitive information, some of which may be inaccurate. A template or one-size-fits-all approach is not going to work," Merrill explains. "The note needs to be personalized to the patient and reflect what actually took place and was discussed with the patient. This starts with the informed consent and applies all the way through the discharge summary."

Do not be afraid to meet with the patient or family if they are unhappy with an outcome or ask questions, Merrill says. Be prepared for the meeting and invite people who can answer the family's questions. Often, these meetings will prevent the family from going to an attorney.

Plan carefully for the meeting. Bring the organized and complete clinical record to respond to questions, and let the patient or family see the record, Merrill advises. Answer the questions truthfully and accurately. If you do not know the answer to the question, find out and get back to the family. Listen empathetically to what the family has to say.

Make Records Available

Ensure the hospital's process for releasing medical records is not overly difficult and that records are released in a timely manner. Often, delays in obtaining records result in a patient or family contacting an attorney.

If you cannot release records to the person requesting them because they are not legally entitled to receive them, explain why and offer advice as to who can request the records on their behalf, Merrill says.

Recently, Merrill attended a pre-suit mediation in an action involving the death of a nursing home resident. The facts of the case were difficult and presented numerous defense challenges.

"In advance of pre-suit mediation, I had met with many frontline staff who provided day-to-day care to the resident, and I listened to their stories as they recalled the well-loved resident. At the mediation, I related how sorry the facility was for the loss of their father, and how they missed the resident, sharing many of their stories with the family," she recalls. "The son and daughter responded to the stories, the tension in the room dissipated, and we were able to demonstrate that the staff and facility

knew and cared about their father. This made an enormous difference to the outcome of the case." ■

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Diagnostic Errors Often Prompt Patients to Sue

The main reason patients sue is for an adverse event caused by delayed, missed, or failed diagnosis, says **Jacqueline Ross**, RN, PhD, coding director for patient safety and risk management with The Doctors Company, a malpractice insurer based in Napa, CA. Diagnostic errors can be multifactorial.

"In healthcare, providers rely on their cognitive skills when considering diagnoses, but they need to be aware of potential cognitive errors," she explains. "One may be anchoring, which can be relying on the initial impression or diagnosis with conflicting information coming."

Ross cites an example involving a patient who visited the emergency department (ED) on three separate occasions. The patient had a history of diabetes and chronic back pain. At the first visit, the patient presented with a fever and elevated white blood cells. After a lumbar puncture, the ED physician diagnosed viral meningitis.

A few days later, the patient returned with ongoing back pain, but with radiation to his abdomen. He also experienced spine tenderness. His white blood cell count had decreased, but his bands were elevated. His fever remained. The ED physician diagnosed ongoing chronic back pain, ordering muscle relaxers and pain medicine.

"Four days later, the patient returned with no feeling or ability to move his legs. Cauda equina syndrome was suspected, and a stat MRI showed a spinal epidural abscess [SEA] at T7-8 with cord compression," she says. "The man now has incomplete paralysis of his legs and a neurogenic bladder. It was noted by multiple clinical experts that the ED physicians failed to note the various stages of the SEA, and if they had, the paralysis would have been avoided."

The patient was in SEA Stage 1, but no one considered this diagnosis or ordered imaging.

"Another factor we picked up was the failure or delay in ordering diagnostic tests in postoperative patients. We completed a study, not yet released, about general surgeons and diagnostic errors and found that CTs were the most common tests delayed or not ordered postoperatively," Ross explains. "There are also problems with misinterpretation of diagnostic tests that can lead to patients filing malpractice claims. Many of those specialties involve radiologists and pathologists."

In a general surgery study, The Doctors Company included a case example of a general surgeon who reviewed a CT angiogram and noted no vascular injury, when an injury existed. The patient lost their leg because of the misread, Ross says. The clinical experts noted the general surgeon was not qualified to read the CT angiogram because of the lack of vascular training.

Failure to Communicate

Another reason patients sue is due to failure of communication, which led to an adverse event. Ross cites one example.

"A patient had laparoscopic surgery and had the abdomen collapse intraoperatively due to the insufflation device being out of gas," Ross recalls. "The general surgeon exchanged tanks and, with the equipment in place, reinflated the abdomen and continued surgery. But there was no documentation of this event."

In the post-anesthesia care unit, the patient had a firm, painful, distended abdomen. A CT of the abdomen with contrast was performed, but the operating room event was not communication to the radiologist.

