HEALTHCARE RISK MANAGEMENT™

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INSIDE

What to Do When a Patient Threatens to Sue

It might not be heard every day, but any time a patient says, "I'm going to sue you for malpractice," a serious response should follow. What does — or does not — happen afterward could significantly affect the course of events far down the road.

Risk managers and clinicians might let their guard down. Data show a decrease in the frequency of medical malpractice lawsuits, with a 2019 report from the insurer CRICO noting a 27% drop in the frequency of malpractice claims and suits against physicians. *(The report is available at this link: https://bit.ly/3zS1kdX.)*

But a recent report from the American Medical Association (AMA), titled *New Data Show the Highest Prevalence of Medical Liability Premium Increases in 15 Years*, shows otherwise. "Increases in medical liability premiums compound the economic stress on medical practices as the COVID-19 pandemic resulted in significant reductions to patient volume and revenue, and higher expenses for scarce medical supplies," AMA President **Susan R. Bailey**, MD, said in a statement.

PLAINTIFFS RECEIVED MORE THAN $4 BILLION IN MALPRACTICE PAYOUTS, WITH 96.5% COMING FROM SETTLEMENTS AND 3.5% FROM COURT JUDGMENTS.

In 14 states, premiums increased 10% or more between 2019 and 2020, according to the report. Kentucky saw the highest premium increases (29.6%), followed by South Carolina (27.8%). *(The AMA report is available at: https://bit.ly/3jORR1B.)*

In 2018, the average payout for

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medical malpractice claims was $348,065, according to data from the National Practitioner Data Bank, analyzed by LeverageRx. Plaintiffs received more than $4 billion in malpractice payouts, with 96.5% coming from settlements and 3.5% from court judgments. *(The report is available at: https://bit.ly/3BP7UCB.)*

Those numbers show the threat of malpractice claims remains a serious matter for hospitals, health systems, and physicians.

Any threat of a malpractice suit should be taken seriously, regardless of whether it sounds legitimate, says **Andrew Barovick**, JD, an attorney in White Plains, NY, who represents plaintiffs in medical malpractice suits. He started in this practice area representing doctors and hospitals.

"I would encourage the patient to meet with the hospital's patient advocate to learn the nature of the complaint, and to get an idea about the credibility of the patient," Barovik says. "I would also institute a policy within the hospital requiring doctors, nurses, or any other staff members to alert risk management if they hear of such complaints."

If the complaint appears legitimate and the patient is credible, Barovick says risk managers should consider informing the hospital's professional liability carrier. If the patient follows through with a lawsuit, the carrier will not have an excuse to disclaim against the hospital.

The risk manager also should investigate the patient's complaint if it sounds serious enough. The sooner the hospital knows what it is up against, the sooner and better it can prepare for a lawsuit, or even a settlement.

"If investigation shows that a true error took place and caused a real injury or death, I would consider having the staff involved apologize to the patient or family," Barovick says. "However, this remains a controversial practice, since the apology may end up being an issue at a trial, which the patient will use to argue that the hospital knew it had done something wrong."

The hospital also might consider how to remedy the error. Could a revision surgery be performed to improve the outcome? Consider performing it at a lower cost, or at no cost.

"If all else fails, consider offering a pre-trial settlement, before lawyers get involved," Barovik advises.

Any Complaint Can Be Costly

Confidence in quality of care does not negate the threat posed by a patient who wants to sue, says **Jonathan C. LaMendola**, JD, an attorney with Cobb Martinez Woodward in Dallas. Anytime a patient or patient's family threatens

EXECUTIVE SUMMARY

The moments after a patient threatens to sue for medical malpractice can be critical. How clinicians and risk managers react can affect the likelihood of a lawsuit and its outcome.

- Take any lawsuit threat seriously.
- Consider notifying your professional liability carrier.
- Look for ways to remedy the source of concern.

to sue, it is a potentially serious matter — even if the standard of care was met, he says.

Regardless of the claim's merits, litigation is costly, time-consuming, and can negatively affect the organization. Often, the threat of litigation comes about after an adverse or unexpected outcome, and the patient and family do not understand why.

"Think about things from the patient's perspective. Many are dealing with emotional, financial, or family stressors, in addition to whatever medical condition or event is at issue," LaMendola says.

Assessment and appropriate communication is key to minimizing the likelihood the threat of litigation will actually result in a claim or lawsuit — and minimizing your exposure.

"I've seen many claims result simply because of the failure to listen to the complaint and explain what happened," LaMendola notes. "Litigation can result when the patient or family did not understand what happened or felt their concerns weren't heard. They suspect negligence or a cover-up because no one explained what happened or what was done to try and address their complaints."

What you say and how you respond varies based on the circumstances, he says, comparing the situation to how a physician makes a differential diagnosis. In some cases, simply listening to and addressing the patient's or family's concerns is sufficient to mitigate the likelihood they will pursue legal action.

"Sometimes, an apology or expression of empathy can de-escalate the situation. Remember, you can be empathetic without admitting fault. In most circumstances, it's inappropriate to comment on the quality of care of others, particularly other disciplines or specialists," LaMendola says. "I've seen lots of lawsuits result from a family member being told by a subsequent caregiver that a prior healthcare provider was negligent or didn't do the right thing."

When confronted by a credible threat of legal action, administration should be notified to take appropriate steps. This may involve remedial steps and other measures to mitigate harm, preserve potential evidence, and establish privilege should any investigation be necessary.

Assess Every Claim

While the level of concern will be fact-specific, every credible threat of litigation should be assessed to some degree for its likelihood and potential exposure, says **David Verschell**, JD, partner with Abrams Fensterman in Lake Success, NY.

A threat of litigation by a patient who suffered a complication during a cardiac catheterization certainly will raise more concern than an outburst from an intoxicated patient in the emergency department with a superficial laceration, of course, but each should receive a preliminary assessment. Then, whether the matter warrants any follow-up or investigation can be determined.

