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Policies Must Be Consistent With Standard of Care, but Fluid Also

Many malpractice cases hinge on whether the defendant’s policies and procedures were consistent with the standard of care, and whether clinicians adhered to those policies and procedures. The first part should be fairly straightforward because, after all, it’s only a matter of writing the standard of care into the hospital’s policies, right?

That’s not always as easy as it sounds.

Defining the standard of care in any clinical situation is an ongoing challenge, says **Kenneth N. Rashbaum, JD**, partner with the Barton law firm in New York City, who has tried dozens of malpractice cases. He also has worked extensively in compliance related to electronic medical records and artificial intelligence.

“It’s the whole reason we have malpractice trials, so we can argue about the standard of care,” he says. “If you adhere too closely to what was the standard of care in 2016, but this is 2018 and nobody has updated your internal standard because you’re too busy treating patients, you’re in trouble.

It’s not something you can establish one time and you’re done.”

Policies and procedures that rely on a standard of care must be reviewed every few months to ensure they are still valid, Rashbaum says. In some cases it will be possible to write evergreen policies that refer clinicians to the current standard of care in their fields,

whatever that is at the moment, rather than defining

it for an internal document that can become outdated.

“IF YOU ADHERE TOO CLOSELY TO WHAT WAS THE STANDARD OF CARE IN 2016, BUT THIS IS 2018 AND NOBODY HAS UPDATED YOUR INTERNAL STANDARD, YOU’RE IN TROUBLE.”

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EDITORIAL QUESTIONS
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There also can be situations in which clinicians within an organization cannot agree on the standard of care. In those cases, the solution may be only to state that clinicians are expected to use their best judgment and refer to the professional bodies and research that can guide them, Rashbaum says.

“There are situations in which the standard of care is truly controversial, and you have a case in which expert A says this and expert B says that. The textbook was outdated on the day it was published, so you don’t have a clear answer,” he says. “Trying to create a policy that says you must do X in this situation only creates problems. Writing these policies is more of an art than a science sometimes.”

Wealth of Data Can Create Risks

Keeping current with the standard of care is increasingly difficult as clinical care and technology advance at a rapid pace, Rashbaum says.

“You can be damned if you do and damned if you don’t. If you use the latest technology and rely on it excessively, you can be liable for that — but the converse is true if you don’t rely on it enough,” he says. “The standard of care is evolving particularly with technology and there are no hard and fast rules about

what you should use and how much you should depend on it, other than the older technology that is clearly accepted.”

For instance, Rashbaum notes that clinicians now have more access to data than ever before and no one has yet determined how much they are obligated to include in their patient care decisions. A physician can be criticized because, in hindsight, he or she had access to relevant information but did not use it, Rashbaum says.

Access to information can lead to standards that are set unreasonably high. Beware of any policy or procedure that requires a clinician to access all available data for any particular patient or to always review the records of any set of patients.

“It’s a problem,” he says. “If you set up a policy to say you must review all outpatient records of any patient coming in to the hospital, and it’s midnight in August under a full moon and it’s raining patients, you just can’t do it. Now you don’t meet your own standard and the plaintiff is going to go to town on that.”

Avoid Outmoded Standards

There also is the danger of setting internal expectations based on outmoded standards of care. This

EXECUTIVE SUMMARY

The standard of care is at the heart of most malpractice allegations, but often disputed. Internal policies and procedures must allow clinicians to follow the standard of care.

- Advancing technology can create standard of care pitfalls.
- Some policies should avoid defining a particular standard of care.
- Consider litigation trends when writing policies and procedures.

can result in insufficient internal policies and procedures; for instance, when a clinical standard does not represent advances that provide better outcomes, or they may be outdated in how they require the use of care steps that are now known to be unnecessary or dangerous.

However, the standard of care can become almost a secondary concern if you don't follow your own policies and procedures. The worst malpractice risk is not following a policy that is in place, Rashbaum says.

"The plaintiff is going to hound you on the fact that you didn't even meet your own internal standards. These were standards that you freely established for yourself as signifying the proper way to care for a patient, so you can't even say that you were doing things in the way you thought proper," he says. "You put it on paper as saying this was what you think is proper care, and then you didn't do it. That is deadly for the defendant."

Include Counsel in Policy-writing

Risk managers and clinical leaders always should involve legal counsel in the establishment of policies and procedures, Rashbaum says, preferably with actively practicing malpractice defense attorneys. Unfortunately, that does not happen as regularly as it should, he says.

"These are the folks who have the in-the-trenches experience in terms of what is trending in the courts and what is the current standard of care," Rashbaum says. "The legal counsel who are in court regularly can tell you that certain policies, or the way you have certain systems set up, are going to be problematic if you have to go to court."

Rashbaum gives an example of how electronic medical records and computerized ordering systems commonly include prompts that question a clinician's orders for drug dosages or other care inputs. Those prompts can improve patient safety and outcomes, but there will be times when the clinician needs to override the prompt and proceed as originally intended.

"The question is whether the record includes an override field to explain why you did it. If there isn't, how are you going to remember why you overrode that when the lawsuit comes in three years later?" Rashbaum

"YOU PUT IT ON PAPER AS SAYING THIS WAS WHAT YOU THINK IS PROPER CARE, AND THEN YOU DIDN'T DO IT. THAT IS DEADLY FOR THE DEFENDANT."

asks. "The prompt is technically a standard of care. If you have overridden it, haven't you deviated from the standard of care and nicely documented for the plaintiff that you did so?"

On the other hand, clinicians may be criticized for following the computerized prompt when there were other clinical signs indicating they shouldn't have, Rashbaum says. That is why policies must be carefully written to avoid requiring clinicians to comply with prompts that are at odds with their own best judgment, and why overrides must allow or even require a contemporaneous justification.