The impression was a pneumoperitoneum, possibly due to recent surgery, Ross says. None of the nurses were aware of the equipment failure and the family was not told. Early in the morning, the patient developed severe abdominal pain, with a very distended abdomen and no bowel sounds. The surgeon was not called.

"A few hours later, the patient had a code and died. This case had multiple failures in communication and missed opportunities to hand off important information," Ross says. "Had the information been shared, then the other healthcare providers could have been aware of potential problems." ■

SOURCE

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Artificial Intelligence Viewed Favorably by Juries, Research Suggests

As artificial intelligence (AI) is used more and more to guide clinical decisions, the perception of jurors in any related malpractice case becomes important. Will jurors look favorably on physicians following AI advice even it if proved to be the wrong decision? Or will they hold the physician responsible for not overruling the AI suggestion?

A recent study revealed potential jurors might not be strongly opposed to providers following AI advice, suggesting physicians and other clinicians could follow AI recommendations with less fear of malpractice liability.[1]

The researchers noted that in recent years, clinical decision support tools have become increasingly reliant on AI to guide physicians regarding diagnosis and treatment recommendations. Sometimes, these recommendations deviate from standard care, and the clinician must decide to follow the AI or overrule it.

The researchers studied a representative sample of 2,000 adults in the United States. They provided each participant with one of four scenarios involving an AI algorithm suggesting a drug dosage to a physician.

Less Liability Than Expected

The results suggest physicians who follow AI advice might be at less risk for liability than commonly thought, says **Alexander Stremitzer**, PhD, JD, study co-author and professor at the ETH Zürich Center for Law & Economics in Switzerland. "They are less skeptical than is commonly thought," he says.

The scenarios in the study varied the AI recommendation from standard and nonstandard drug dosage. The physician either followed the recommendation or rejected it. No matter the physician's decision, each scenario led to patient harm.

The participants determined if the physician's action was reasonable. Two factors seemed to guide participants' decisions: whether the treatment provided was standard, and whether the physician followed the AI recommendation.

The participants judged physicians who accepted a standard AI recommendation more favorably than those who rejected it. For a physician who received a nonstandard AI recommendation, rejecting it did not make him or her safer from liability.

The main finding is the threat of physician liability from following AI recommendations is smaller than might be expected, Stremitzer says. The basic question the researchers wanted to answer is whether physicians who rely on AI tools are likely to face legal liability after an adverse outcome.

"Medical malpractice requires a deviation from a care standard, and this standard is usually met if the physician exercises due care. Physicians might expose themselves to increased liability when accepting nonstandard AI advice," Stremitzer says. "On the other hand, it could be that accepting the AI advice is the new standard. We recruited a sample of U.S. adults and said this is a model of a jury, presenting them

EXECUTIVE SUMMARY

Jurors may accept the use of artificial intelligence (AI) in medicine more than commonly thought. Research suggests jurors might be sympathetic to a physician who used AI even if it harmed the patient.

- Study participants favored physicians who followed AI recommendations even when they turned out to be wrong.
- Physicians should follow AI recommendations unless they feel strongly that it is wrong.
- The tort system does not have to hinder more adoption of AI in medicine.

with different versions of a scenario in which a physician had to decide what dosage of a chemotherapy drug to give to a patient."

Favorable to Following AI

The researchers found the "jurors" evaluated the physician more favorably when the physician accepted the AI advice, Stremitzer says. That finding was particularly strong when the physician followed AI advice to provide standard care, even when that decision was wrong and harmed the patient. But the participants still supported physicians who followed AI advice to provide nonstandard care, which harmed the patient.

"This experiment is just one piece of the complex picture of tort liability. The determination of liability depends also on the testimony of experts and a dynamic with the jurors at trial, and other factors," Stremitzer says. "The bottom line is we found that people were very open to the use of AI."

The researchers noted the study should not dissuade healthcare organizations from adopting AI. The experimental scenarios studied assume that an AI recommendation is already offered routinely.

"The study has nothing to say about the relative likelihood of liability for physicians who have not received advice from an AI system and therefore does not support any inference that healthcare institutions should avoid introducing AI systems," the researchers noted. "Additionally, those decisions will likely involve nonlegal factors as well, such as the competitive pressure to maintain state-of-the-art facilities and their ability to set guidelines for the appropriate use of the AI system."[1]

This research appears to be the first of its kind, Stremitzer says. Previous thinking on the matter suggested a physician's safest play was to reject a nonstandard recommendation from AI to minimize potential liability. That is a reasonable theory, Stremitzer says, because one could assume a jury would be skeptical of a physician trusting AI over his or own decision.

