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INSIDE

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10 Things Never to Say to a Patient or Family Member

Healthcare and risk management are full of things one should say and do, including the best practices that improve outcomes and lower liability risk. But there also are plenty of things a risk manager never wants to hear uttered by a healthcare employee.

These are the things that one should never say to patients or family members because they could lead to a lawsuit or complicate a lawsuit defense. Many forbidden comments involve promising too much to the patient, says **Erin O'Leary**, producer with the Graham Company in Philadelphia.

O'Leary and **Bette McNee**, RN, NHA, clinical risk management consultant at Graham Company, offer this list of things never to say in healthcare:

> THESE ARE THE THINGS THAT ONE SHOULD NEVER SAY TO PATIENTS OR FAMILY MEMBERS BECAUSE THEY COULD LEAD TO A LAWSUIT OR COMPLICATE A LAWSUIT DEFENSE.

1. Never make a promise. It can be tempting to make promises when reassuring anxious patients or describing the likely course of events during treatment, but O'Leary says risk managers should train staff to never promise anything. Nothing is guaranteed in healthcare, and a promise can be taken literally by the patient and family members, she says.

It will not help for the healthcare provider to explain that he or she did not mean the comment as a literal promise for a specific outcome, she says. Once the party hears "I promise…" the damage is done, she says.

2. Do not offer a guarantee. A statement like "We guarantee your satisfaction" can be even worse than a promise because it can be interpreted, accurately or not, as a

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legally binding statement, O'Leary says.

3. Do not overstate qualifications or what is possible. This can be problematic in marketing materials, which may offer "constant supervision" or "the best possible care."

"Those are the kinds of statements that plaintiffs' attorneys are turning around and using on organizations, directors and officers, or practitioners to say that they are not providing the care they stated they would provide," O'Leary says.

4. Never offer personal opinions. Nurses can find themselves in awkward positions when they get to know patients and family members, and those people look to the nurse as a trusted source of information. Nurses may be asked for their "real, honest" opinions about a colleague, or their own opinion on another clinician's judgment. Risk managers should remind nurses that they must deflect this sort of inquiry.

"When you are at work, you are an agent of that organization, but a lot of patients and families will try to get personal opinions from staff, without realizing that when you are at work you can't really speak your mind in a personal way," McNee says. "It is very important for people to understand that they can't give a personal opinion when someone asks them what they think of a doctor's qualifications, for instance. As much as you want to be helpful and friendly, you are still an employee of the hospital or health system."

5. Do not let patients and visitors hear staff griping. Everyone complains about their workplaces, but it is unprofessional to allow nonemployees to hear nurses or physicians griping about housekeeping, food services, other clinicians, or any other aspect of the organization, McNee says.

Such comments may be relatively minor venting for the nurse or physician but they can undermine confidence in the patient's care and encourage a sense that that organization is not well run, she says.

6. Avoid topics in the news that are related to a patient's care. Even if the subject comes up in an abstract way, like a patient asking the nurse's opinion on a nursing staff ratio bill that is in the news, the topic should be off limits, O'Leary says.

"It's like how you don't talk about religion or politics at dinner. You have to have a policy that you don't talk about these in-house problems or debates, even if someone asks you directly for your opinion, or if you want to use it as an explanation for why you're not at

EXECUTIVE SUMMARY

There are certain things nurses and physicians should never say to a patient or family member because they can lead to an increased risk of liability and dissatisfaction. Risk managers should educate clinicians about these comments to avoid.

- Some remarks involve promising too much or making a guarantee.
- Staff also should not let people hear them complaining about internal issues, such as staffing shortages.
- Risk managers should work closely with the communications department to ensure printed and digital materials do not contain these messages.

fault in a given situation," O'Leary says. "If you express concern about nursing staff ratios, what are you saying to that patient about his or her care? You may say you're not talking about this institution, but when you're in those scrubs, you are an agent of that hospital and have to avoid that kind of discussion."

Do Not Say Care Is Insufficient

7. Never tell a patient that care is substandard. That would seem like a no-brainer, but it happens all the time because staff do not realize they are saying exactly that, McNee says. They think they are rightly defending themselves from a patient's complaint.

In response to an unhappy patient or family member, healthcare providers may talk about institutional problems such as short staffing, scheduling difficulties, supply problems, or similar issues. This can be difficult for nurses who are genuinely frustrated and want to explain to an unsatisfied patient why they cannot fix the problem. But O'Leary says they must avoid the temptation to say "We're short staffed" or "Administration won't give us the help we need."

That can sound like an admission of guilt, a direct statement that the clinical team is providing inadequate care, McNee says. Such a statement can be used against someone in litigation, she says.

8. Do not tell a patient you are providing certain care because "That is what your insurance will pay for." This happens more in therapy or specialty services than typical floor units, but McNee says a healthcare worker sometimes will comment that the patient's plan of care was determined by what their insurance covers.

"That brings up huge red flags. If I'm lying in that bed, and they're looking at my options for care and tell me we have to do this thing first because of insurance, it certainly doesn't sit well," McNee says. "It's not just whether this procedure or test is covered. It's telling patients that you think they should go on to option B, but you have to do option A first so that your insurance requires that. That makes me feel like you're not giving me the care you know is best for me."

9. Do not use insurance as a scapegoat for avoiding a better answer. Doctors and nurses often encounter patients and family members who think they know the best course of treatment because they read something online. It can be tempting to dismiss the discussion by saying "Your insurance won't pay for that." It is a quick way to get out of a discussion, and deflects any dissatisfaction to the insurance company rather than the clinician, McNee notes.

But that response can give the false impression that clinicians are basing clinical decisions on insurance coverage rather than what is appropriate for the patient, she says. Even if it takes longer, the better response is to tell the whole truth, which may be "At this point, you don't have the signs and symptoms that would suggest that test is appropriate, so there's no need to perform that test now. It's not clinically indicated."

It may be true that the insurance will not pay for that test, McNee explains, but the more complete explanation is better.