"When I talk to the IT folks at hospitals about this, they're like a deer in headlights, especially if this is a proprietary system. They say, sure, they had input from legal experts before they went online, but it was all legal licensing and IT legal," Rashbaum says. "No input from lawyers with trial experience."

Reasonableness Is Expected

The question in most healthcare litigation will be what the plaintiff could have reasonably expected from a typical hospital or provider, says **David S. Waxman**, JD, partner with the law firm of Saul Ewing Arnstein & Lehr in Chicago. If something is important enough that a hospital needs to write a policy or guideline for it, then it is important enough for someone to perform the research to find out what others do, he says.

"You have to know what the state of the science is, and to assess whether their hospital's policy is in accordance with both the marketplace and the science. It's best, from a legal standpoint, not to be an outlier," Waxman says. "Thorough and well-documented research ensures that policies meet this standard."

Waxman notes a recent North Carolina case in which clinicians followed internal policies and procedures, but the plaintiff alleged that they did not meet the standard of care. In *Johnson v. Wayne Memorial Hospital, Inc.*, the plaintiff claimed that the hospital's policy on when a radiologist should overread an emergency room physician's X-ray interpretation allowed too much time to pass.

The defendant prevailed when the plaintiff's expert witness could not

establish what the standard of care was, or what surrounding hospitals did in those situations. (*See the story below for more on that case.*)

If the plaintiff had retained a better witness or the expert had conducted some supportive research, the hospital would have been in the position of proving that its policy complied with the standard of care, Waxman says.

“This could have been done, for example, by showing what similar hospitals do under the circumstances. It could have been done by showing how physicians are taught to handle such a situation,” he says. “For example,

they might have shown what North Carolina teaching hospitals do about radiologist availability, or it could have been done by referring to the specialty care organizations for radiologists and emergency physicians, which have authored relevant guidelines.”

Hospitals and their departments should regularly review their policies and ensure that they are consistent with current medical literature and best practices. This is especially true when there are changes in thinking on how to address a particular condition, such as the changes regarding when to administer tPA in the ED, Waxman says.

“Outdated guidelines, in the hands of a skilled advocate on the other side of litigation, pose great danger for a hospital when an adverse patient care outcome occurs, and when the hospital’s policy is a step behind the current science,” he says. ■

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Plaintiff Challenges Hospital Policy on Radiology

A recent malpractice case in North Carolina illustrates how plaintiffs may challenge the validity of a hospital’s standard of care for a particular situation.

In *Johnson v. Wayne Memorial Hospital, Inc.*, the hospital in Goldsboro, NC, was sued by a patient who had been treated in the ED. The patient had a history of sickle cell anemia and presented with pain. A physician ordered a chest X-ray and other studies.

The emergency physician interpreted the chest X-ray as normal, discharging the patient soon after. Per hospital policy, a radiologist read the patient’s chest X-ray a few hours later. The radiologist documented a left lobe infiltrate, which he said was not “dangerous, ominous, or concerning.”

Hospital policy did not require the radiologist to immediately report the finding or the discrepancy with the emergency physician’s

conclusion, so the conflict was only noted by an ED clinician 14 hours after the patient was discharged.

The patient had returned because of continuing pain and was already admitted with a diagnosis of acute chest syndrome, a complication of sickle cell anemia that can be fatal in some situations.

The patient died the next day and the family sued, alleging that hospital policy should have required the radiologist to report the X-ray reading discrepancy in a timelier manner. Evidence provided during the trial indicated that it was common for that report to take up to 24 hours at Wayne Memorial, but such a long time frame did not violate hospital policy as long as the radiologist did not judge a need for faster notification.

To prove the allegation that the hospital policy did not meet the standard of care, the plaintiff had to show that it “was not in accordance with the standards of practice

among members of the same healthcare profession with similar training and experience situated in the same or similar communities under the same or similar circumstances at the time of the alleged act giving rise to the cause of action,” the court indicated.

The plaintiff’s expert witness testified that he had not researched similar policies at other hospitals and how the Wayne Memorial policy was similar or different. The trial court dismissed the case.

The Court of Appeals of North Carolina upheld the dismissal, saying the plaintiff failed to offer any evidence of “either (1) the standard of care to which a hospital in the same or similar community should adhere in its process for the review of X-rays, or (2) the hospital’s breach of the standard of care.”

The appeals court decision is available online at: <http://bit.ly/2qM8LnY>. ■

Work Carefully With Counsel to Ensure Best Results

Risk managers and legal counsel work closely in any healthcare organization — or, at least, they should. Neither can perform optimally without relying on the other, and a poor working relationship can endanger the organization.

However, that good working relationship does not happen without some effort. Risk managers should take the initiative to cultivate good interactions with both in-house and external legal counsel.

One of the biggest mistakes in this relationship involves a breakdown in communication between the risk manager and defense counsel, says **Diane Doherty**, senior vice president of Chubb Healthcare in New York City. Many of the efforts focus on communication and teamwork.

Medical professional liability cases are among the most complex medical cases to litigate and require a defense firm with specialized knowledge, experience, and a successful track record, she says. The risk manager will remain directly involved during litigation, and good lines of communication are essential.

“The more direct the communication, the greater likelihood of an optimal resolution of the claim,” Doherty says. “To avoid a breakdown in communication, risk

managers should proactively develop clear and concise guidelines for the defense counsel to ensure only the highest-quality legal services are provided.”

Establishing good communications with legal counsel is essential long before a malpractice case arises, she notes. It is important to recognize that no hospital or provider is immune from professional liability exposures, she says. She adds that the best approach for defending medical malpractice claims is to pre-emptively establish a comprehensive and effective claim and litigation management program, spearheaded by the risk manager.