People seem to trust AI more than that. "We came to this with an open mind and said, 'Let's try to test it,'" he says. "We have plans to test this further because an interesting difference between the U.S. and Europe is that in the U.S., this is something jurors get to decide, but in Europe, this is something that judges get to decide."

Advice to Physicians

Stremitzer says the research suggests:

- accepting the AI advice on standard treatment if the physician does not have a strong intuition that the recommendation is wrong;
- using best judgment when the AI recommends a nonstandard treatment. But when in doubt, accept the recommendation.

"Everything our study speaks to is the liability of doctors, conditional on harm occurring," he says. "Doctors still should use their judgment. If they have a strong opinion that actually the AI might be wrong in its recommendations, it is still a good idea not to follow the advice because it could prevent harm."

Stremitzer and his colleagues may conduct the study in Switzerland to see if laypeople hold different attitudes toward AI and malpractice liability, but also with a sample of judges or the medical experts they rely on for deciding malpractice cases. Policymakers also should take note of the research results.

"A common opinion is that the tort system might actually undermine the use of AI tools, and we suggest that is not the case," Stremitzer says. ■

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Proactive Programs Needed to Address Vaccine Resistance

Even as millions of Americans continue to receive the COVID-19 vaccine, some healthcare organizations still struggle with a worrying number of employees who will not accept the vaccines.

It seems counterintuitive that healthcare professionals would resist the vaccines, but a Kaiser Family Foundation survey of 1,676 American adults revealed 29% of the respondents who worked in a healthcare setting were hesitant to accept the vaccine, compared to only 27% of other respondents. *(The survey findings are available online at: https://bit.ly/3dleXIN.)*

The health nonprofit Surgo Ventures interviewed 2,504 healthcare workers. Fifteen percent of those who were offered the vaccine said they had refused it. *(The report is available at: https://bit.ly/3u8d88M.)*

Vizient, a healthcare performance improvement company based in Irving, TX, recently surveyed its member hospitals and found 72% of hospital executives said overcoming staff hesitancy or reluctance toward the COVID-19 vaccine was a major concern.

Hospitals currently cannot mandate the vaccines, so they find themselves in the peculiar situation of trying to protect their employees and overcome concerns about adverse effects and the perception of insufficient clinical data about the vaccine, says **Tomas Villanueva**, DO, MBA, FACPE, SFHM, associate vice president for clinical resources with Vizient and a physician in Miami.

The Food and Drug Administration (FDA) granted emergency use authorizations (EUAs) for three COVID-19 vaccines. Nationwide distribution began with the first doses going to frontline healthcare workers and long-term care residents at skilled nursing and assisted living facilities. The vaccines now are available to most people in many states.

Because the vaccines only received EUAs and not full approval, many legal sources advise healthcare employers not to mandate vaccination for employees until the FDA expands authorization. At that time, healthcare employers would be free to require COVID-19 vaccination as a condition of employment, they say. *(For more on this legal issue, see "Vaccine Rollout Brings Legal, Labor Concerns for Employers" in the February issue of* Healthcare Risk Management *at: https://bit.ly/3uaBlLM.)*

Vaccine hesitancy is not uniform across the healthcare field, Villanueva notes. There is a high rate of acceptance among physicians, and the rate drops with nurses and ancillary services.

Healthcare employees with more education in science are more likely to understand the vaccine process and accept the COVID-19 vaccines, he says. Others may not understand the science, and when faced with overwhelming information, they may turn to similarly situated colleagues and others who reinforce skepticism and misinformation.

"Some of it may be historical in that there can be a racial component, with some data showing that among all healthcare professionals, there is more hesitancy among Black and Latino healthcare workers," Villanueva explains. "A lot of it has to do with a lack of understanding about how the vaccine came about."

Hospitals should address the issue head-on with a proactive information campaign. "One of the ways to address fear is giving people straight-up information," he says. "Use your physicians, nurses, physician assistants, and leverage a diverse group of providers to give the same message about how they have had the vaccine themselves, and why they chose the vaccine."

Among those who are hesitant, stories tend to be more effective than just reciting facts and statistics, Villanueva says. He tells others about his recent experience with visiting his mother after both were vaccinated.

"Last week, for the first time in over a year, I got to hug my 77-year-old mother. Mom not only is elderly, but has multiple comorbidities. I got to hug her for the first time without either of us wearing a mask," he

EXECUTIVE SUMMARY

A surprising number of healthcare employees are resisting the COVID-19 vaccines. Hospitals should take a proactive approach to educate them and encourage vaccination.