"It's simply too easy for a patient with a supposed real claimed injury to convince an attorney to take his or her case," Verschell says. "Remember, while not every threat will turn into a lawsuit, this is the one opportunity risk management has to get ahead of the eight ball on a case that ultimately goes to litigation."

The way clinicians respond to a lawsuit threat is important, Verschell says. Doctors and nurses need to understand that once a patient or family member threatens to sue, any reasonable medical discussion generally is over. A polite "I'm sorry you feel that way," or "Well, I can't respond to that," usually is sufficient to allow the healthcare professional to complete the task at hand and then exit the situation promptly.

"Any attempt to dissuade the proponent from following through on the threat will likely inflame the situation or result. Even worse, the healthcare provider may give ill-conceived explanations or statements which are inaccurate or, more likely, misunderstood," Verschell says. "If the proponent is intent on speaking with an attorney, any reasonable explanation or discussion will likely fall on deaf ears, while ill-chosen statements will almost certainly register and be remembered."

A clinician or other staff member who hears a lawsuit threat should provide a brief statement to administration during or after the shift, delivering a general background on the proponent of the threat, the events leading up to the threat, and the contents of the threat. That person also should note anyone else who was present at the time of the threat. That should be sufficient for risk management to determine whether any further inquiry is necessary.

"Keep in mind that initial reports from the healthcare professional may not be protected from disclosure should litigation ensue," Verschell explains. "It's only when the written reports or investigation cross over to being directed toward quality assurance or in anticipation of litigation that privileges and protections may apply. Accordingly, the initial information should provide the necessary information while still being succinct."

Every report needs to be evaluated on a case-specific basis, Verschell says. For any report that raises a red flag, all staff involved should be interviewed to determine whether written

statements should be obtained, whether facility policy and procedure was followed, and whether the care and treatment giving rise to the complaint is documented properly and timely.

For example, the failure of staff to follow the facility's own written policies or procedures, or waiting for weeks for the doctor to dictate an operative/procedure, can easily sway a jury to an adverse verdict, he says.

Avoid the mistakes that can come with getting defensive or emotional. Verschell's rule of thumb to healthcare providers and administrators is to be polite and "stick to the medicine."

"Too often, I hear plaintiffs state that they never intended to sue until their complaints were ignored or they were treated poorly by the provider or administration," he says. "For the healthcare professionals, provide information on the patient's condition and treatment provided. Don't drift or be drawn off to discuss treatment options that weren't provided or considered. The more you speak, the more ammunition you potentially give the patient."

Also, avoid any statements that could be viewed as an admission of fault. Be careful about expressing remorse.

"While we all have sympathy for a person who is suffering, the open-ended 'I'm sorry' can be a powerful weapon for a plaintiff's attorney," Verschell says.

All lawsuit threats from patients should be taken seriously. If you do not, there are plenty of plaintiff attorneys who will, says **David N. Vozza**, JD, an attorney with Norris McLaughlin in New York City. One can see from the prevalence of TV and radio advertisements there is no shortage of malpractice attorneys who will pursue lawsuits, even those without merit.

When patients make such comments, this presents a window of opportunity for the practitioner to discuss their concerns in an open and genuine manner.

"Very often, patients are unsophisticated when it comes to complex medical issues. An honest discussion about their health and the practitioners' treatment plan may go a long way in preventing an uninformed malpractice action," Vozza says. "Of course, these discussions must be documented in the patient medical records as well."

Sometimes, healthcare organizations and physicians are obligated to report threatened malpractice claims to their liability insurance carriers. "Very often, the carrier will provide strategic advice on how to proceed and what to do if the patient follows through in filing a claim," he says. "In a hospital or group setting, it is good practice to notify respective administration, given those entities will likely be exposed to a possible claim as well."

A risk manager or hospital administrator should implement a procedure for internally investigating such threats and timely introduce remedial measures. As with practitioners, medical groups and hospitals also are encouraged to refer threatened claims to their malpractice carriers.

"Obviously, it is in no one's best interest to fight or argue with patients who verbalize concerns," Vozza says. "Most importantly, practitioners must not alter the medical records of a patient who threatens a malpractice claim to help his or her defense to the same. If a practitioner is found to have altered a record, it would almost certainly result in the revocation of his or her medical license." ■

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Proposed Patient Safety Foundation Could Benefit Patients, Industry

When an airplane crashes, whether a commercial airliner or a small private plane, federal investigators swoop in quickly to collect evidence so independent experts can determine what happened and how to prevent it from happening again.

That does not happen in the event of a medical error. Some healthcare leaders are proposing the creation of a federal patient safety board that would take a similar approach to improving safety in the healthcare system.

The Institute of Medicine's groundbreaking report, *To Err is Human,* was published 20 years ago and spurred a vigorous effort to improve patient safety, but preventable medical errors still cause an estimated 250,000 deaths a year in the United States, making this problem the third-leading cause of death. *(More information is available at: https://bit.ly/3jVBTmb.)*

Well-intentioned efforts to improve processes and change behavior in the healthcare industry have been decentralized and resulted in minimal improvements, says **Karen Wolk Feinstein**, PhD, president and chief executive officer of the Pittsburgh Regional Health Initiative and Jewish Healthcare Foundation. The failure can be traced to the lack of a single federal agency that investigates healthcare errors and identifies ways to prevent them, she says.

Following the Lead of the NTSB

Feinstein is spearheading the creation of a proposed federal independent agency, the National Patient Safety Board (NPSB), modeled after the federal National Transportation Safety Board (NTSB) that investigates accidents involving airplanes, railways, motor vehicles, and other modes of transportation.