This program should define responsibilities and ensure transparency around costs and expectations related to medical malpractice lawsuits. A risk manager who takes a proactive approach when it comes to professional liability claims and litigation management can affect the healthcare organization’s resources and bottom line positively, she says.

The risk manager’s responsibilities should include selecting an experienced, knowledgeable defense firm, consistently and effectively communicating with outside counsel, helping control legal expenses, auditing performance of the defense

firm, and managing hospital C-suite expectations, Doherty says.

Billing Can Be Contentious

Sometimes, billing processes can derail a relationship and cause trouble internally for the risk manager, Doherty says.

“A risk manager’s goal is to provide effective litigation management while also controlling expenses. This can be challenging for both the risk manager and legal counsel depending on the type of case,” she says. “Litigation can be quite costly and if not properly managed, legal costs can become enormous, especially when the life of the claim goes on for an extended period of time. Also, specialty experts and trial costs can be expensive.”

A successful claims and litigation program must balance how best to spend defense costs while trying to minimize settlements, Doherty says. Establishing comprehensive and standardized billing protocols that include legal counsel’s estimated budget for each claim, updated regularly, helps to reduce the likelihood of any surprises.

In addition, Doherty says the protocols also should address billing rates, frequency of billing, expenses, travel expenses, use of multiple attorneys, and research activities.

“Timely and effective communication between the risk manager, legal counsel, and insurers, when applicable, are essential, as ineffective communication can create unnecessary barriers to the successful resolution of a case,” Doherty

EXECUTIVE SUMMARY

Risk managers must work well with legal counsel, but doing so is not automatic. Take the right steps to improve communication.

- Understand each other’s roles and responsibilities.
- Establish good communications early, even before a case arises.
- Risk managers with legal backgrounds should avoid overstepping their roles.

says. “At the end of the day, active communication ensures coordinated activities, collaborative decision-making, and the implementation of realistic strategies and good business judgment.”

Risk Manager Is Client

The challenge is establishing a relationship of trust between the risk manager and counsel, says **David Richman**, JD, partner with the law firm of Rivkin Radler in Uniondale, NY. Particularly in the case of outside counsel, the burden is on the attorney to establish trust with the risk manager — as the risk manager is the client, he says.

At the same time, the risk manager must have an open mind and be willing to trust counsel, to know that the advice is well considered, Richman says. That will depend in large part on how the attorney communicates with the risk manager, he says.

“The worst thing that the attorney can do is let the risk manager be surprised by the information or a change in strategy. That burden of reducing or eliminating surprise addresses so much of what mistakes can sour the relationship,” Richman says. “The relationship can be damaged greatly if counsel fails to be accountable and readily available, or if counsel fails to advise the risk manager of problems with the litigation. The risk manager often is involved with setting reserves in a case and the last thing you want is to make those adjustments in strategy or thinking without current knowledge.”

Richman says a good defense attorney considers it a top priority to report regularly to the risk manager and to make the risk manager’s job

easier, even to make the risk manager look good within the organization, he says.

Risk managers should hold counsel to high expectations for the value of their work, Richman says. He notes that too often, counsel’s reports to risk managers will be essentially just a synopsis of the records that were provided.

“That is worthless and you haven’t earned the money you’re being paid,” he says. “Counsel should be analyzing what is in the record and how it affects the strategy that was being formulated up to that point.”

Meet Face to Face

Richman is a strong believer in holding face-to-face meetings with the risk managers at the hospital, saying they yield far better communication than just relying on emails and documents. A risk manager also should require telephone conference calls or videoconferencing at key moments in the litigation, to discuss strategy and essential tasks.

If the risk manager believes that legal counsel is not providing enough communication or the right kind of communication, Richman says you should pick up the phone and say so. Don’t wait and let the relationship deteriorate further, he says.

Risk managers can sour the relationship as well. Richman has seen instances in which risk managers thought they had not received reports from legal counsel and rather than inquiring directly with the law firm, which closely tracks the delivery of reports, the risk manager complained to his or her superior at the hospital, who then complained to the managing partner at the law firm.

“That puts counsel in a very bad

position because they know they didn’t do anything wrong, but if they push back they can make the risk manager look bad in his or her own organization and undermine that relationship,” Richman says. “It’s those kinds of things that damage a relationship, so try not to go over the head of someone and get everyone’s bosses involved if you don’t have to.”

In-house Counsel May Be Different

If a hospital or health system employs in-house counsel, risk managers should develop a close relationship, says **John C. Ivins, Jr.**, JD, partner with the Hirschler Fleischer law firm in Richmond, VA. Keep in mind that a health system’s in-house counsel may be responsible for multiple facilities and all the related issues, he says, and unlike outside counsel may be unable to give you as much hand-holding.

Outside counsel should see the risk manager as a client and work to make him or her happy, whereas in-house counsel has other risk managers and systemwide concerns that will necessitate a more streamlined interaction.

That means communication with in-house counsel should be complete and clear, Ivins says. The problem you’re bringing to the attention of in-house counsel may be the biggest problem your hospital faces at the moment, but the health system counsel may have an inbox full of similar problems. Ivins suggests that your introductory email about the issue should include a succinct description in the subject line and then information broken into sections like background, key facts, questions, and recommended solutions.

Ivins also reminds risk managers

that they cannot assume information is privileged just because they are talking to in-house counsel. There is case law that draws a distinction between when in-house counsel is giving legal advice and when they are giving business advice, Ivins notes.

“Before you put everything in an email, try to make a determination whether it might be some sort of business advice that might not be protected,” he says. “I had a case recently in which the plaintiff wanted to depose the in-house counsel because they had discussed an issue

that later was determined to be a business matter and not a legal concern.”