- Vaccine hesitancy varies according to employees' education in science.
- Physicians and other leaders should address concerned employees and correct misinformation.
- Personal stories will be more effective than reciting data and statistics.

recalls. "That is a good reason to be vaccinated."

Villanueva has visited environmental services in a hospital to explain how he decided to get the vaccine and to answer any questions employees might ask. As a Cuban American, he makes an effort to connect with others of the same background in Miami.

One common concern is people do not understand how the FDA approved the vaccines so quickly. Villanueva explains the FDA did not skip steps or ease the approval process. Rather, they managed to speed up the process of the usual procedures.

"There are multiple steps involved that usually are done sequentially, but they started bringing in ways to do them in a parallel way," he explains. "The FDA really didn't take any shortcuts whatsoever. They were very meticulous in how they approved the vaccines under the emergency waiver."

Another concern is the vaccines themselves were developed quickly. The science behind the vaccines has been developing for years before the pandemic, and researchers were able to accelerate the vaccine science in response to COVID-19.

Healthcare workers also might worry the vaccines will give them COVID-19, after a year of indoctrination about how dangerous the disease is, Villanueva notes. That is not possible with the vaccines.

It also is not possible for the vaccines to alter a person's DNA. That misconception arose from how the vaccines use a messenger RNA approach.

Another false rumor is the vaccines will cause infertility. "This has gained traction particularly among some of our younger healthcare workers of childbearing age, who have received unfortunately false information about a protein that helps the placenta bind to the uterus. There are some similarities in the genome of that protein and the neutralizing antibody," Villanueva explains. "But the similarities are very small. It's like if your phone number and my phone number both have the number one in them, they're similar. But they don't function the same way." ■

SOURCE

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Specialty Pharmacists Play Important Role in Patient Safety

Specialty pharmacists can play an important role in patient safety. Risk managers can encourage them to embrace this part of their job, suggests **Jill Paslier**, PharmD, CSP, ISMP international medication safety management fellow with the Institute for Safe Medication Practices (ISMP) in Horsham, PA.

Specialty pharmacy involves high-cost, high-touch medication therapy for patients with complex disease states, according to the American Pharmacists Association. "Medications in specialty pharmacy range from oral to cutting-edge injectable and biologic products. The disease states treated range from cancer, multiple sclerosis, and rheumatoid arthritis to rare genetic conditions," the group says. *(More information is available at: https://bit.ly/3dPgdUA.)*

More so than a typical hospital or retail pharmacy, a specialty pharmacy handles expensive medications, ranging from a cost of $1,000 per month to $30,000 per month, Paslier notes. The medications often require special handling and detailed instructions to the patient on usage.

"Because of the high-cost and high-touch aspects of these medications, instead of being dispensed from a regular pharmacy, they are dispensed from a specialty pharmacy," Paslier explains. "The specialty pharmacist has special training on all these diseases and medications, and a specialty pharmacy may provide

EXECUTIVE SUMMARY

Specialty pharmacists can be influential with encouraging other pharmacists to improve patient safety. Those at a health system level work with many pharmacy departments.

- Specialty pharmacists work with high-cost medications requiring special handling.
- They can lead the way with encouraging pharmacists to report errors.
- An error-reporting process should be simple to use and not time-consuming.

additional medication management programs."

It is important to focus specialty pharmacy staff members on their role in patient safety, Paslier says. Specialty pharmacies at the health system level are particularly well placed to influence patient safety because they work with pharmacy departments throughout the health system.

"The specialty pharmacist has somewhat of a position of influence. They may be managing other pharmacists or pharmacy technicians, and they have a level of professionalism that includes interacting on a day-to-day basis with patients and providers," she says. "I think they certainly can influence a positive safety culture by encouraging others to report medication concerns, errors, or hazards."

For instance, specialty pharmacy staff should share "good catches" that prevent a medication error from reaching a patient.

Specialty pharmacy staff can be directly involved in the quality improvement process and error-reporting process, Paslier says. They can work to promote trust among pharmacy staff in the organization's just culture and dispel fears of being punished for reporting errors.

Error reports should be easy to file and not time consuming. Those submitting error reports should be acknowledged and praised for participating in the patient safety process. Staff also should receive feedback so they understand how their error reports are used and how they are helping improve patient safety, Paslier says.