10. Do not speak too freely or defensively after an adverse event. The aftermath of an adverse event can be stressful on everyone involved, and as McNee jokingly says, they tend to only happen on nights and weekends when there is no specially trained supervisor or administrator to respond. Unfortunately, a lack of training and the high emotions can lead healthcare professionals to say the wrong thing, she says.

"When you have to call a family member to say that their mom fell while trying to get out of bed to the bathroom and reinjured the knee she just had surgery on, that initial communication is so important," McNee says. "Thankfully, we don't have to make those calls, or even worse calls, too often. But the bad thing is that when people have to make those calls, they forget the key things they have to convey, and what they are supposed to say and not supposed to say."

Provide a Script

Many hospitals try to cover these situations in a customer service or professional education module, but McNee recommends providing a carefully worded script that is posted on care units for nurses to use when making such calls. The script should be direct but simple, providing what happened, the initial condition of the patient, what is being done for the patient, and that the incident is under investigation.

"Also, tell them that they will receive a call from a specific person you name, not just a nursing supervisor, by a certain time, and give them that person's phone number and extension," McNee says. "You give them very specific information that they will want to know. If they ask questions you can't answer at that time, tell them that the right person

will provide that information when it is available."

It is important not to be defensive in this conversation, O'Leary notes. That can be difficult when the nurse is stressed from the experience and the family member is concerned about the patient, she says.

"You don't want to be defensive about yourself, the other caregivers, or the organization. Rather, you want to focus on providing the other person the information that matters to the family," O'Leary says. "Covering yourself can feel like the natural thing to do, but that's not what the family is interested in. They want the information that will make them feel more confident in the care that is being provided. A defensive response can actually make them feel very doubtful about that."

Make sure nurses do not sound too perfunctory or blasé about the incident, McNee says. They should express some concern, and speak as if they care about the patient.

"If family are hearing you make a call just because it's on the to-do list after an incident, and you sound like you're annoyed at even having to do it, you're doing more harm than good at that point. You don't want staff members saying, 'I don't really know what happened, but I'm just calling to let you know something happened, and now I have to get back to work,'" she explains. "That uncaring voice would be probably the worst thing at that point."

Make sure all your media avoid these mistakes, O'Leary says. Healthcare organizations use so many methods of communication now, both digital and print, that it is easy to overlook some of these problems, she says. Risk managers should work closely with the communications department to educate them on what should not be said in official communications, like offering promises and guarantees, O'Leary says.

"It's so important to set the proper expectations up front. We're constantly seeing changes in case law and what kind of cases are being brought against healthcare facilities, so it is important to choose your verbiage carefully to protect yourself proactively," she says. "This applies to all the information you're providing to patients before and during their stay, and also all the information you're sending their loved ones. Make sure your staff understands that what you're saying in writing is what you'll be held to." ■

SOURCES

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Peer Review Can Lead to Liability Risks; Preventive Steps Needed

The hospital peer review process can be contentious, with physicians fighting to defend their reputations and careers, while others are just as passionate about protecting patients. Disagreements can spill over into court but good processes can minimize that risk.

Usually, the credentialing process at most facilities usually is robust and well-designed, but problems can occur when a facility must discipline a physician or revoke privileges, says **Callan G. Stein**, JD, partner with Pepper Hamilton in Boston. Medical staff bylaws will detail a process for these reviews, but even when the review is conducted to the highest standards the targeted physician still may respond poorly. That type of proceeding represents the biggest liability risk related to peer review, Stein says.

"When physicians have their privileges terminated, it is a very significant event in their careers. They have the means, the fortitude, and the motivation to pursue legal action against the facility," Stein explains. "It often leads to some knock-down, drag-out litigation that airs the facility's business in open court. Not only does the hospital face damages, which given what many physicians make could be extremely high, but they also face some potential damage in the court of public opinion as well."

The Health Care Quality Improvement Act of 1986 (HCQIA) was intended to promote quality in healthcare by providing immunity to some participants in the peer review process, Stein notes. The act does help, but does not eliminate all liability risks, he says.

"Where it can go off the rails is if the facility does not provide a real, fair process to the physician. If there are things in the process that a physician can credibly claim were not fair, they will often bring a lawsuit and challenge the immunity that is presumed to exist under that statute," Stein says. "If they are able to overturn that immunity, there can be some real problems for everyone involved."

To enjoy immunity under the HCQIA, a facility must meet four requirements with its peer review process, Stein says. First, the action against the physician must have been taken in reasonable belief that it was in the furtherance of providing quality healthcare. That point often is not contested, Stein says.

The second requirement is that there must have been a reasonable effort to obtain the facts of the matter. Due process as found in the judicial system is not required, but the healthcare organization is obligated to conduct a genuine investigation of the matter before issuing any punishment, Stein explains.

"One way I've seen hospitals get in trouble is by jumping the gun with summary suspension before they've had an opportunity to really figure out what's going on," Stein says. "There definitely are situations where summary suspension is warranted, as when patients are at imminent risk of harm, but if it is overused that opens the possibility for the physician to claim that factor was not met."

There also must be adequate notice of hearing procedures to the physician. This perhaps is the most important requirement, Stein says. The medical staff should set forth the hearing procedures in bylaws. Then, the hospital must strictly adhere to those procedures, he says. Any deviation will give the physician an opening to claim there was not adequate notice, and the peer review decision must be voided, he explains.

The last requirement for immunity is that, after the facts of the case are known, whatever action was taken was warranted. Stein notes that this is a backward-looking requirement that seems to give an opening for judges to simply make their own assessment rather than relying on the judgment of the peer review participants. But they usually do not.

"It sounds like this would allow the judge to go back and reweigh the evidence, but courts typically will give a lot of deference to the peer review committee," Stein explains. "You can get into trouble if the evidence presented was either tainted or biased, or just so insufficient to justify the action that it can't be ignored. There is the opportunity for the physician who has had his or her privileges terminated or suspended to go to court and have the evidence reassessed."