The NTSB is renowned for its thorough investigation of accidents, followed by an objective analysis that yields a report detailing how the accident occurred, what lessons might be learned from it, and sometimes specific recommendations for changing requirements within the industry. *(An example of an NTSB report is available at this link: https://bit.ly/3hgPy5A.)*

Most NTSB recommendations become standard practice and are widely adopted, contributing to significant increases in transportation safety since its creation in 1967. The NTSB has issued more than 15,000 safety recommendations. "Because the NTSB has no formal authority to regulate the transportation industry, our effectiveness depends on our reputation for conducting thorough, accurate, and independent investigations and for producing timely, well-considered recommendations to enhance transportation safety," the board reports.

The proposed NPSB would operate similarly with investigations, but also by monitoring and anticipating adverse events with artificial intelligence, studies, and recommendations to prevent medical error, Feinstein says.

A coalition of leading healthcare organizations and experts is calling for the creation of the NPSB. *(More information about the effort is available at: npsb.org.)*

Started with Lean Management

Feinstein was spurred to act on patient safety when she learned of the high error rates in medicine and the lack of a national structure to study and learn from them. She sought help from industry leaders who had addressed safety issues, starting with a local executive, Paul O'Neill, who ran the major aluminum producer Alcoa. The company was known for improving safety in its own organization and within the industry.

"He brought his solutions from industry, including Lean, quality

EXECUTIVE SUMMARY

A coalition of more than 50 leading healthcare organizations is calling for the creation of a National Patient Safety Board. The board would be modeled after the National Transportation Safety Board.

- The board's goal would be to reduce medical errors and improve patient safety.
- The board would be a federal agency but would not issue regulations.
- Two decades of focus on medical errors have produced few significant improvements.

improvement, and his perspective on leadership. We formed a regional health improvement collaborative called the Pittsburgh Regional Health Initiative," Feinstein recalls. "We got a lot of support from the Bush and Obama administrations, but I realized that Lean quality improvement was not working to improve patient safety the way we wanted."

The solution depended on trained coaches and champions to driving improvement. But every time those people were transferred from a unit or moved to another employer, the quality indicators reverted to baseline, she says.

The experience helped Feinstein see what does and does not work when improving safety. Over the years since 1994's *Error in Medicine* by Lucian Leape, MD, and *To Err is Human*, the healthcare industry has talked a lot about improving patient safety without making significant strides forward.

"Every time there's a leak in the dam, someone sticks a finger in. That's where I think we've been for the last 20 years," she says. "We try a lot of solutions that are, I hate to say it, the easy way out. Things like learning collaboratives that are so neutral they offend no one and are just a gathering of believers."

More recently, Feinstein sensed a societal desire to improve patient safety as part of reforming the entire healthcare system, but she worried the industry might just try "a heavier dose of what didn't work before. More of the same."

True improvement would come only if there were an authority at the top of the entire healthcare system that is responsible for overseeing and determining ways to reduce medical errors, Feinstein concludes. This agency should be patterned after the existing NTSB that has proven the effectiveness of its approach.

"In healthcare — unlike aviation, nuclear, or any other complex, high-risk industry — there is no commitment at the highest level to acknowledge that we are incredibly dangerous," she says.

The healthcare industry has made little progress in improving patient safety in the past two decades, Feinstein says, even though one of the most often-cited successes is the 68% reduction of central line infections in the 32 Pittsburgh hospitals in her own Pittsburgh Regional Healthcare Initiative. She was involved with that success and was proud of it at the time — in 2002. *(The 2005 report on the initiative can be found at this link: https://bit.ly/2X5zWuY.)*

> "IN HEALTHCARE — UNLIKE AVIATION, NUCLEAR, OR ANY OTHER COMPLEX, HIGH-RISK INDUSTRY — THERE IS NO COMMITMENT AT THE HIGHEST LEVEL TO ACKNOWLEDGE THAT WE ARE INCREDIBLY DANGEROUS."

"It's now almost 2022 and I'm supposed to be excited about something we proved was possible in 2002 in conjunction with the CDC? Looking backward doesn't help," Feinstein says. "But I'm also tired of people bashing *To Err is Human* for not creating miracles. It's not up to the people who did *To Err is Human* to fix things now; it's up to every stakeholder in the healthcare community to make changes that will have real impact."

With that idea in mind, Feinstein tried to think of a solution that would not involve regulation, shame, and blame because those approaches do not bring the best results in healthcare. She found the NTSB to be a good model that can work in healthcare.

"They study and they recommend solutions. Healthcare has more accidents than the NTSB could study, but we can start by picking out the biggest and most serious risks to patients," she says. "We can look at the conditions that precede these errors, when are they occurring, what could we do to prevent them, and what technology do we have to make that prevention autonomous. We need to take the burden off the front line."

One aspect of the NTSB is the way it embraces technology to prevent errors — something the healthcare industry should do more, Feinstein says. The NTSB also makes better use of data collected across the industry to identify potential safety issues and recommend changes.

Public Wants Improvements

The NPSB coalition includes more than 50 members. Organizations supporting the proposed NPSB include Cincinnati Children's Hospital Medical Center, Dartmouth-Hitchcock, IHI Lucian Leape Institute, Institute for Healthcare Improvement, National Alliance of Healthcare Purchaser Coalitions, National Association for

Healthcare Quality, National Quality Forum, The John A. Hartford Foundation, and The Leapfrog Group.

"Everyone in the industry acknowledges that there is so little trust of the medical community right now. People are saying, 'Stop telling me you're hiring a new head of equity and you should trust us. No, we want our friends to get out alive when they go in for outpatient surgery,'" Feinstein says. "Hiring a new head of equity and diversity doesn't address why they don't trust us."

The creation of a NPSB will require the support of Congress and the American Health Association, Feinstein says. They can push for more data-sharing among healthcare organizations, which is vital to the proposed NPSB to anticipate medical errors and provide solutions rather than only responding after a patient has been harmed. Congressional action also would be necessary to create the federal agency.