Creating a just culture can help specialty pharmacists improve patient safety and reduce errors. Paslier, who has worked in specialty pharmacy with a health system, notes the culture of an organization is influenced from the top down.

"You start at the top to promote a just culture and a positive atmosphere that encourages reporting errors, rather than one that punishes the person or focuses only on the person making a mistake," she says. "We need to look at the big picture and how to prevent errors with high-level strategies rather than just reminding people to be more careful." ■

SOURCE

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Analysis: Few EMTALA Violations for Vascular-Related Issues

By Stacey Kusterbeck

Few EMTALA violations involve vascular-related issues, according to the authors of a recent analysis. *(The analysis can be found at: http://bit.ly/30jQBZO)*

"Our motivation for the study was to assess for EMTALA violations in our field, vascular surgery, in order to better understand how these happen," says **Jeffrey Siracuse**, MD, MBA, one of the study's authors and an attending surgeon in the division of vascular and endovascular surgery at Boston Medical Center.

Of 7,001 patients with an EMTALA violation from 2011 to 2018, only 1.4% were vascular-related.

"An example would be not adequately stabilizing or fixing a vascular emergency, such as a symptomatic or ruptured aortic aneurysm, when the capability exists," Siracuse explains.

Cases included cerebrovascular, ruptured aortic aneurisms, aortic dissections, vascular trauma, peripheral arterial disease, venous thromboembolism, dialysis access, and bowel ischemia.

"Vascular surgical emergencies can sometimes be difficult to diagnose and recognize, even by diligent and well-meaning physicians and staff," Siracuse notes.

These are the most common reasons for EMTALA violations, according to the analysis: Unavailability of specialists, inappropriate documentation, misdiagnosis, poor communication, inappropriate triage, failure to obtain diagnostic labs or imaging, and ancillary/nursing staff issues. The most frequent vascular-related violations specifically involved lack of vascular specialist availability. "This highlights an important issue. There are potential shortages of specialists, particularly outside of major cities," Siracuse says.

Early diagnosis and triage is important in a vascular surgery emergency. "Developing specialist networks and having adequate call coverage can help improve patient access to emergency services," Siracuse offers. ■

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **What does Savera Sandhu, JD, say is a key factor in whether a patient or family decides to sue after an adverse event?**

   a. The physician-patient relationship
   b. The cost of the procedure
   c. Influence from family and friends
   d. Their understanding of the risks

3. **What does Tomas Villanueva, DO, MBA, FACPE, SFHM, suggest as a way to convince hesitant healthcare employees to accept the COVID-19 vaccines?**

   a. Show them a PowerPoint presentation on the data behind vaccination.
   b. Encourage peer pressure to shame those who are not vaccinated.
   c. Tell them the vaccines soon will be mandatory anyway.
   d. Tell them personal stories about your experience with COVID-19 vaccination.

4. **In the study from the ETH Zürich Center for Law & Economics, which physicians did the "juror" participants judge more favorably?**

   a. The physicians who accepted the AI advice
   b. The physicians who rejected the AI advice
   c. The physicians who did not seek AI advice
   d. The physicians who had no access to AI advice

2. **What does Jeffrey Randolph Saxby, JD, recommend as one way to improve the physician-patient relationship?**

   a. Visiting inpatients more often than the usual daily check-in
   b. Handwritten correspondence
   c. Sharing personal stories from the physician's family
   d. Showing pictures of the physician's family

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Punitive Damages Award Upheld for Wrongful Death Action Alleging Mere Negligence

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News: Two surgeons advised a patient that his only treatment options for a bladder issue were surgery or the permanent implementation of a catheter. The surgeons did not advise the patient of other non-invasive treatment options, including a transurethral microwave treatment or use of different medications. The patient chose surgery, which led to complications, another emergency surgery, and ultimately the patient's death a year later.

The patient's estate filed a wrongful lawsuit death arising from negligent medical care, and was awarded $870,000 in damages, including $300,000 in punitive damages. The Supreme Court of Missouri held that while punitive damages are rare for cases alleging mere negligence (as opposed to intentional wrongdoing), they were appropriate here because this was an example of an extraordinary case in which the doctors' actions were so grossly negligent that they were tantamount to intentional wrongdoing.

Background: In October 2012, a urological surgeon was treating the patient for an enlarged prostate. The surgeon informed the patient his only treatment options for a bladder issue were surgery or the permanent implementation of a catheter. The surgeon performed the transurethral resection of the prostate (TURP) and a transurethral incision of the bladder neck (TUIBN) to allow easier placement of a catheter.