Patients Also Can Sue

Patients can sue for negligent credentialing, alleging that their injuries were the result of the hospital granting privileges to an unqualified physician, but Stein says that risk is much lower than the risk of being sued by a disciplined physician. Most hospitals in his area use such robust credentialing programs that they verge on overkill, he says. That lowers the chance of a patient claiming they let a poorly qualified doctor harm a patient.

Nonetheless, it is important to ensure the credentialing process is tightly controlled to avoid any appearance of impropriety, he says. It is paramount that there are no conflicts of interest among the physicians participating in the credentialing process.

Not only could a physician argue that he or she was denied credentials because of a peer review participant who had a conflict of interest, but a patient also could argue in the other direction: that a relationship with a committee member resulted in an unqualified applicant receiving privileges.

"It would be a mistake to have a physician contribute to a key decision to credential someone else that they have a pre-existing relationship with, whether that relationship is familial, mentor/mentee, or a longstanding friendship. The safest course of action would be to have that person recuse himself or herself," Stein says. "On the discipline side, you wouldn't want someone participating in the peer review process who has longstanding issues with the physician being reviewed, or is a competitor with that physician. Often, it's not about just eliminating actual conflicts, but it's about eliminating even apparent conflicts that could call into question what may have actually been a very legitimate decision. It can be tainted later by the appearance of impropriety."

Process Challenged

Physicians who challenge a peer review process in court often will

EXECUTIVE SUMMARY

The peer review process can lead to litigation when physicians challenge the validity of disciplinary hearings or are denied privileges. Strict adherence to good processes can reduce the risks.

- Patients also can sue for negligent credentialing.
- Conflicts of interest must be avoided.
- Educate participants about issues that can cast doubt on the legitimacy of the process.

allege that it was a sham to justify a decision that already had been made, Stein says. The doctor may allege conflicts of interest and cite comments from peer review participants before, during, and after the process, often taking the comments out of context to try to prove a bias, he says.

"That underscores the importance of really crossing your T's and dotting your I's, not only when you're conducting the peer review process, but when you're making assignments and putting together your committee," Stein says. "It's important that whoever is leading that process should remind everyone to keep an open mind. That person has to be on the lookout to prevent the appearance of impropriety or the procedure being a sham."

Stein cautions that peer review litigation can get ugly. He once represented a hospital that was sued by a physician who had been terminated for a long history of insubordination. The doctor argued that the insubordination was just a pretext, and he really was dismissed for speaking out against the hospital's practice of trying to keep patients in-network.

"As you can imagine, the plaintiff was able to get some traction in the news media with that allegation, and it caused all kinds of problems for this medical facility," Stein says. "In that one, you had a physician who had been dismissed for bad behavior but he was positioning himself as the victim of some grand retaliation scheme. It can be very difficult for a hospital to deal with."

NPDB Report Questioned

Stein also has seen a case in which the physician alleged a report to the National Practitioner Data Bank (NPDB) was improper because the investigation and peer review process were tainted. The physician alleged the report was defamatory.

Those cases are especially difficult because the hospital is obligated to make those reports, and the physician is never going to be happy with the decision to report, he says.

Stein says hospitals should employ someone who is charged with not only knowing the proper process for peer review but also how to protect the findings of the process when they are challenged. That person could be the risk manager, in-house counsel, or an outside attorney, he says.

"These hearings are quasi-judicial proceedings conducted by physicians and hospital personnel who may not be as experienced as they need to be in these areas to keep peer review proceedings from ending in litigation, or preserving the legitimacy of the outcome when they do have to go to court," Stein says. "It is a process that is vital to the healthcare organization, and has to be protected." ■

SOURCE

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Opioid-Related Claims Show Need for Good Processes

The opioid crisis continues to create increased liability risks for healthcare providers, who must contend with more scrutiny over prescribing and management practices. A review of closed claims indicates hospitals and physicians can improve the way they follow guidelines and processes designed to reduce the risk.

The sharp increase in opioid use has led to a high number of addiction and severe injuries, according to a report from Coverys, a Boston-based medical professional liability insurance provider. The report is based on an analysis of closed opioid-related malpractice claims over a five-year period.

These are some findings from *Red Signal Report — Opioids*:

- 51% of events involved a high-severity patient injury and accounted for 85% of indemnity paid;
- 43% of events had root-cause factors related to medication screening and prescribing;
- 25% of events had root-cause factors related to monitoring and management;
- 23% of events had root-cause factors related to dispensing and administering.

"The opioid epidemic in the United States has become pervasive throughout our communities, and addressing it has proven to be very challenging. Caught in the middle of this crisis are healthcare providers," the report authors wrote. "Many have been accused of prescribing practices that fuel addictions. From 1999 to 2017, the opioid epidemic in the United States contributed to the deaths of

over 700,000 people; the number of opioid-related overdose deaths was six times higher in 2017 than in 1999." *(The report is available online at: https://bit.ly/2QvjRsu.)*

Multistage Process

Addressing the opioid crisis and the potential liability that can flow from it requires action at every stage of the prescription process, says **Ann Lambrecht**, RN, BSN, JD, FASHRM, senior risk specialist with Coverys in Charlotte, NC.

The Coverys analysis indicates risk managers should assess risk factors and safety vulnerabilities within the pain management process proactively, Lambrecht says. The assessment should include a review of internal processes related to opioid screening, prescribing, dispensing, administration, monitoring, and management, Lambrecht says.

Prevention of drug diversion is another concern, she says. Tapering and discontinuation of opioids has become more important as the medical community realizes the risks of opioid use, Lambrecht says. Physicians should discuss tapering and discontinuation with patients from the start so that they understand the medication only can be used for a limited time, she says, establishing in the patient's mind that there will be an end date.

The Coverys report includes these recommendations on tapering and discontinuation for hospitals and other facilities:

- Ensure prescribers understand and comply with recommendations for discontinuation;
- Ensure two authorized healthcare providers resolve discrepancies within the same shift or business day;
- Require lock boxes are in all areas where opioids may be left unattended;
- Create a process for wastage of opened, unused opioids;
- Ensure the hospital participates in a drug disposal program that complies with state and federal laws and guidelines;
- Require discontinued opioids to be returned to the pharmacy within a defined time frame.