"Everyone would agree that it's time. The public is getting more and more cranky because of COVID and this lack of faith in our healthcare system, which creates even more mayhem in hospitals and practices," Feinstein says. "It's time to do something that assures everyone that our health system acts in the public interest." ■

SOURCE

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Nursing License Complaints Must Be Taken Seriously, Avoided if Possible

A complaint filed against a nursing license can destroy a nurse's career. It is crucial for risk managers and nurses to understand the risks and the best practices to protect against these complaints.

Every state requires a nurse to meet minimum requirements to hold a license to practice nursing. Each state's board of nursing exists to protect the public, says **Jennifer Flynn**, CPHRM, risk manager with Nurses Service Organization (NSO) in Fort Washington, PA. Complaints against nurses are filed with the board, which can take action against the nurse's license.

That is separate from any civil malpractice action, which would be resolved with a monetary payment, she explains. Even if a nurse loses a malpractice case and must pay damages, the nurse usually can continue practicing afterward.

"Comparing that to what happens when a complaint is filed with the state board of nursing, the consequences can be quite different. The state board of nursing investigates all complaints filed against a nurse and the result of that investigation can end a nurse's career," Flynn says. "When anyone files a complaint, it can be a harrowing experience, but they may not take it as seriously as a medical malpractice claim. The potential cost to their lives is just as serious."

Range of Potential Actions

Anyone can file a complaint, but it most often is the patient, a relative, a co-worker, or an employer, Flynn says. In some cases, the employer or co-worker is obligated to report concerns about competence or deviations from the standard of care to the state nursing board.

"It doesn't necessarily have to be related to the nurse's clinical practice. It could be related to nonclinical issues like billing, substance abuse, or unprofessional behavior," she says. "In some states, the nurses themselves are required to report to the nursing board if they get a DUI or a criminal conviction, for example. There is a whole host of reasons a complaint might be filed."

If the complaint is found to be substantive, the nursing board's action can range from the benign, such as requiring additional continuing education credits or a fine, up to probation or even license revocation.

"The nursing license is their livelihood, so protecting it becomes paramount," Flynn says. "Nurses must be equipped to adequately defend themselves. We can help them by making them aware of the instances of license matters we see and how they are resolving and by providing them with risk control recommendations that will decrease the likelihood of having complaints filed against them."

NSO's most recent analysis of professional liability exposure for nurses revealed that one-third of the time, the primary allegation against the nurse involved professional conduct. *(The report is available at: https://bit.ly/3A2KERh.)*

The second most common allegation involved scope of practice, and the third was documentation errors or omissions. With professional conduct, complaints were filed against a nurse's license for substance abuse more than 40% of the time.

"That is a very strong allegation," Flynn says. "We recognize that nursing has some vulnerabilities there with stress, patient load, and access to medications, so we should always provide nurses with education on how they can deal with the stress of the job and protect themselves."

Costlier to Defend

According to the report, the past five years have seen a slight increase in the instances of license protection matters for nurses, but the cost of defending a nursing license has increased sharply.

In 2015, about 1,300 license protection matters arose against nursing professionals, costing about $3,900 each to defend the allegation. In 2020, there were 1,377 cases but the cost increased to an average of $5,330.

"Compared to a malpractice payout where the payout might be much greater, there actually is more likelihood of the nurse having a license protection matter over a malpractice claim," Flynn says. "Data from the National Practitioner Data Bank indicate a nurse was 62% more likely to be involved in an adverse licensing action than a medical malpractice payment. That underscores that nurses need to take these matters seriously and defend themselves if they have a complaint filed against them."

The time required to resolve a license matter can be about the same as for a malpractice claim — an average of one to two years, Flynn says. The disciplinary process by the state nursing board involves an investigation by people who might not be nurses, so they may not always appreciate some of the working conditions and limitations imposed on nurses in the workplace.

"They don't always understand the workarounds that might be accepted in your facility but which don't comply with national standards," Flynn notes. "The investigators can use various methods to investigate the facts, including interviewing those who were present at the time of the alleged infraction, and reviewing pertinent records. If impairment is alleged, they can conduct drug screens. They will compile any pertinent facts and report back to the board."

Not Always Taken Seriously

The nurse and his or her representatives will have an opportunity to present a defense, but Flynn says nurses often do not take this situation as seriously as they should and forgo the opportunity to provide a response. They might believe the allegation is so unfounded that they can rely on the board dismissing it.

Sometimes, nurses do not see it as seriously as a malpractice claim and they do not even hire an attorney to represent them, Flynn says. In about 45% of license claims, the case is closed with no action, which might seem reassuring. But that means 55% of the time there is an action taken against the nurse, Flynn says.

"We also found in our most recent 2020 data that a surrender of the license increased to 4.8% of license matters, up from 3.2% from the previous report," she says. "With license surrenders increasing, I'm not sure nurses realize that the board has the authority to essentially cause the nurse to not be able to practice in their state."

Flynn urges risk managers to educate nurses about the potential risks of complaints to the state licensing board and to urge a concentration on the matters most likely to generate a complaint — adhering to the nurse's scope of practice, compliance with the employer's policies and procedures, and meeting the standard of care.

"Documentation is a key element in defending state licensing matters the same way it is with malpractice allegations. Pay attention to documenting patient care assessments, observations, communications with any other providers on the team, and the actions you took as a nurse," she says. "The documentation should be timely, compete, and in line with your facility standards."

Nurses should be cautioned to never alter a record, especially after

EXECUTIVE SUMMARY

Complaints against a nurse's license can bring significant consequences, including revocation. Nurses do not always take such complaints seriously enough.

- Risk managers should educate nurses about the risks and how to avoid license complaints.
- The cost of defending a license allegation has sharply increased.
- More than half of license allegations result in some action against the nurse.

learning of a complaint. All changes in electronic medical records are time-stamped, so any alteration can appear self-serving and deceptive.