Shortly after surgery, the patient complained of abdominal pain, renal failure, and difficulty breathing. The surgeon ordered imaging studies, which showed free air in the patient's abdomen and retroperitoneal area. The surgeon concluded it was caused by a perforation of the gastrointestinal tract, and requested a surgical consultation.

A general surgeon performed an exploratory laparotomy to examine the patient's GI tract. After identifying "fatty tissue" in the sigmoid colon but no perforation, misplaced catheter, or any irrigation fluid in the patient's abdomen, the general surgeon concluded a ruptured diverticulum had caused the free air but sealed before the laparotomy. Afterward, the patient developed sepsis and respiratory and kidney complications.

Two weeks after the prostate surgery, medical center nurses removed and replaced the original catheter. Urologists subsequently removed and replaced the second catheter, drained his bladder, and drained fluid that had collected in his abdomen. The patient improved and was discharged to a smaller hospital, where the catheter was removed; however, while there, he suffered a stroke. During the next 10 months, he was transferred between hospitals and nursing facilities and ultimately into palliative care. The patient died in October 2013, approximately one year after the prostate surgery.

The patient's estate filed a wrongful death lawsuit against the medical facility, alleging the patient's death was caused by the surgeon's misplacement of the catheter and both doctors' failure to discover the misplacement. As for the surgeon, two experts for the plaintiff testified he misplaced the catheter outside the patient's bladder during the prostate surgery, failed to recognize his error or discover it during due care, failed to properly identify the source of the free air when the general surgeon did not find a perforated viscous during the laparotomy, failed to properly investigate the patient's

decline in health caused by his other errors, improperly reported the patient did not have a urine leak without conducting testing, and should not have performed the TUIBN with the TURP.

The patient's estate also presented expert evidence alleging the general surgeon failed to obtain additional diagnostic testing before surgery and failed to locate (or conduct additional testing to find) the source of the free air. On the other hand, the medical center presented evidence indicating both prostate procedures were appropriate and met the standard of care. The surgeon properly placed the catheter within the patient's bladder during the surgery, and both doctors were justified in performing emergent exploratory surgery without additional presurgical testing. The medical center concluded the catheter must have been misplaced when the nurses placed a new catheter more than two weeks after the prostate surgery, but the misplaced catheter did not cause or contribute to the patient's death by stroke-related complications. The jury found in the estate's favor, awarding nearly $1 million: $270,000 in damages, $300,000 in noneconomic damages, and $300,000 in punitive damages.

The Supreme Court of Missouri affirmed the $870,000 verdict, including punitive damages, noting the plaintiff provided sufficient evidence the healthcare providers exhibited a reckless indifference or conscious disregard of the patient's well-being. The court reasoned the issue of punitive damages was appropriate for the jury because the family had presented substantial evidence showing the surgeon acted with "a complete indifference to or in conscious disregard for the rights or safety of others" when she "incorrectly informed" the patient that "the only two treatment options were surgery or to self-catheterize for the remainder of his life" when the surgeon "knew there were other non-invasive treatment options, including a transurethral microwave treatment or use of different medications." Because the surgeon knew or should have known these treatments could have addressed the patient's concerns, but chose not to inform the patient of them, she could be liable for punitive damages. The court also found substantial evidence supported the jury's finding because the surgeons knew the patient suffered from severe pain, kidney failure, and possible sepsis, but did not perform any tests to determine whether the bladder was perforated or the catheter was outside the bladder. Even when two other doctors expressed concerns, the surgeons failed to acknowledge or otherwise take the necessary steps to address the numerous complications.

In a concurring opinion, another judge noted punitive damages "are rarely recoverable" in negligence suits, and may be appropriate only in "truly extraordinary cases." A different judge dissented, arguing damages should only be awarded in cases of intentional wrongdoing because even gross negligence is not "tantamount to intentional wrongdoing." This disagreement highlights how these issues are not always cut and dry, and often are state-specific. Be sure to consult with qualified legal counsel in local jurisdictions.

What this means to you: This case demonstrates the need to fully inform patients of their treatment options — especially in non-emergency situations — and to carefully monitor patients during the relevant times, particularly during and after surgery, and to investigate abnormal conditions appearing after the surgery. A well-considered and documented informed consent can be as important to the patient's safety from harm — and the physician's protection from litigation — as making the correct diagnoses, prescribing the appropriate medications, or skillfully performing the correct procedures. Yet, many physicians find it difficult, time-consuming, and, quite remarkably, a task that can be delegated to non-physician healthcare providers. Providing informed consent to the patient timely enough so he or she can review it with family, ask questions, perform their own research, or even find a second opinion is ideal, but seldom practice. However, providing informed consent in a pre-op setting moments before a patient is anesthetized is a high-risk practice. Physicians and surgeons should correct this behavior and give patients the best chance to make an informed decision about what they want done to their bodies, what they value as quality of life, and what they want their end-of-life choices to look like.