Each Step in Process Is Important

Risk managers must address all steps in the process, Lambrecht says. "It's not just one thing to focus on. We used to think it could be isolated to one area of the medication process, but now we are seeing that there can be fall-downs in every single stage of that process," Lambrecht says. "More than half the events in this study involved errors that occurred in more than one stage of care."

Not everyone is involved in each stage of care, so communication is paramount, Lambrecht says. Clinicians also must understand that an error in one stage of care can affect the other stages, she says.

"It's easy to find ways for everyone else to change their processes and practices, but that is a very slippery slope. If everyone involved doesn't stay on top of every single phase of care, there are going to be problems," she says.

Lambrecht cites an example from the report involving a physician who prescribed long-acting hydrocodone to a patient on an initial office visit without realizing the patient was taking oxycodone already. That error occurred because of failures involving screening, prescribing, monitoring program databases, and medication reconciliation, Lambrecht explains.

Other examples involve patients with comorbid conditions, which should prompt extreme caution in prescribing, and failure to follow postadministration guidelines, she says.

"Another area where we have looked very closely in terms of our data and recommendations is how prescribers often do not realize what their own responsibilities are," Lambrecht says. "Physicians who do procedures and prescribe for a very short period of time, like orthopedic surgeons, may not realize that a patient can become dependent and addicted within five days. If they don't do the upfront work about screening, assessing, medication

EXECUTIVE SUMMARY

A review of closed claims related to opioid use underscores the need for good processes that minimize the risk of abuse. Risk managers should assess how their organizations adhere to opioid prescribing guidelines.

- Many physicians do not understand their responsibility in complying with opioid prescribing guidelines.
- Specialty physicians often assume the primary care doctor will handle opioid prescribing processes.
- Tapering and discontinuation should be explained to the patient from the start.

reconciliation, and checking the prescription drug monitoring database, they can get into trouble because they think these patients will soon go back to their primary care physicians and it's not their responsibility."

Guidelines Available From CMS, Others

Guidelines from the Centers for Medicare & Medicaid Services (CMS), the CDC, and many specialty colleges offer direction on opioid prescribing, but Lambrecht says a disconnect can occur between clinicians and hospitals or health systems when it comes to who is ensuring compliance with guidelines. Physicians and administrators should proactively address the issue by agreeing on what guidelines are to be followed, and who is responsible for ensuring compliance, she says.

"Many times, physicians just don't know what the CMS guidelines are, and they assume the hospital is taking care of that. Then, you talk to the hospital and they're assuming the physicians are checking the drug monitoring database because they're the ones who are prescribing," Lambrecht says. "A good start is to perform an assessment of what current practices are so you can see if there is a gap. Most hospitals have few precautions in place, and there is usually a lot of room for improvement."

For example, the hospital and physicians should determine who is responsible for each step in the process. Will patient screening be solely the responsibility of the prescriber, or does the hospital have some responsibility in that step? That question should be answered for every step of the process so that nothing slips through the cracks, Lambrecht says.

> "PHYSICIAN OFFICES NEED SPECIAL ATTENTION BECAUSE THESE LOCATIONS ACCOUNT FOR MORE THAN 80% OF INDEMNITY RELATED TO OPIOID PRESCRIBING."

"You also need monitoring of those practices and real-time feedback. A lot of times, if physicians don't hear otherwise, they will assume they are doing a great job," she says. "Physician offices need special attention because these locations account for more than 80% of indemnity related to opioid prescribing. Also. remember that half of all opioid events involve a high-severity patient injury, including patient death. Those high severity events account for 85% of all indemnity payments."

Risk managers overseeing affiliated physician practices should make a point of educating physicians about what guidelines apply and what resources are available, she says.

"In particular, it is important to help them understand that this is the prescribing physician's responsibility, not just the primary care physician's. They can collaborate with primary care physicians, but the prescribing physician should perform the screening, and take all the other steps to make sure that the process is being followed all the way through," Lambrecht says. ■

SOURCE

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Patient Safety Act Affords Protection for Adverse Event Investigations

Although the Patient Safety and Quality Improvement Act (PSQIA) has been around since 2005, many risk managers and other administrators are unclear on how it offers legal protections to hospitals investigating medical errors. The law protects much of the information gathered in an adverse event investigation from discovery by plaintiffs' attorneys, but only if one understands how the PSQIA works and how to take full advantage of it.

The PSQIA was passed in response to the Institute of Medicine's *To Err is Human: Building a Safer Healthcare System* report, which put a spotlight on medical errors. It facilitates the confidential review and reporting of adverse patient events, says **Bruce D. Lamb**, JD, shareholder with Gunster in Tampa, FL.

Data Protected During Analysis

To encourage patient safety by allowing hospitals to investigate events without fear of the information being used against them, the PSQIA created a federal peer review privilege and evidentiary protections for some materials. This protection is broader than that afforded by most state laws.

The PSQIA created a uniform national protection that allows healthcare organizations to fully investigate and share information regarding medical errors. The law protects a wide variety of data submitted to a Patient Safety Organization (PSO), making it a protected Patient Safety Work Product (PSWP).

"The collection of facts and management of reporting information to a PSO also is protected, so that pathway is the initial process before you've completed the documentation. That protects the information while you're analyzing it but before you've reported it," Lamb explains. "In most states, there is a parallel obligation to look at events and possibly report them as adverse events. That information is not protected. In Florida, the state also recently passed a law giving patients and potential patients the right to get adverse incident reports."

That means that for risk managers to maximize the protection afforded by the PSQIA, it is necessary to designate information as PSWP and cull the facts that must be reported in accordance with adverse event reporting requirements, he says. That limited data set should be maintained in a separate file, and may be subject to discovery by potential litigants, Lamb explains.