The best approach to the relationship between the compliance officer or risk manager and legal counsel is to view it as a partnership, says **Richard W. Westling**, JD, an attorney with the law firm of Epstein Becker Green in Washington, DC.

“Each partner has to understand his or her respective role and its limits. Communication, respect, and trust are the keys to any effective partnership,” Westling says. “Taking

the time to communicate and to build a respect and trust will go a long way toward making the compliance officer/risk manager relationship with counsel successful.”

Often, an individual serving as a risk manager or compliance officer is trained as a lawyer. That might seem like it would foster a good relationship, but often it has the opposite effect, Westling says.

“Despite that training, that individual is not acting as a lawyer when serving in their risk management or compliance role. It is important to take off the lawyer hat and to leave the legal analysis and opinions to legal counsel,” he says. “Failure to avoid this mistake can adversely affect the existence of attorney-client privilege, which generally does not cover communications by an attorney who is not employed in a legal function.”

Distrust between the two parties, for whatever reason, is a time bomb, Westling says. If either counsel or the compliance officer/risk manager believes they are not in this effort together, the relationship is doomed.

Another problem is failing to understand the differences in their respective roles.

“A compliance officer is focused on developing a compliant culture, monitoring for compliance, and reporting noncompliance up and out. In-house legal counsel is, in some cases, thinking more about liability, which can result in a desire to overcontrol an issue and to think too defensively,” Westling says. “The result is that these individuals find themselves at cross purposes and unable to resolve the issue. It is essential that these key corporate leaders learn to walk in one another’s shoes so they can see that a coordinated approach will be best for the company.”

Don't Forget Human Resources in Litigation

Human resources often is overlooked in situations that could lead to a lawsuit, says **Roger Hillman**, JD, an attorney with the Paramount Law Group in Seattle.

Risk managers should notify human resources of an employee’s involvement in potential litigation, Hillman says. He has encountered cases in which he was hired to defend a company and needed to interview an employee who had witnessed the incident in question or otherwise was involved, only to find that the employee was no longer with the company.

The employee may have left voluntarily or might have been terminated, which would be more troublesome, he says. But it should not be a surprise to counsel, and ideally that person should not be terminated until the matter is resolved.

“Just as you send out a litigation hold memo to tell everyone not to destroy anything, it would be a good practice to send a notice to human resources identifying the employees who are either potential parties suing us in this action or witnesses to the event,” he says. “Ask human resources, before taking any action on these employees, to please notify risk management, who will, in turn, notify defense counsel.”

If the employee leaves voluntarily, human resources should try to obtain contact information.

“If they need to be let go for good cause, you don’t have to hang on to them,” Hillman says. “But human resources can let risk management know so the risk manager can do any damage control and at a minimum be aware of the termination and the justification for it.” ■

SOURCE

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Communicate Early, Clearly

Risk managers should take an active role in communicating with and assisting legal counsel as early as possible in any case, says **Sara Obermark**, JD, a shareholder and head of the healthcare group with the law firm of Sandberg Phoenix in St. Louis.

“For example, when a case is assigned to outside counsel, it is extremely beneficial when the risk manager immediately prepares the medical chart for production to the attorney, provides any internal investigation completed, and identifies those providers involved and whether they remain employed by the hospital,” she says. “The most common mistake is waiting too long to obtain information for legal counsel.”

Typically, legal counsel sends discovery to the risk manager to assist in answering and document requests, Obermark says. If the risk

manager waits too long to work on obtaining the information, it can become stressful for everyone as legal counsel is trying to meet the deadline, she says.

Risk managers also can derail the work of a defense attorney, intentionally or inadvertently, Obermark says.

“In one instance, I had a risk manager sit in on the preparation of a nurse for her deposition,” she recalls. “The risk manager did not like some of the information the nurse was providing and made it known, which only resulted in the nurse no longer wanting to cooperate with the defense of the case.”

The risk manager and legal counsel need to work as a team, Obermark says, and that requires an understanding of each other’s roles and work methods.

“The risk manager needs to understand legal counsel is going to request a significant amount of information that may be difficult to

obtain. Legal counsel is not trying to make the risk manager’s job more difficult,” she says. “At times, I think risk managers get frustrated with the number of requests they receive from counsel, which can cause tension in the relationship.” ■

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Risk Management Lessons from Running With the Bulls in Spain

By *Jeanne Braun*

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As a risk management professional, it’s difficult to turn off my safety radar simply because I’m on vacation.

This year, I decided to experience the San Fermín Festival in Pamplona, Spain, more commonly referred to as “the running of the bulls.” As a New Yorker, my exposure had been limited to hyped-up television coverage of the run and hurried profiles of those poor, unfortunate ones gored by the bulls.

For most people, this is adequate, but in my world, this was on the long list of things to do before I lost interest or kicked the bucket.

No, I did not actually run with the bulls, opting for a safe and reserved spot on a lovely balcony overlooking the street. Equally exhilarating and terrifying, the overall experience reinforced many things I already knew and understood about safety and risk management. But more about that later.

The San Fermín Festival is held every year in July. Thousands of people from around the world descend on a small town in northern Spain and enjoy the food, sangria, live music, and nightly fireworks of the festival. The running of the bulls takes place almost every morning during the festival, and there is a bullfight every night. People dress in the ceremonial white outfit with a red scarf and a red sash, a nice contrast to the grand old historical

buildings that line the streets of Pamplona. But the run is the focal point.

As part of the ceremony, three gun shots are fired. Along the theme of “get ready, get set, go!” each shot is separated by about 10 seconds. The first shot is the “get ready” warning. The second shot gives the runners a head start on their route, and the third lets them know the bulls are on the way.