Generally, medical providers only are subject to punitive awards for damages caused by their intentional conduct, but not for the results of negligent, or even grossly negligent, medical care. However, in limited cases such as this, and in some jurisdictions, medical providers whose negligence rises to the level of "complete indifference to or in conscious disregard for the rights or safety of others" may properly be subjected to punitive damages. The goal of punitive damages is to punish the wrongdoer and deter others from similar actions; levying punitive damages in cases involving intentional wrongdoing or conduct so egregious that it is tantamount to such conduct furthers that goal.

While this was a 5-2 decision, and at least one of the dissenting judges argued punitive damages are proper only in cases alleging intentional conduct, this case leans toward a shift to punitive damages in cases of gross negligence. Specifically, punitive

damages may be available to an aggrieved plaintiff where a patient was incorrectly advised of surgical treatments to a mild prostate issue but not non-surgical treatments, and those surgical treatments led to complications the medical providers failed to properly investigate or prevent from causing further harm to the patient.

More generally, the most determinative factor in whether punitive damages should be available to a jury deciding a wrongful death action arising from alleged negligence is whether the plaintiff "made a submissible case" for aggravated circumstances damages by properly introducing evidence of "complete indifference to or conscious disregard" for the patient's safety. Where such evidence has been submitted to a jury, the courts will not find error in the jury's award of punitive damages to the plaintiff. ■

REFERENCE

- Decided March 2, 2021, in the Supreme Court of Missouri, Case Number SC 98327 (2021 WL 822828).

Patient's Notice of Claim Not Time-Barred for Filing Two Years After Injury

News: In September 2017, a patient was treated for leg cellulitis with a leg debridement, and subsequently developed abdominal problems. After undergoing rehabilitation and separate treatment for those abdominal problems for two years, the patient discovered in June 2019 that his condition may have been a surgical complication following the debridement, and thus attributable to the doctor's negligence. The patient filed a notice of claim and complaint against the doctor and hospital.

Although patients typically must submit a notice of claim within 90 days of the negligent act causing injury, the patient was allowed to file the notice nearly two years later because a reasonable person in his position would not have known his injuries could have been caused by another person. Because the patient filed suit within 90 days of discovering facts, his lawsuit was not time-barred.

Background: On Sept. 11, 2017, a patient in New Jersey was admitted to a hospital and diagnosed with right leg cellulitis (bacterial skin infection). A doctor performed drainage procedures and debridement. A few days later, while still hospitalized, the patient also was diagnosed with colonic obstruction. As a result, the doctor and his surgical team performed an exploratory laparotomy, lysis of adhesions, and subtotal colectomy and creation of end ileostomy. The patient was discharged a week later and was readmitted after a few days; he was discharged again three weeks later. Immediately thereafter, the patient received almost continuous treatment from various wound care centers and rehabilitation facilities for about two years. At the time of the appeal, the patient still was receiving treatment for his injuries.

On July 22, 2019, the patient went to lunch with a physician friend. The patient told his friend about his abdominal problems. The friend was concerned by what he heard. The patient also became concerned and asked the friend to write a letter expressing his concerns about the patient's treatment.

In a letter dated Sept. 2, 2019, the friend detailed his discussion with the patient about his abdominal problems. He wrote that he "thought it was strange that no radiologic studies were done in an effort to diagnose the abdominal problem medically before the surgery." Further, he informed the patient about a phone app called UpToDate that provides "detailed medical information for clinical diagnosis and treatment of various conditions." Upon searching UpToDate for postsurgical complications following a leg debridement, the app identified the standard diagnostic approach as placing a nasogastric tube and conducting a CT scan of the abdomen without contrast before performing abdominal surgery.