"We often hear nurses facing a state nursing board complaint say they really wish they could go to talk to the patient and explain what happened. But we advise not discussing the matter with anyone but the nurse's defense attorney or the professionals handling your matter, because in trying to resolve the case you may say something that works to your detriment," Flynn says. "The way you approach the person making the complaint may be misconstrued and have the opposite effect of what you're trying to achieve."

Flynn also urges nurses to retain letters of recommendation, performance evaluations, thank-you letters from patients, awards, continuing education certificates, and anything else that support the nurse's character, work ethic, and professional standards.

"Nurses should never respond to a board complaint without consulting with their insurer or legal counsel. Because board matters sometimes have a fast turnaround for a response, you want to seek professional advice immediately," Flynn says. ■

SOURCE

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Hospital Reduces Alarms in Burn Center ICU

When a team set out to address alarm fatigue at a North Carolina burn center ICU, they found success with implementing new best practices that addressed some of the most common reasons for nuisance alarms. But they also found those wins can slip when staff changes bring new people who were not trained in the updated ways and new leadership that was not there for the initial effort.

The North Carolina Jaycee Burn Center at the University of North Carolina Medical Center reduced nonactionable and false alarms from the baseline of more than 100 alarms per bed per day. The staff developed new skin preparation processes to improve the adherence of ECG leads for burn patients.

The effort was rooted in The Joint Commission's National Patient Safety Goal (NPSG.06.01.01) on clinical alarm safety in 2014, says **Rayna Gorisek**, MSN, RN, CCRN, CNL, lead author of the report on the hospital's success. *(An abstract of the report is available online at: https://bit.ly/3jOEKxf.)* Gorisek was a clinical nurse IV in the Jaycee Burn Center at the time and now is the clinical nurse leader in the surgical ICU at the Durham VA Medical Center.

The NPSG spurred hospital leaders to look at their own alarm rates. The burn center identified specific issues that needed attention.

"We identified particular things that involved our patients in the burn ICU that were not necessarily common to the rest of the hospital," Gorisek says. "We wanted to make an improvement, so we started with seeing what exactly was going on in our ICU with alarms, which we hoped would lead us to some education pathways and show us how to make the biggest impact."

Beginning in January 2016, the Jaycee Burn Center team collected a four-week baseline alarm sample that revealed a mean of 110 alarms per bed per day — lower than the 187 alarms per bed they had seen from other facilities but still high enough to warrant action.

The alarms were differentiated as critical, alert, or inoperative. The critical alarms required an immediate response and might be triggered by life-threatening conditions such as apnea or asystole.

Alarms were triggered when predefined parameters approached thresholds that might trip a critical alarm. Inoperative alarms simply meant the monitor could not detect a signal. A common cause of an inoperative alarm was an ECG coming loose or disconnecting from skin. This was particularly important, Gorisek explains, because loose or detached ECG leads were responsible for 96% of inoperative alarms in the baseline.

"With burn patients, it can be a constant challenge to keep the leads on because the skin is damaged and there are substances that have to be applied to the burns that, unfortunately, can make it difficult for the leads to adhere," she explains. "We identified that as a problem unique to our type of care that could be contributing to the number of alarms."

Four Intervention Modules

Using the baseline data, the team created four educational modules for the burn center staff to raise awareness, apply evidence-based tactics for improvement, and to promote interprofessional collaboration, Gorisek says. One of the resources they consulted was a practice alert, "Managing Alarms in Acute Care Across the Life Span: Electrocardiography and Pulse Oximetry" from the American Association of Critical-Care Nurses (AACN). *(The module is available to AACN members at: https://bit.ly/3BRqQRg.)*

Gorisek, assisted by a critical care nurse, presented one module each month to all burn center ICU nurses, nursing assistants, and respiratory therapists at monthly staff meetings and unit in-service training sessions. The first module explained the baseline data, along with education about alarm fatigue and how it can affect patient safety. The module also explained The Joint Commission's NPSG on alarm safety.

> "THESE OBSERVATIONS EMPHASIZE THE IMPORTANCE OF UNDERSTANDING THE POSSIBLE IMPACT OF UNIT-LEVEL CULTURE AND SOURCES OF WORK STRESS WHILE UNDERTAKING IMPROVEMENT INITIATIVES."

"We tried to impress on them how much this can affect patient safety. We used an example that was almost like a sentinel event, trying to make it more impactful," she says. "We wanted them motivated to bring it to their everyday practice, to think that this is something that actually could happen to them and their patients."

The example involved a patient with a tracheostomy whose pulse oximeter fell off and did not alert the nurses to a lack of oxygen — with a fatal outcome. In the example, alarm fatigue may have contributed to the nurses' failure to recognize the problem until it was too late.

"I read that to them to start the education portion, to make an impact about how bad this can be and show that it was something that could happen to any of us," Gorisek says.

In addition, Gorisek and her team posted the NPSG on unit bulletin boards and reviewed it during daily unit safety huddles on the unit.

Placing ECG Leads

The second module addressed how to place ECG leads correctly to reduce inoperative alarms as well as how changing the leads during each patient's daily bath could improve skin adherence.

As part of this module, the alarm fatigue team searched for best practices on how to place ECG leads over burned tissue in an ICU to reduce instances of the lead coming loose, but they found none in the literature. In response, they asked for advice from burn center nurses and physicians.

That spurred the development of three best practice methods for securing ECG leads on patients in the burn center ICU. The leads for patients with chest burns could be

EXECUTIVE SUMMARY

Staff at a burn center ICU worked to reduce alarm fatigue. They developed four modules of best practices and educational material.

- Many alarms were related to ECG leads becoming loose or disconnecting from the skin.
- The team consulted physicians and nurses to develop new best practices.
- Some improvement slipped when staff and leadership changed.

applied directly into silver sulfadiazine cream. For patients with diaphoresis, nurses could use a liquid adhesive on the leads.