Of course, parties do not always agree on what information should be included in those files. Plaintiffs' attorneys often argue that data maintained only in the PSWP file should be discoverable and provided to the state.

"There is a lot of litigation over this issue because the determination of what is protected and what is not protected can be difficult. We recently had a case here in Florida where a judge ruled that informed maintained as patient safety work product was not discoverable by the plaintiff, so that was a victory," Lamb says. "But we have had other cases where the hospital asserted that documents were protected when they had never been submitted to a PSO. Time had passed, and it wasn't like they were in the analytical stage, so that information was judged to be discoverable. If you don't follow the steps, you don't have any chance of it being protected as work product."

Hospital administrators often do not fully understand the PSQIA and how to obtain the protections of PSWP until it is too late, Lamb says. They may not follow the proper procedures to protect the information. By the time a judge rules against them, it is too late to protect the material in that case, he says.

"Then, they'll start talking to their lawyers and figuring out how to improve their processes," Lamb says.

EXECUTIVE SUMMARY

The Patient Safety and Quality Improvement Act of 2005 affords substantial protections from discovery for information related to adverse events. Hospital leaders and clinicians often do not fully understand how to use these protections.

- Information must be provided to a patient safety organization to be protected.
- Protected work product is not discoverable by plaintiffs' attorneys.
- Potentially protected information should be segregated from other material from the start of the investigation.

"There is a lot of inconsistency, which is clearly indicated by the number of cases in which work product claims are contested, and the variability in outcomes with hospitals getting confirmation that the information is protected, and others being ordered to turn over the material. It's not very well understood, and it's also an evolving area of the law."

State laws can affect how the protections afforded by the PSQIA are interpreted, Lamb explains. State laws affording more aggressive and broader discovery may result in a weakening of the PSQIA protections, he says.

Risk managers and compliance officers may understand PSQIA protections and the process that must be followed, but it is common for others who handle the information to be clueless, Lamb says.

For instance, a quality committee may not understand this method of protecting information as PSWP, Lamb says. Committees, and especially new members, should be educated on how the PSQIA affords certain protections, and how committee members must handle sensitive material to preserve that protection. Lamb suggests creating an orientation briefing sheet for committee members.

Follow-through is another potential failure point, Lamb says. While the PSQIA affords protection during the information-gathering and analytical phase, that information must be sent to the PSO in a timely fashion to remain protected, he explains. Hospital administrators sometimes make the mistake of thinking that if they deem material to be PSWP intended for transmittal to a PSO, that information is protected from discovery indefinitely, he says.

Not so. A judge may rule that failing to send the information to the PSO suggests the hospital was not acting in good faith. Even if the hospital had every intention of sending the information, the failure to do so in a timely manner voided the protections of PSWP, Lamb says.

Lamb encourages risk managers to keep PSWP in mind from the beginning of any event investigation.

"You have to start protecting things immediately when you're starting to gather information and believe an adverse event might have occurred. Sometimes, you don't know at first if it will be an incident that requires reporting, but as soon as there is a bad outcome you have to start labelling things as protected," Lamb says.

"You have to train the people who are handling it to know that it is protected, so that if they are deposed later they can respond appropriately," he adds. "One of things that needs to be done in most facilities is to identify the key players, and help them understand why you are doing some things in a certain fashion." ■

SOURCE

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Sparsely Charted History and Physical Complicates Med/Mal Defense

Thorough charting on the history and physical (H&P) of an ED patient can prove the standard of care was met. Still, the medical record often contains little more than a series of checkboxes.

"Lack of documentation may lead to questioning of the care that occurred," says **Bryan Baskin**, DO, FACEP, associate quality improvement officer at the Cleveland Clinic's Emergency Services Institute and assistant professor at Cleveland Clinic Lerner College of Medicine.

The ED chart should clearly show what was considered, and what was ruled out, during the visit. "This is primarily dictated by the H&P, which is where much of emergency medicine malpractice is alleged," Baskin observes.

Thoroughness leads the emergency physician (EP) to the appropriate testing, treatment, and disposition. A poorly documented H&P leads to the exact opposite. "That is where we have less optimal outcomes," Baskin says. "When a bad outcome occurs, plaintiffs will point to a lack of H&P as to why said outcome occurred."

David Sumner, JD, a Tucson, AZ, medical malpractice attorney, warns: "If you are over-relying upon electronic record templates for charting, you may be in trouble."

An EP defendant can prevail in malpractice litigation even if the diagnosis turned out to be wrong — if the chart demonstrates sound decision-making. "Free texting, even in electronic records, is your ally," Sumner stresses.

Many times, ED template charts are silent as to the EP's rationale and differential diagnoses. "I exploit all charting omissions and irregularities at provider depositions," Sumner reports.

The EP may offer a good reason for withholding aggressive IV fluid therapy in an acute pancreatitis patient. "The contraindication to otherwise appropriate treatment needs to be charted," Sumner says.

For example, the patient might present with a history of congestive heart failure or chronic renal insufficiency. If this is not charted contemporaneously, Sumner warns "your after-the-fact explanation will sound self-serving at deposition three years later."

Template charting makes it easy for plaintiff attorneys to paint a picture of subpar care. "They are a real time-saver, but also a real trap," says **Mark Spiro**, MD, FACEP. "We have records that are incredibly long and complex. But it often misses what's important."

A recent malpractice case involved a man with a missed epidural abscess. The plaintiff attorney made a big issue of an incorrectly checked box. The checkbox indicated the presence of "abnormal vaginal discharge."

"Malpractice did not occur because the emergency physician clicked the wrong box. But it did make it look like the ED care was sloppy," says Spiro, chief medical officer of the Walnut Creek, CA-based The Mutual Risk Retention Group.

Sparse documentation, even if accurate, is just as problematic. If all the ED chart shows for the H&P on a missed epidural abscess patient is a bunch of checkboxes, it does not give the defense anything to work with. "We have had a number of cases where it was just a templated exam," Spiro recalls.