On Sept. 5, the patient retained counsel and filed a notice of claim under the New Jersey Tort Claims Act (TCA), and ultimately filed a malpractice suit. The TCA establishes that public entities generally are immune from tort liability, except in certain limited circumstances. If those circumstances apply, a patient must first file a notice of claim with the public entity within 90 days of accrual of the cause of action to preserve the right to file a lawsuit. Then, the claimant must wait a minimum of six months before commencing an action in the appropriate court, but must do so before two years have passed since the accrual of the claim. In the complaint, the patient attested that before speaking with the friend in July 2019, he never had reason to suspect the doctor had injured him, and no other medical professional had ever indicated that another person could have caused his conditions. However, after reading the friend's letter, he believed for the first time that he was the victim of medical malpractice.

The doctor and the medical facility moved to dismiss the case as a matter of law, but the trial court denied the motion based on the patient's allegation that a "reasonable person in his position exercising ordinary diligence would not have recognized that his injuries were [caused by] ... another until he met with" the friend, given the patient was receiving treatment for two consecutive years after the alleged malpractice and had never been informed or had any reason to believe the original doctor could be at fault. The trial court found that at the earliest, the patient received notice of a possible cause of action when he met with his friend in July 2019. Therefore, plaintiff's September 2019 TCA notice of claim was timely.

On appeal, the original doctor and the medical facility argued the patient's notice of claim was not timely. The TCA does not define the time at which a cause of action accrues, but generally, in the case of tortious conduct resulting in injury, the date of accrual will be the date of the incident on which the negligent act or omission took place. However, an exception to this standard is the "discovery rule," which applies "where the victim either is unaware that he has been injured or, although aware of an injury, does not know that a third party is responsible." When applying the discovery rule, the proper inquiry is whether the facts presented would alert a reasonable person, exercising ordinary diligence, that he was injured due to the fault of another.

The court of appeal affirmed the trial court's findings, rejecting the defense arguing the notice of claim was not timely because the patient received continuous treatment for almost two years. During that time, no doctor or healthcare professional treating the plaintiff told him the doctor was possibly at fault for his continued complications, and no other facts in the record gave rise to any duty to investigate. In essence, there were no facts indicating the plaintiff should have questioned the doctor's diagnosis and treatment. The court also found that while the patient did not comply with the TCA's six-month waiting period requirement, his premature filing of the complaint did not prejudice the original doctor or the medical facility. Therefore, it affirmed the trial court's denial of the motion to dismiss in its entirety.

What this means to you: One defense tool often available to medical providers is preclusion of litigation where statutory filing requirements are not properly observed. This case is important to learn how time restraints are applied in medical malpractice suits. All states use specific statutes of limitations, and some states enacted additional time requirements to prevent a patient from waiting too little or too long before notifying the medical provider of intention to file suit. These statutory requirements were enacted to protect public hospitals from unfair prejudice caused by a patient's unreasonable delay. Such statutes require the patient to provide the public entity with prompt notification of a claim to allow the hospital to adequately investigate the facts and prepare a defense.

The general rule is the clock starts when the negligent act or omission took place. However, in certain situations like this case, the accrual date is tolled from the date of the tortious act or injury because the injured patient either does not know of the injury, or does not know the injury was caused by a third person. It is rare for a surgeon to perform an open abdominal procedure without the benefit of diagnostic data and radiologic imaging. This places the patient, surgeon, and hospital at extreme risk and should be considered negligence, and any untoward outcome malpractice. Regardless of the cause of the injury, the reckless way this case was managed needs to be addressed by the courts as soon as the patient realizes the harm he suffered was unnecessary or could be mitigated through a more thoughtful approach that fell within the standard of care.

This ruling is based on notions of fairness, which often are considered when calculating time constraints for lawsuits. The appeals court reasoned the mere fact the patient was admitted to the hospital for one condition and subsequently underwent treatment for an additional condition would not necessarily cause a reasonable person to suspect his or her physician committed malpractice. A patient could be treated for a second condition and still receive appropriate treatment and care. To hold otherwise would be to hold that all patients must second-guess medical treatment, even if no facts suggest malpractice occurred. Here, the patient "was only able to realize the possibility of malpractice during the short time he was not receiving treatment and was able to meet a friend for lunch."

Moreover, this case shows that even where a patient does not abide by the statutorily required six-month waiting period between notifying the hospital of his claim and filing suit, the complaint still might survive unless the hospital can concretely show prejudice. Here, although the patient waited only one single day between filing a notice of claim and filing his complaint, the hospital could only speculate this failure to wait six months would negatively affect the hospital's investigation. The appeals court found "[d]ismissal without prejudice would have little impact other than consuming the parties' and court's resources." ■

REFERENCE

- Decided March 15, 2021, in the Superior Court of New Jersey, Appellate Division, Case Number A-2357-19.