The third best practice addressed patients with Stevens-Johnson syndrome/toxic epidermal necrolysis, in which the skin peels off. Staff were instructed to wash chest wounds with soap and water, pat the area dry, and place the leads before applying silver-impregnated dressings.

Those best practices were presented with the same methods as the first module, but with the addition of one-on-one instruction. The third module addressed the correct use of pulse oximetry probes, with nurses taught to change the probe and move it to a different site each shift.

During this process, the alarms were turned off to avoid inoperative alarms. When burns on the fingers and toes hampered the typical use of oximetry probes, nurses were told to use an ear clip pulse if possible.

For each patient on a ventilator, Gorisek and her team worked with respiratory therapists and nurses to establish acceptable end-tidal carbon dioxide monitoring parameters, and importantly, to pause the alarms while performing tracheostomy care or suctioning. Those working with the patient at that time would know the alarms were false, Gorisek explains, but they nonetheless contributed to the cacophony of alarms in the unit.

Customizing Alarms and Settings

In the fourth module, nurses learned how to customize continuous patient monitoring system alarm parameters for each patient as well as how to review monitor settings at each patient handoff. They also learned how proper use of the monitors could improve patient safety.

"Tailoring alarms to be specific to the patient was very important. If we knew someone's blood pressure was high, or if their baseline rhythm was an [atrial fibrillation] rhythm and we didn't need to be alerted to that, tailoring the alarm to the individual could make a big difference," Gorisek says. "We really made a lot of effort to educate nurses about that."

The alarm fatigue team worked with each nurse individually to ensure they were all comfortable with customizing the alarm settings, then they mounted laminated 10 × 5 cm signs at the central monitoring stations to remind them. The sign included a rhythm strip graphic and asked, "Have you customized your alarms?"

After the initial education period, Gorisek's team updated the staff at six-month intervals with the number and type of alarms on the unit. They also implemented an annual refresher on the four modules. New graduates coming to the ICU also were educated on the four modules.

The number of alarms decreased more than 50%. But six months after the project began, the alarms increased and were approaching the baseline numbers. Gorisek and her colleagues studied the data and determined significant changes in unit leadership and staffing contributed to the uptick in alarms.

Six months later, staffing had stabilized and education efforts resumed. The number of alarms fell to the those seen immediately after the first intervention period.

"The increase in alarms in January 2017 and the decrease in alarms in June 2017 were likely related to the stressors the nursing staff were experiencing," the team wrote in their report. "These observations emphasize the importance of understanding the possible impact of unit-level culture and sources of work stress while undertaking improvement initiatives."

The unit also implemented new default alarm values for the adult ICU unit in January 2017. The team concluded the decreases in alarm numbers in June 2017 and January 2018 probably were partially attributable to the new default alarm values.

Gorisek notes the literature indicates changing the default alarm values can reliably reduce overall alarm numbers.

"We tried to involve any stakeholders who were involved in this process when we were developing the modules and implementing our strategies for sustaining the improvements," Gorisek says. "You have to keep monitoring and reviewing the data, and weeding the garden as you move forward. Perseverance is key." ■

SOURCE

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COMING IN FUTURE MONTHS

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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **According to Jennifer Flynn, CPHRM, how have the data changed regarding the percentage of license surrenders in nursing license complaints?**

   a. 2020 data show license surrenders increased to 4.8% of license matters, up from 3.2% from the previous report.
   b. 2020 data show license surrenders decreased to 3.2% of license matters, down from 4.8% from the previous report.
   c. 2020 data show license surrenders occurred primarily in cases involving documentation errors, a change from the previous report.
   d. 2020 data show license surrenders occurred primarily in cases involving scope of practice, a change from the previous report.

2. **In the alarm baseline measurements at The North Carolina Jaycee Burn Center, what was responsible for 96% of inoperative alarms?**

   a. Loose or detached pulse oximeters
   b. Loose or detached ECG leads
   c. Incorrect parameters programmed into alarms
   d. Incorrect data for relays to monitoring stations

3. **What was the key finding of a 2021 American Medical Association Policy Research Perspectives paper?**

   a. Data show the highest prevalence of medical liability premium increases in 15 years.
   b. Data show the lowest prevalence of medical liability premium increases in 15 years.
   c. Data show the COVID-19 pandemic has prompted an increase in medical malpractice claims.
   d. Data show the COVID-19 pandemic has prompted a decrease in medical malpractice claims.

4. **What federal agency does Karen Wolk Feinstein, PhD, suggest as a model for the proposed National Patient Safety Board?**

   a. The Federal Aviation Administration
   b. The National Transportation Safety Board
   c. The Food and Drug Administration
   d. The Centers for Disease Control and Prevention.

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

$3 Million Judgment for Delayed Cancer Diagnosis

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UCLA School of Law, May 2021

News: A patient's ultrasound revealed fluid in a portion of the pelvis. The patient's physician failed to notify the patient, order further testing, or refer the patient to a specialist. The patient subsequently was diagnosed with ovarian cancer, and passed away.

The patient's estate filed a lawsuit against the physician and the healthcare providers for wrongful death and medical malpractice. The defendants denied liability. A jury returned an award of $3.8 million, which was reduced by approximately $650,000 following an appeal.

Background: A physician ordered an ultrasound for a female patient. The ultrasound revealed fluid in the cul-de-sac portion of the pelvis. However, the physician failed to notify the patient of this fluid, did not order a cancer antigen 125 blood test to further assess the patient's condition, and did not refer the patient to a gynecologic oncologist.

Eventually, the patient was diagnosed with ovarian cancer. By that time, the cancer had progressed significantly, and the patient passed away.