The gun shots begin. Standing on a balcony just 10 feet above the street, my adrenaline starts pumping and everyone starts cheering. Looking down, I observe that the street was freshly washed by the town’s sanitation department and the cobblestones were moist and slippery. The runners started jogging a bit, casually, waiting for the bulls to catch up. Most had their heads facing sideways or backwards over their shoulders, trying to catch a glimpse of the bulls behind them.

Suddenly, two young men slipped, fell hard, and were unable to get out of the way of the crowd or the bulls. Other runners started tripping and falling over them. Some were experienced runners, even marathoners, but that made no difference when you’re in a sea of people running from 16 bulls, each the size and weight of a small car. Fear overtook the runners as they pushed and shoved others to the sides. Some were seriously injured.

Many of the runners are repeaters. They run every year and plan their strategy way in advance. Most are not. One lovely gal I met on the trip decided impulsively that she was going to run the following morning.

About late 40s, Ellen (name changed) and I had seemed to have a lot in common. An experienced traveler with a bucket list, she

worked in an executive-level position with a growing financial firm and lived by the “work hard, play hard” mantra to which many of us alpha females subscribe.

She felt confident. It seemed like fun when we were watching it from the balcony. Several people in our group completed the run and survived. Why couldn’t she?

I caught up with Ellen the next day. Limping somewhat and pretending not to be in pain, she wasn’t too proud to admit that she made a terrible decision, that she could have been seriously hurt and hadn’t conducted enough research to figure out what she was getting herself into.

I wasn’t aware of this, but apparently when the crowd and bulls empty out into the bull arena it’s sort of a free-for-all. To avoid getting gored, one must either outrun the bulls or jump over a six-foot fence. With tears in her eyes, Ellen relayed the terror of trying to climb over a fence with a bull just a few feet behind her. With the full force of adrenaline and fear, she climbed up the fence, but being out of shape, got stuck on the top with one leg dangling on either side. It was every man for himself, so no one was around to help push her to safety. Eventually, she jumped and limped her way back to the hotel.

Ellen’s overconfidence and lack of experience was the basis for her poor judgment, and while, luckily, she came through with her body parts intact, it could have ended tragically.

Overconfidence in Healthcare

So, how does this relate to healthcare risk management?

Can overconfidence and poor

judgment lead to bad outcomes in patient care? I wondered.

A small share of doctors (11%) purportedly account for about 25% of complications, according to ongoing analyses of Medicare data. The issue of patient safety always has been a top priority, but landed in the spotlight when the Institute of Medicine published its “To Err is Human” report in 1999. Research reveals that performing a procedure with great frequency reduces the potential for bad outcomes or complications.

In fact, healthcare reimbursement now is tied to performance, a roundabout way of incentivizing healthcare providers to specialize in what they do. Knowing what procedures to avoid is a little like avoiding a confrontation with a bull.

I spoke with **Michael Brisman**, MD, a Harvard-trained neurosurgeon practicing in New York. Brisman is president of Neurosurgical Group, PC (NSPC), where he oversees a well-respected practice of more than 20 neurosurgeons and relationships with about six hospitals. According to Brisman, doctors who specialize in an area are the least likely to encounter problems due to lack of experience.

“When hospitals or physicians attempt to perform procedures in which they have little experience, it’s a red flag. It’s important to properly credential physicians per their training and background and resist the urge to treat a patient that needs a higher level of care,” he said. “Delaying a transfer can seriously harm a patient and may result in more complications, and possibly death.”

Stress as a Loss Factor

I also spoke with **Poonam Alaigh**, MD, a national healthcare leader and expert with an extensive

background in healthcare risk management. She has seen firsthand how training, supervision, and drills are crucial to the patient care experience. We spoke briefly about the San Fermín Festival and my observations about the healthcare industry.

“Risk management in a hospital setting requires 100% commitment from every staff member and every physician and has to be core to how we deliver care, not an afterthought. Most hospitals are committed to doing it well. However, bad outcomes do occur,” she said. “Sometimes, they are due to inexperience, but there are a wide host of factors that contribute to a patient injury. Protocols and care plans attempt to identify every possible scenario, but even so, problems that you didn’t anticipate can happen.”

A review of the 2015 Medical Professional Liability report issued by Conning, Inc., reflects an entire section devoted to physician stress as a loss factor in the medical professional liability industry. It speculates about physicians finding themselves increasingly overextended

and under stress and wonders if this results in more malpractice claims. The report authors cite a survey commissioned by The Physicians Foundation, where 20,000 physicians were interviewed in 2015. More than 80% of physicians were either overextended or at full capacity. *(The report is available for purchase at: <http://bit.ly/2D5Pov3>.)*

In Over Their Heads

I contacted **Robert Elliott**, managing partner at Bartlett LLP in Mineola, NY. He is a former risk manager and nurse, and has much to add about medical malpractice overall.

We talked about Ellen, the now-repentant runner at San Fermín, and how her overconfidence could be played out in a healthcare setting.

“We have, unfortunately, seen a number of claims related to providers treating patients where they were in over their heads,” Elliott noted. “Generally, it’s an emergency situation and everyone is trying to do the right thing. Sometimes, claims occur because the

hospital should be transferring the patient to another facility and there are delays in making that decision. Yes, it could be poor judgment, lack of experience, not enough planning, or a combination of all of the above.”

We agreed that Ellen’s overconfidence neatly parallels events transpiring in healthcare facilities every day. We also discussed the fear factor, how the lack of preparation can derail the situation simply because you are caught off guard, quite like a bull charging you from behind.

With the ever-increasing focus on quality of care, healthcare professionals at every level can transfer some of the lessons learned from my vacation. Running with the bulls is exhilarating — but sometimes the best view, in risky situations, is from the balcony. ■

SOURCE

- **Jeanne Braun**, President, Braun Strategies, a division of the Capacity Group NY, LLC — an EPIC Company, Lake Success, NY. Phone: (516) 277-8368. Email: jeanne.braun@epicbrokers.com.