For instance, documentation on the neurological exam merely indicated "cranial nerves normal" and "no focal neural findings." It did not say whether the patient could walk. "This has come up on more than one occasion when patients had spinal masses. It has led to really bad outcomes for patients, as well as really large settlements," Spiro says.

The same issue arises with cardiac workups. Several cases of missed aortic dissection lacked any evidence in the ED chart indicating the EP checked for abnormal pulses. On this crucial point, the template offered little in the EP's defense. There were only generic comments such as "cardiac exam normal" and "no murmurs or extra sounds."

"There was no detail," Spiro says. "It really doesn't help us when the exam is so skimpy." Considering that a lawsuit happens many months after the ED visit, it is doubtful an EP defendant recalls the patient or the specifics of the case. Thus, the EP who documented with checkboxes and no narrative is left with one unappealing option: To say it is their "usual and customary" practice to check pulses.

This was the EP's testimony in a recent malpractice claim. The plaintiff attorney focused on the complete lack of documentation on assessment of pulses. "The attorney said, 'You didn't have two minutes to check this, and it would have saved the patient's life? The patient's life was not worth two minutes?'" Spiro recalls.

Conducting a careful neurological exam as part of the H&P, and documenting it just as carefully, gives the EP a strong defense in the event something is missed. "If there is a bad case, it can help the defense to show that you were thorough," Spiro suggests.

Also, there is a more intangible benefit to this kind of narrative charting. "It forces the emergency physician to slow down for a moment to document the findings," Spiro adds.

In some cases, taking a minute to write something about the evaluation may cause the EP to rethink the patient's disposition entirely. Possibly, the back pain patient's story is suggestive of a spinal mass or cauda equina syndrome, at least enough so to cause the EP to hold off on discharge or to order an additional test. "By documenting, you are also thinking about it, and then you look for it," Spiro explains.

The patient might register an unexplained low-grade fever or mild tachycardia. "By putting a little bit of narrative in your medical decision-making that kind of describes what you are thinking, you could be preventing a devastating injury for the patient," Spiro says.

Lack of clarity as to timing of when the evaluation occurred also is problematic for the defense. In one case, an intoxicated woman was brought to an ED, and the template charting indicated an inability to move her left side. "The patient was too uncooperative to examine in any but the most cursory manner," Spiro says.

Later, the EP testified this worrisome finding was noted four hours after the patient's arrival. The checkbox-style charting did not indicate one way or the other. This allowed the plaintiff attorney to argue the finding was there at the time the patient arrived.

This possibility made it difficult for the defense to refute the main allegation in the lawsuit, that delayed diagnosis of stroke caused the patient to miss the treatment window for tPA.

The EP continued to insist there was no such finding at the time of presentation, but there was nothing in the chart to prove it. The case settled out of court for an undisclosed amount. "In almost all of these cases, we do the right thing," Spiro says. "We do the neuro or cardiac exam. We just don't document it." ■

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **Why does Erin O'Leary say clinicians and administrators should not make promises to patients?**

   a. Nothing is guaranteed in healthcare, and a promise can be taken literally by the patient and family members.
   b. The clinician or administrator may not be fully informed about what is being promised.
   c. Patients feel it is condescending.
   d. A patient's care may be altered to comply with a promise.

2. **What is one requirement a hospital must meet to gain immunity under the Health Care Quality Improvement Act of 1986 for peer review proceedings?**

   a. The proceedings must take place entirely within the hospital setting.
   b. The action against the physician must have been taken in reasonable belief that it was in the furtherance of providing quality healthcare.
   c. The proceedings must last no longer than six months.
   d. The proceedings must allow the physician to have legal representation and access to all evidence.

3. **Which is one recommendation from Ann Lambrecht, RN, BSN, JD, FASHRM, for reducing the liability risks associated with opioid prescribing?**

   a. Coordinate with physicians and hospital leaders so they understand who is responsible for each step of the prescribing process.
   b. Appoint a single physician to oversee all opioid prescriptions for a hospital.
   c. Require that only physicians be responsible for each step of the prescribing process.
   d. Require that only hospitals be responsible for each step of the prescribing process.

4. **Under the Patient Safety and Quality Improvement Act of 2005, what is one requirement for information to be protected from discovery as Patient Safety Work Product?**

   a. It must be reported to a Patient Safety Organization.
   b. It must not be used for defense in litigation.
   c. It must have no material bearing on any lawsuit.
   d. It must not show any fault or wrongdoing by the hospital or physicians.

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

Birth Injury Litigation Results in $7.5 Million Settlement

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News: A patient who was 40 weeks pregnant presented to a tribal hospital with low amniotic fluid. During delivery, the newborn suffered brain damage and other severe injuries. The family filed a lawsuit against the federal government, alleging that the hospital failed to perform proper tests and negligently administered a labor-inducing drug. Due to complications, an emergency cesarean section was performed, and the infant suffered injuries that resulted in developmental delays and other permanent injuries.

Before trial, the government settled with the newborn's family for $7.5 million. The structure of the settlement called for an immediate payment of $3.75 million, with the remainder of the payment to be used to purchase an annuity to provide the child with monthly payments.

Background: In November 2015, a patient who was 40 weeks pregnant was admitted to a tribal hospital with low amniotic fluid. Physicians decided to induce labor. At the time of labor induction, fetal monitoring showed regular functions, normal behavioral responses, and no danger of hypoxia or ischemia. Physicians believed the fetus was neurologically intact. Labor induction lasted more than 60 hours, which is an extraordinary length of time and unusual circumstance. Fetal monitoring revealed a progressive increase in the fetus' heart rate. Ultimately, it reached tachycardia.

Following the 60-hour induction, physicians decided to perform a cesarean section. The newborn was not breathing when he was delivered, and his oxygen levels were in the low 50% range; physicians resuscitated him. In addition, the infant was hemorrhaging and had sustained a head injury, likely a result of the delivery. The infant suffered from permanent brain damage and seizures.