The patient's estate filed a lawsuit against the physician and hospital, alleging the physician's multiple failures constituted medical malpractice. According to the estate and its experts, following up with the patient and referring her for treatment could have led to a timely ovarian cancer diagnosis, allowing the patient a greater chance for survival.

The estate and the defendants presented expert testimony. The jury found the defendant physician and hospital liable for malpractice. According to the jury, the defendants' actions breached the applicable standard of care and were a substantial factor in the delayed diagnosis, diminishing the patient's chances for a better outcome. The jury awarded $3.8 million, including $2 million for the patient's pain and suffering and $525,000 for each of the patient's two surviving children.

THE PHYSICIAN FAILED TO NOTIFY THE PATIENT OF THIS FLUID, DID NOT ORDER A CANCER ANTIGEN 125 BLOOD TEST TO FURTHER ASSESS THE PATIENT'S CONDITION, AND DID NOT REFER THE PATIENT TO A GYNECOLOGIC ONCOLOGIST.

The defendants appealed, contesting the liability and the verdict amount. The appellate court found that given the evidence provided during trial, a rational jury could determine the physician breached the duty of care. The court also explained that to establish proximate causation, a plaintiff must present sufficient medical evidence from which a reasonable person might conclude it was more probable than not that the physician's departure from accepted community standards of practice was a substantial factor in causing the injury. Here, a valid line of reasoning existed, indicating the physician's actions delayed the patient's diagnosis of ovarian cancer, diminishing her chances of recovery. In another attempt to contest the liability, the

defendants argued the verdict is contrary to the weight of the evidence, and thus should be set aside. Again, the appellate court found the verdict could be set aside, as it was reached after a "fair interpretation" of the evidence provided through both sides' medical expert testimony.

As for the verdict amount, the appellate court stated the damages amount is a question for the jury, and such determination will not be disturbed unless the award deviated materially from what would be reasonable compensation. Damages in a wrongful death action are tied to pecuniary injuries suffered, which can include compensable losses of a personal nature or loss of guidance. The court was satisfied with the evidence provided to show some pecuniary damages, but determined the amount was somewhat excessive. The appellate court reduced the award from $525,000 for each child to $275,000 for one child and $125,000 for the other child. Other than this reduction, the appellate court confirmed the propriety of the jury's verdict on liability and damages.

What this case means to you: This case presents lessons getting to the substantive heart of medical malpractice actions: Liability arises if a physician or care provider fails to abide by the applicable standard of care and that failure causes harm to the patient. Determining the applicable standard of care falls within the purview of a jury that usually is presented with two competing versions of what the purported standard of care should be — one version from the patient's experts, and one version from the physician or care provider's experts. Juries must rely on the evidence to make such a determination, and a material deviation or disregard of that evidence can result in an appellate court subsequently reversing the jury's findings. However, absent such a significant deviation or disregard, appellate courts can and regularly do confirm juries' findings, such as in this case where the appellate court confirmed the estate's expert presented sufficient evidence and analysis that was beyond mere speculation.

When a physician orders a diagnostic study, he or she is obligated to obtain the results of that study, compare the reported result to the clinical presentation of the patient, inform the patient of the finding from the study. If the results are abnormal or questionable, present the patient with a plan of care. Anything less may be considered practice below the standard of care, a breach of the physician's duties to the patient, and constitute medical malpractice if the patient suffered harm. In this case, the trial and appellate courts affirmed the jury's verdict.

Determining the amount of damages necessary to remedy a patient's harm also is the jury's responsibility. Courts intervene in reducing such damages awards only under limited circumstances; for instance, if the compensation deviates from the evidence presented or if the compensation is beyond what would be considered reasonable. When malpractice results in a patient's death, there are many different types of damages that can be awarded to the patient's estate or to the patient's surviving family, including loss of support, voluntary assistance, possible inheritance, and medical and funeral expenses incidental to death. In this case, the defendants' appeal was partially successful as it reduced the amount of the damages award by approximately $650,000 as the appellate court found that more closely represented "reasonable compensation." ■

REFERENCE

- Decided July 28, 2021, in the Supreme Court of New York, Appellate Division, Second Department, Case Number 2018-10993.

Expert Witness Opinion Insufficient to Advance Medical Malpractice Suit

News: A pregnant woman sought treatment at a medical center after experiencing vaginal discharge. The patient was advised to visit her primary care physician. She subsequently returned to the medical center upon recommendation by the primary care physician and was administered magnesium sulfate and antenatal steroids when it became clear preterm labor was imminent. The woman was transferred to a hospital and gave birth.

Several years later, the patient filed a medical malpractice lawsuit, alleging failure to administer the correct course of steroids constituted malpractice. The defendants denied liability. The trial and appellate courts rejected the patient's arguments, noting a lack of evidence to support her claims.

Background: In May 2011, a woman visited a medical center

reporting vagina discharge. At the time, the woman was 23 weeks pregnant. A nurse put the patient on a fetal monitor, which showed no signs of uterine contractions. A physician ordered fluids and a cervical examination, finding the patient had reached 20% cervical effacement. The patient was sent home with instructions to consult with her primary care physician the next day.

The following day, the patient saw her primary physician by 4 p.m., at which time the vaginal discharge was described to have increased to a copious amount and included an observation of a bluish mass protruding from her cervix. The primary care physician considered the possibility of preterm labor but was unfamiliar with the bluish-mass abnormality. The physician referred the woman back to the initial medical center for an ultrasound to assess cervical length.

At the medical center, an ultrasound revealed the cervix was dilated 3 cm and the amniotic sac was protruding. A physician ordered staff to administer magnesium sulfate to delay preterm labor and antenatal steroids (ANS) to accelerate fetal organ maturity. The patient was transferred to a hospital. By 11:50 p.m., she was moved to the delivery room, and gave birth an hour later to a baby weighing 1.4 lbs. The baby spent 4.5 months in a neonatal ICU. The child now suffers from serious developmental delays and medical conditions, including prematurity, various brain bleeds, cerebellar hemispheric atrophy, cerebral palsy, and seizures.