Study: Residents Want to Be Involved in Error Disclosure

Residents’ error disclosure skills have improved over time, according to a recent study.¹ Researchers compared residents’ skills in 2012 and 2013 with the skills they had in 2005, and found significant improvement.

“This was surprising and a relatively novel finding, in that no prior studies had been able to demonstrate such improvement,”

says **Brian M. Wong**, MD, FRCPC, associate professor in the department of medicine at the University of Toronto.

The researchers were curious to know whether the training that they’d provided to residents over the years was the reason for the improvement. “Of course, we hoped we would find residents who had received this training would have better disclosure

skills,” says Wong. However, this wasn’t the case.

“In some ways, though, this was more disappointing than surprising,” says Wong. “It really should not surprise us that a single half-day workshop might not have a major impact on error disclosure skills.”

This raised the question as to what, if not the training, had improved the residents’ error

disclosure skills. “To further explore this, we interviewed nine residents from three different training programs: internal medicine, pediatrics, and orthopedic surgery,” says Wong.

The researchers asked the residents about their experiences learning how to disclose errors. The residents felt that faculty role-modeling and debriefings were helpful. Residents also turned to one another for peer support and mentoring.

“It turned out that while formal training was acknowledged as having some role, the more important learning experiences were the informal ones,” says Wong.

Some residents reported that they felt personally responsible for disclosing errors, and wanted to be a part of the conversation with the patient or family. “For us, this was perhaps the most surprising finding,” says Wong. “The residents saw disclosing errors as an important professional responsibility that they wanted to be directly involved with.”

Some even revealed that they’d disclosed errors independently without faculty present. This raises the ethical question of whether it’s ever permissible for residents to disclose errors on their own.

“When residents want to take ownership of the error disclosure process, it is our job as faculty members to ensure that they are prepared to disclose, and negotiate with them when they are ready to communicate effectively without direct supervision,” says **Lynfa Stroud**, MD, MEd, another of the study’s authors. Stroud is associate professor in the Department of Medicine at the University of Toronto and a general internist at Sunnybrook Health Sciences Centre.

Timely and candid communication with a patient or family after a medical error can help limit harm, and is a professional and organizational ethical imperative, says **Jonathan D. Stewart**, JD, director of risk management and patient safety at Alamo, CA-based Beta Healthcare Group.

“Silence by organizations and physicians following medical injury compounds the harm experienced by patients and families. But clumsy ‘disclosure’ of an actual or apparent error can be even worse than silence,” says Stewart.

Ideally, clinicians have some preparation before disclosing an error to a patient or family. This might take the form of formal pre-event training with an opportunity to practice. “At a minimum, the clinician should have just-in-time training, with the benefit of a team huddle to prepare,” says Stewart.

The team should review the known facts and identify questions that still must be answered. “Avoiding engaging in confusing and potentially counterproductive speculation in front of the patient or family is very important from an organizational risk management perspective,” says Stewart.

Ideally, initial communication with a patient or family about a serious harm event happens within an hour.² Organizations should identify individuals to support clinicians in preparing for these often difficult initial and follow-up conversations, says Stewart: “Medical ethicists may be well-suited for these roles.”

Ethicists may bring valuable skills to the pre-conversation meeting, in which the team agrees on the goals of the communication, attunes their message to the patient’s or family’s level of sophistication, and possibly rehearses the conversation.

“When an organization makes — and internally communicates — its commitment to timely and transparent communication after harm, it becomes possible to prepare for a swift and consistent response to such events,” says Stewart. ■

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SOURCES

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CE QUESTIONS

- 1. How often does Kenneth N. Rashbaum, JD, partner with the Barton law firm in New York City, advise reviewing policies and procedures regarding standard of care?**
 - a. Every few months
 - b. Every year
 - c. Every five years
 - d. Only when the standard of care is known to have recently changed.
- 2. In *Johnson v. Wayne Memorial Hospital, Inc.*, what did the plaintiff allege?**
 - a. The emergency physician did not read the X-ray.
 - b. The radiologist did not read the X-ray.
 - c. The emergency physician overrode the recommendation of the radiologist.
 - d. The hospital's policy should have required a timelier report by the radiologist.
- 3. What does David Richman, JD, say is the worst thing legal counsel can do to damage a relationship with a risk manager?**
 - a. Allow the risk manager to be surprised by a change in case facts or strategy.
 - b. Communicate too often and provide the risk manager too much information.
 - c. Assume the risk manager has no training or background in the law.
 - d. Require the risk manager to provide excessive background material.
- 4. What does Roger Hillman, JD, advise telling human resources regarding employees involved in potential litigation?**
 - a. The employees may not be terminated until the matter is resolved.
 - b. The employees may not be terminated after a lawsuit has been filed.
 - c. Notify risk management of any human resources action regarding the employees, or their voluntary departure.
 - d. Withhold all access to information about the employees.



LEGAL REVIEW & COMMENTARY

EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

Failure to Diagnose Breast Cancer Results in \$21.5 Million Verdict

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News: A woman presented to a hospital to evaluate a lump in her left breast. The hospital conducted tests and the results were concerning, but no biopsy was conducted on the mass. The patient was referred to a general surgeon for surgery secondary to persistent mastitis. After the procedure, the patient returned to the surgeon for a workup on a new lump.

The patient then presented to the original hospital for testing on the new lump, and again no biopsy was performed. The same surgeon recommended a biopsy; however, he neglected to perform or schedule the biopsy. The patient presented to a different hospital for a biopsy, revealing stage three breast cancer.