THE INFANT WAS HEMORRHAGING AND HAD SUSTAINED A HEAD INJURY, LIKELY A RESULT OF THE DELIVERY. THE INFANT SUFFERED FROM PERMANENT BRAIN DAMAGE AND SEIZURES.

The newborn's parents filed a medical malpractice lawsuit against the U.S. Department of Health and Human Services because of the hospital's status on tribal land. The plaintiffs alleged the newborn's injuries could have been prevented had the care providers adhered to the appropriate standard of care. Specifically, the plaintiffs claimed the physician's assessment of the heart rate and weight of the fetus was negligent, and that their decision to induce labor through the administration of labor-inducing drugs constituted malpractice.

The parties entered into a settlement agreement whereby the federal government agreed to pay the newborn's family $3.75 million up front, plus another $3.75 million to purchase an annuity providing monthly payments of $4,500. The settlement will enable the family to pay for the child's past and future medical costs, which will be significant due to the child's permanent injuries.

What this means to you: This case raises a few lessons for physicians and care providers. Among the main issues in the case were whether the physicians failed to preserve and test either cord blood gases or the placenta, whether the physicians breached the applicable standard of care regarding the use of labor-inducing drugs and failing to monitor the fetus prior to delivery, and whether the physicians failed to ensure employees were aware of and complied with the hospital's policies and procedures.

Specifically, the family alleged the hospital did not properly estimate the weight of the fetus, even though the ultrasound estimate was more than the average weight. The family also asserted that the hospital failed in assessing the safety of vaginal delivery, which constituted malpractice. Finally, the family claimed the hospital did not recognize the deteriorating fetal heart rate pattern, which showed decelerations and a rising baseline. The family stated that if the hospital and its staff adhered to the appropriate standard of care, the infant's injuries could have been prevented.

Through careful monitoring, the physicians would have noted that delivery via cesarean section was viable — and, in fact, the most appropriate option. This is reinforced because despite the administration of labor-inducing drugs, delivery had not occurred after 60 hours. This timing should have concerned the physicians and care providers, and they should have re-evaluated their initial course of treatment. Absent any evidence indicating otherwise, the abnormal 60-hour labor period could easily have injured the fetus. Whether the physicians acted negligently while monitoring the fetus' heart rate would likely have been a significant material issue in this case. However, the family presented strong evidence that the care providers were negligent based on the totality of the circumstances and obvious disregard of cause for concern.

The hospital's failure to preserve and test cord blood also presented a problem. Such testing may have revealed the presence of specific conditions in the fetus that may have enabled physicians to adopt a different course of action. In absence of such testing, the family's allegation that that the injuries were a direct result of the botched delivery was persuasive, particularly because the newborn required resuscitation, and his oxygen levels were low at birth.

Yet another failure to adhere to the applicable standards of practice surrounds the administration of the labor-inducing drugs. These were administered in excessive doses, and were higher than those recommended by the manufacturer. Another point in support of the family's claims was that the drug was administered without a work order, which constituted a breach of hospital policy. A reasonable physician in the same or similar circumstances would not overadminister such drugs, and likely would not exceed manufacturer recommendations.

This case serves as an example of the consequences of disconnects, not only between the physician and the patient, but also between the hospital and its staff and the accepted policies, procedures, and standards of care now well-recognized in obstetrical settings across the globe. The deviations from standards are so many and so egregious that it is almost unbelievable that this happened without any attempts by staff to intervene to protect the unborn infant. Signs of fetal distress on a monitor strip are easily recognizable to anyone trained to read a fetal monitor. Hospitals and care providers must ensure that proper procedures are in place so physicians and staff both have the same interpretation of the strip. Most importantly, staff should feel emboldened by the organization to intervene and direct the physician to rethink the plan of care when staff recognize a problem the physician may not be aware of — or, though aware, has chosen an inappropriate course of treatment, or simply not to treat. The lack of training and adherence to, or absence of, multidepartmental standards and protocols is astounding, and unfortunately quite lethal. Physicians and care providers need to be cognizant of the standards within their facilities. In addition, a keen self-awareness of their own knowledge, abilities, and expertise is essential if they want the best outcomes for their patients and for themselves.

Finally, another lesson from this case is for physicians and care providers to honestly and critically evaluate litigation brought against them. This may seem like a daunting task, as recognizing one's fault is never easy. Nevertheless, when faced with the prospect of an adverse verdict, it is critical for a defendant in a malpractice action to evaluate the risks of proceeding to trial, particularly when the patient's injuries are undisputed as in this case, and the benefits of settling prior to trial. Settlement allows the parties to control the outcome and eliminate potential "runaway" verdicts. In this case, the defendant settled the matter for $7.5 million when the matter caused significant injuries to a newborn that will require

ongoing medical care. A judge or jury evaluating the same facts and malpractice could easily award figures higher than that amount. Physicians and care providers may be well-served to acknowledge their own shortcomings, and prevent excessive adverse verdicts by engaging in settlement efforts with an injured plaintiff. ■

REFERENCE

Decided on Nov. 19, 2019, in the United States District Court for the Eastern District of Oklahoma, Case Number 6:17-cv-00329.

Expert's Inadequate Testimony Leads to Dismissal of Medical Malpractice Lawsuit

News: An appellate court affirmed summary judgment in favor of a physician who failed to detect a leak in a patient's bile duct during gallbladder removal surgery. Shortly after the surgery, the patient experienced abdominal pain, and returned to the hospital. Further testing revealed a small leak in the patient's bile duct. A second surgery was performed, and the patient healed fully.

The patient filed a medical malpractice lawsuit, alleging the physician was negligent in causing the bile duct leak. However, according to the court, the plaintiff's medical expert failed to include any reference to the applicable standard of care, and did not testify as to whether the physician deviated from the standard. Furthermore, the expert testified in his deposition the procedure seemed "reasonable." An appellate court affirmed that this testimony was insufficient, and the trial court's dismissal was appropriate.