In 2018, the patient, on behalf of her minor child, sued both her primary care physician and the attending physician at the initial medical center for negligent treatment, malpractice, and a loss of chance claim. The patient alleged her cervical examinations revealed preterm labor requiring the immediate administration of magnesium sulfate and ANS, and that a completed course of ANS would have reduced risk of morbidities.

During the trial, the patient proffered two expert witnesses to support her claims. However, the court determined one expert's testimony was insufficiently reliable to be permitted. According to the trial court, the expert failed to rule out periviability in his differential diagnosis and relied on studies that were too attenuated from the circumstances of the case. Even though the second expert's testimony was considered reliable, the court determined that without the first expert's testimony or any other evidence to prove causation, the patient failed to provide sufficient evidence of malpractice. As a result, the court granted judgment for the defendant care providers.

The patient appealed this adverse determination. Although the appellate court found the trial court improperly excluded the first expert's testimony, they nevertheless affirmed the trial court's judgment for the defendants. According to the appellate court, the first expert was an experienced neonatology specialist who justified his opinion using a differential diagnosis based on review of the mother's and child's medical presentation. Throughout the process of eliminating plausible alternate causes, the expert acknowledged the "biggest risk factor" for the child was periviability and that it was likely to cause an unfavorable effect regardless of any ANS exposure. Thus, the expert could not explain why this plausible alternative cause was not the sole reason for the child's morbidities. The expert's testimony relied on 12 peer-reviewed medical studies and articles. Of these, a majority shared a similar methodological flaw as they did not provide separate analyses on the effect a partial course of ANS vs. a full course of ANS.

In this case, the patient argued a full course of ANS could have significantly reduced or eliminated several of the child's lifelong health issues. This clear juxtaposition was found in two studies the expert provided, making them the only reliable evidence to support his testimony. The authors of the two studies concluded a full course of ANS provided a marginal risk reduction over partial ANS, between 4.1% and 4.3%. This determination supported the opinion of the expert (i.e., the full course could have affected the child's current morbities). The appellate court determined the district court was wrong in excluding the entire testimony.

Although the first expert's testimony was found to have a sufficient foundation, the appellate court agreed with the trial court's judgment for the defendants. According to the appellate court, the patient failed to provide sufficient evidence to establish the necessary elements on her theory that the allegedly negligent incomplete ANS course was the cause of her child's morbidities. It was determined through the studies provided by the experts that even a complete course of ANS could cause less-than-likely injuries. The evidence failed to prove the full course of ANS would have eliminated the morbidities. The court also noted the patient's loss-of-chance malpractice claim was unfounded. The first step required to support this claim is to measure the chance lost. Neither of the patient's experts provided a specific percentage showing the chances the child could

have been born with no disabilities or mild disabilities but for the alleged negligent treatment. The court mentioned that even if the experts specified a percentage of chances, the medical opinion of the first expert suggesting a percentage loss of 4.1% and 4.3% would be insufficient for a claim of medical malpractice. Therefore, the trial court's judgment for defendants was appropriate.

What this case means to you: This case confirms how expert testimony can significantly affect — or even solely determine — the outcome of a medical malpractice case. Expert opinions are almost inevitably necessary to enable a clearer and more technical understanding of disputed issues as those pertain to required elements for a medical malpractice action. These include issues relating to causation and whether the physician or care provider's action or inaction caused patient's alleged harm. Such opinions are offered to help juries make a fully informed decision. If those opinions are deemed unreliable, confusing, or unhelpful, courts are charged with preventing juries from hearing such unreliable opinions. Thus, it is of critical importance for care providers to recognize the importance of choosing the right expert and challenging an opposing party's deficient expert.

In this case, the court analyzed the foundational reliability of the experts' opinions. While the trial court believed the first expert was insufficiently supported, the appellate court disagreed. The expert presented at least two studies that supported a marginal risk reduction for a full course of ANS vs. a partial course. In this case, the end result was the same because the patient still failed to provide sufficient evidence on causation, even with the first expert's testimony considered. But it is not always so — the exclusion or inclusion of an expert can make or break a medical malpractice action.

Appellate procedures, while not always invoked, can provide a useful mechanism for care providers to remedy erroneous rulings by a trial court. Like all litigation, medical malpractice actions are a long, time-consuming, and expensive process. Unfortunately, judges and juries do not always reach the right result. A trial court's adverse ruling is particularly subject to an appeal, compared to a factual determination by a jury that is afforded much more deference. Fortunately for the care providers in this case, although the trial court erroneously excluded the patient's expert, the appellate court's reversal did not affect the result of the case. When the roles are reversed and a care provider's expert is improperly excluded, a timely appeal can fix such an erroneous determination.

A fetus with a gestational age of 23 weeks is on the cusp of the age the American College of Obstetricians and Gynecologists considers viable, and therefore, under all circumstances, would have a minimal or no chance of surviving without significant defects resulting from the extreme prematurity of the lungs and other vital organs. Another consideration is the cause of the premature labor and subsequent delivery of the frail infant. A fetus of 21 or 22 weeks gestation that aborts spontaneously would have been considered a miscarriage. These often occur because there is something wrong with the fetus or with the mother's ability to maintain the pregnancy. It is possible the defects currently present in the child might themselves have been the cause of the preterm labor and subsequent delivery, rather than the other way around. Whether the defendant care providers retained an expert to offer such an opinion is unclear, but this is another lesson for care providers: Explore all potential cause-and-effect relationships. Presenting a jury with different possibilities on causation will facilitate defense verdicts in medical malpractice actions, as the jury might agree the defendant care provider's actions were not the cause of injuries. ■

REFERENCE

- Decided Aug. 2, 2021, in the Court of Appeals, Minnesota, Case Number A20-1134.