The patient filed suit against various medical professionals and entities, and received a \$21.5 million jury verdict.

Background: On Sept. 21, 2013, a woman presented to a hospital to examine a lump in her breast she had felt for more than a week. At the hospital, an ultrasound was conducted and interpreted by a physician who believed the mass was caused by cellulitis. The physician recommended

a follow-up appointment within the next six months for a repeat ultrasound.

On Oct. 2, 2013, the patient presented to an imaging services company with the history of the previous ultrasound, the detected mass believed to be caused by cellulitis, and a history of left breast pain and swelling, and antibiotic treatment. A physician reviewed and interpreted the ultrasound and noted that it showed no masses, but he did note skin thickening and a lymph node abnormality.

Five days later, the patient was referred to a general surgeon for breast surgery secondary to persistent mastitis. A week later, the surgeon saw the patient again for a workup on a new mass in her left breast. No biopsy was performed or scheduled. On Jan. 8, 2014, the patient attended a follow-up appointment with the surgeon, who again did not perform a biopsy.

Nine days later, the patient presented to the hospital for a repeat ultrasound and mammogram, both of which were performed by the hospital physician who conducted the original ultrasound. The physician again noted the presence of diffuse left breast skin thickening and noted the presence of a 14 mm lymph node in the left axilla, which he described as smaller since the prior exam in September. The physician's impression of the left breast was skin thickening compatible with patient's history of mastitis, and recommended a follow-up in six months for a repeat ultrasound. On June 11, 2014, the surgeon recommended testing for autoimmune disease and a breast biopsy, which he did not schedule or perform. After the initial hospital, physicians, and surgeons failed to perform biopsies, the patient eventually had biopsies performed at a different hospital, which revealed stage three breast cancer.

THE SURGEON
SAW THE PATIENT
AGAIN FOR A
WORKUP ON A
NEW MASS IN
HER LEFT BREAST.
NO BIOPSY WAS
PERFORMED OR
SCHEDULED.

The patient filed suit against the initial hospital, the imaging company, the surgeon, the initial hospital's physician, and medical professionals. The patient alleged several causes of action, including negligent diagnosis, negligent treatment, negligent examination, negligent follow-up prior to discharge, failure to obtain informed consent, negligent interpretation, and negligent imaging. The patient claimed that this deviation from the standard of care caused her permanent or continuing pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money, and/or aggravation of a previously existing condition. The patient's husband also alleged that the negligence caused him to suffer loss of comfort companionship and consortium.

At trial, the physician argued that he was not liable because another defendant failed to place a transducer over the patient's breast lump to capture it on the ultrasound. He further claimed he was not provided the original film, which was disputed by the medical record.

A jury returned a verdict in favor of the patient and her husband against the physician and surgeon for \$21.5 million, comprised of \$2 million for past medical expenses; \$156,000 for past lost earnings; \$1.4 million for lost earning capacity; \$7 million for past pain and suffering; and \$11 million for future pain and suffering.

What this means to you: This case illustrates the need for reviewing medical records in their entirety, and the need to establish a risk analysis procedure for each patient's circumstances and symptoms. This

case also provides an opportunity to survey the treatment options and procedures for persistent mastitis. To provide competent medical services for a patient, medical professionals must review the patient's medical record. Given the burden of reviewing a potentially voluminous record, this can be a difficult balancing decision between taking the time to fully review and thoroughly understand a patient's medical record and efficiently treating a large volume of patients. One method for increasing efficiency of medical record review is to improve organization of the record through standardization and implementation of optimized electronic recordkeeping. Standardization reduces time spent interpreting patient data, allowing for more analysis and patient interaction time. Electronic medical records can display different types of patient data and multiple provider data in one view, suggest diagnoses based on keywords, and aid in verifying diagnoses. Optimizing patient recordkeeping has tremendous benefits and can boost hospital efficiency significantly.

However, this patient did not have mastitis, and the first set of medical professionals failed to recognize this for multiple reasons. First, mammography, the gold standard for visualizing breast abnormalities, was not performed. While an ultrasound is the appropriate test to focus on a specific finding following an abnormal mammogram, the mammogram provides useful diagnostic information about the general health of breast tissue. Second, the assumption of a diagnosis without the confirmation of a consulting radiological oncologist is problematic. While a diagnosis of mastitis is much less traumatic for a patient to deal with, further review

of the ultrasound results should have been performed by a consulting radiologist. Additionally, when the patient's symptoms failed to respond to the initial treatment plan, a biopsy should have been the next option and the appropriate standard of care. Physicians place their patients and themselves at risk when following the "path of least resistance" to save time, money, or a patient's peace of mind. All physicians involved in the first round of care for this patient relied on the first diagnostic assumption without confirmatory data.

To reduce the frequency of injured patients and medical malpractice claims, hospitals should encourage professionals to engage in a risk-benefit analysis with each patient based on their unique circumstances and symptoms. A common test for whether a defendant acted negligently is whether the burden of performing an act outweighs the product of the gravity of the potential harm and the probability of that harm occurring. If the burden outweighs the potential harm to the plaintiff, the defendant is not negligent. While this test should not be the final determinate of whether to provide medical services, it can be a useful tool for medical professionals.

As applied to this case, the burden is performing a biopsy, which includes factors such as the level of invasiveness of the biopsy, the cost to the patient, and the cost to the hospital in terms of surgeon time and equipment costs. Breast biopsies can be performed with minimal invasion of the patient via fine needle aspiration, a core biopsy, a vacuum-assisted breast biopsy, or an image-guided needle biopsy. The cost to the patient often is subsidized by insurance companies to encourage early diagnosis, and the cost to

hospitals is offset by a reduction in defending medical malpractice claims and judgment payouts.