Background: A patient was admitted to a hospital on June 12, 2014, after experiencing abdominal pain, diarrhea, and bloating for one to two months. Based on test results, a laparoscopic cholecystectomy was recommended, and performed on July 21, 2014. The surgeon did not report or note any complications, and the patient was discharged. However, the same evening, the patient experienced pain in his abdomen and left shoulder. The patient arrived at the ED where an ECG and lab work were performed. His symptoms were consistent with gas in a postsurgery patient. Although his white blood cell count was mildly elevated, it was still within the normal range. His other test results also were normal. Nevertheless, the ED staff contacted the patient's physician, who instructed the patient to return the next day. According to the ED staff, the patient did not present sufficient symptoms for admission, and was sent home.

The next day, the plaintiff called his physician and reported severe pain. The physician prescribed Naprosyn and instructed the patient to report any changes in his condition. The patient's pain did not subside, and he returned to the ED complaining of severe pain and acute distress. Hospital staff contacted his physician. Although his lab work was within normal ranges, the patient presented an elevated white cell count. A CT scan revealed a small amount of fluid in the patient's pelvis, which is common after surgery. The patient was admitted to the hospital, but no leak was detected. After 24 hours, a second scan was taken. Results revealed a small leak in the patient's bile duct, which was not detected by the CT scan. The physician inserted a stent to relieve the pressure and drain the fluid. The patient fully recovered within two weeks.

The patient filed a medical malpractice suit against the physician for failing to detect the leak. The patient chose a board-certified internist as an expert witness, who was deposed during the litigation. In his deposition, the expert described the standard ED protocol for evaluating a post-cholecystectomy patient. The expert specified that he would not testify as to a surgeon's standard of care, and that he viewed the issue as whether the ED physicians had properly evaluated the patient's condition. The expert never criticized or commented on the defendant's alleged negligence or departure from the necessary standard of care.

Based on the patient's expert, the defendant physician brought a motion for summary judgment, which seeks to fully or partially resolve matters when there is no material issue of fact. The court granted the motion because the patient failed to produce evidence that the defendant deviated from the standard of care. The patient appealed, but the appellate court affirmed.

What this means to you: Although the facts of the case seem to indicate the physician acted within the accepted standard of care, the outcome may have been different had the patient selected a more experienced, better-suited expert and presented his claim with more

specificity. In particular, the patient failed to explain how the physician breached his duty of care, and how a physician acting within the necessary standard should have addressed the patient's postsurgery symptoms. From the complaint, it was unclear as to whether the patient attributed his pain and suffering to the physician not acting immediately after the first visit to the ED, or whether the leak should have been avoided during the first surgery.

Laparoscopic cholecystectomy procedures, while less invasive, can have unexpected consequences due to a narrower visual field that limits the physician's ability to see a laceration or puncture of a nearby organ or blood vessel. Physicians and care providers can inform patients about such prospective consequences, and help protect physicians in the event of a malpractice action. Written informed consent should be presented to patients and discussed before a procedure. The written consent should describe the procedure and complications in detail. Furthermore, written discharge instructions should be provided to postsurgical patients, including instructions to notify the physician or go to the ED if pain worsens or the patient develops a fever.

Unfortunately, this type of complication is not uncommon. That is why physicians and care providers in any setting are well served by listening to a patient's complaints. Physicians and care providers must follow up with appropriate assessments and repeated diagnostic testing until they determine a diagnosis and required interventions. If unable to make this determination, a physician should not hesitate to consult with peers or specialists for possible solutions.

The expert witness testified in his deposition that, based on the lab results and scans performed at the ED during the patient's first post-surgery visit, the defendant physician acted reasonably in instructing the patient to contact him the following day. Specifically, the expert explained the scans did not show any fluid and, other than a mildly elevated white blood cell count, all other values were normal. As a result, no leak was suspected at that point, and the leak was not detected until two days later when the second scan was performed.

The expert said the defendant had selected the least invasive treatment for the patient's condition: inserting a stent to drain the fluid. The patient did not suffer any permanent damage. According to the expert, the procedure to treat the leak would have been identical even if performed on the previous day. In essence, the expert's testimony stated that the deviation from the standard of care occurred when the ED did not admit the patient for observation on July 21. A 24-hour observation period would have been appropriate to assess the condition of the patient. If the pain had been caused by gas, it would have resolved itself within that period. Alternatively, if the pain was caused by a leak, it would have progressively worsened, and the patient could have been treated earlier, thus causing less pain and suffering to the patient.

Since the procedure would have been the same, this presented an issue for the patient because causation and damages are required elements in a medical malpractice action. Beyond the considerations of the applicable standard of care and whether the standard was met, a medical malpractice plaintiff also must that the physician's negligence was a substantial factor in causing the patient's harm. If the patient would have suffered harm despite a physician's actions, or if a physician's delay in providing treatment did not increase the amount of harm, then the patient may not be able to satisfy these necessary elements. Accordingly, even if a physician did not act within the standard of care, an uninjured patient is not entitled to recover damages. Physicians and care providers should carefully analyze a patient's purported injuries, the factors contributing to such injuries, and the extent of such injuries.

In analyzing the trial court's decision, the court of appeals identified deficiencies with the patient's written briefing and argument. The appellate court noted that the plaintiff's argument merely regurgitated citations of the expert's deposition and citations of similar cases. However, the applicability of those citations was left unexplained. Furthermore, the court found the brief did not follow procedural rules, and generally was deficient. The court read and analyzed transcripts from the expert's deposition, and how that testimony prompted the defendant's motion for summary judgment. On review, the appellate court determined the plaintiff had failed to show how the defendant deviated from the standard of care, and summary judgment had been properly granted. This successful defense judgment shows that there are multiple ways to challenge a medical malpractice action. Judgment need not wait until trial as significant defects in a plaintiff's case may be brought to light earlier. Physicians and care providers should consult with counsel and their own experts to evaluate a patient's claims with an eye toward finding such missing required elements. ■

REFERENCE

Decided on Nov. 22, 2019, in the Court of Appeals of Kentucky, Case Number 2019 WL 6245830.