The gravity of harm associated with failing to timely diagnose breast cancer is significant. Early diagnosis increases a patient's chances of survival, reduces the chances of the cancer spreading, and reduces the overall harm to the patient. It is difficult to estimate the probability that any individual patient will develop breast cancer; however, one interesting data point from a

2008-2010 study is that 20-30% of breast biopsies reveal cancer. The relatively low burden associated with performing a biopsy coupled with the high gravity of harm and high probability of harm show that, based on her symptoms, failure to biopsy the patient in this case was not worth the risk.

Ultimately, it is up to each individual hospital and medical professional to balance the risks of providing a specific service or performing a specific test, compared

to the potential harms of not providing or performing those. Regardless of those balancing efforts, patients should be informed of the options and should have the opportunity to engage in their own risk analysis and reach informed decisions on their treatment. ■

REFERENCE

Decided on April 20, 2017, in the Florida Circuit Court, Eleventh Judicial Circuit, Miami-Dade County; Case No. 2015-028411-CA-01.

Failure to Diagnose and Provide Follow-up Care Causes Death and \$2.5 Million Verdict

News: In March 2013, a middle-aged man presented to a hospital for treatment of chest pain. After consulting with a cardiologist, the patient underwent multiple ECGs, which revealed an infarction. The patient was discharged with instructions to follow up with his general physician based on a determination that his symptoms were noncardiac-based. Several months passed and the patient did not seek a general physician for diagnosis or treatment. The patient eventually passed away due to a heart attack.

The patient's widow sued the cardiologist and multiple healthcare entities, alleging medical malpractice and wrongful death claims. The case proceeded to trial where the jury awarded the plaintiff more than \$2.5 million.

Background: On March 30, 2013, a 66-year-old journalism professor presented to an ED with acute chest pain lasting two weeks and made worse with activity. A cardiologist treated the patient and performed a series of ECGs.

An ECG performed on the patient at 10:41 a.m. was described as abnormal with a possible interior infarct. Another ECG performed nine hours later confirmed the interior infarct. The assessment provided by the cardiologist referenced an "unstable angina," and the next day, at approximately 10:00 a.m., a stress test was completed. The same day, the cardiologist determined that the patient's symptoms were noncardiac and discharged the patient with a recommendation of a noncardiac follow-up. However, the patient failed to seek the recommended follow-up appointment, and on Oct. 17, 2013, he died because of a ruptured myocardial infarction.

The patient's widow filed a medical malpractice action on Dec. 16, 2014, against the cardiologist, the hospital, and a physician management company. The plaintiff claimed that the cardiologist was negligent in failing to provide the appropriate cardiac follow-up care, failing to order a cardiac catheterization, and failing to appropriately diagnose the patient's

chest pain. The plaintiff's claim against the hospital and physician management company were based on a vicarious liability theory.

The plaintiff sought damages for past and future loss of earnings, loss of net accumulations, medical and funeral expenses, past and future loss of support and services, loss of the decedent's parental and spousal companionship, parental instruction and guidance, spousal protection, and for spousal and parental mental pain and suffering. The plaintiff identified five experts who were intended to testify regarding cardiology, interventional cardiology, economic damages, autopsy findings and the patient's cardiovascular system as it related to his cause of death, and the psychological care and treatment of the surviving widow.

The jury found the cardiologist 95% negligent and the patient 5% negligent and awarded the plaintiff \$31,000 for past medical expenses and \$383,000 for loss of support and services, and the jury awarded the patient's minor surviving son \$22,500

for loss of support and services and \$2 million in noneconomic damages. The court entered a final judgment holding the cardiologist, the hospital, and the physician management company jointly and severally liable for the jury verdict.

The defendants filed multiple post-trial motions, including a motion for new trial (which the court denied) and a motion for setoff and remittitur (which, as of press time, remains pending). The defendant's theory for setoff is that the past medical expenses should be reduced to the amount paid by the plaintiff, and that the loss of support and services damages should be reduced to present value.

What this means to you: This case demonstrates the need for physicians to create and adhere to adequate follow-up procedures. It is imperative for hospitals and medical professionals to review and update such procedures to ensure they have not become outdated with changing technology and best practices. A study published in the *Annals of Family Medicine* found that the optimum follow-up time frame on average is seven days. Example follow-up procedures include emails, a brief satisfaction survey, periodic emails that educate patients on diseases and medical regimes, phone calls by staff, automated phone calling services, and post mail. Hospitals should consider who will be following up with patients, the time frame of the follow-ups, how follow-ups will be accomplished and scheduled, and how to monitor and evaluate the procedures for efficiency and value.

These follow-up procedures must be more than merely administrative. Follow-ups can be used to evaluate medication efficacy and side effects, monitor and track changes in patient health, reinforce knowledge and action plans, confirm medical regimes, schedule new appointments, verify follow-

through on referrals, and discuss lab results. A follow-up appointment that fails to accomplish these goals results in a waste of hospital resources and patients' time, and does nothing to meaningfully mitigate risk. Specific, objective goals should be established for these return appointments. To obtain meaningful benefit from follow-ups and to preserve medical records, patients should be encouraged to truthfully track their compliance with post-discharge actions.

Whenever new procedures are implemented in a hospital, such as new follow-up procedures, hospitals should plan for and evaluate medical professional buy-in. Many hospitals already have implemented procedures for following up with patients, but medical professionals may not adhere to those policies. When rolling out new procedures, hospitals should, at a minimum, ensure the following are established: a full understanding of the new procedure and its purpose to reduce the risk of resistance to change, an understanding of the medical professionals' roles in the procedure to avoid miscommunication, an understanding of the connection between the new procedure and higher-quality medical care, an identification of potential barriers to the implementation and a strategy for overcoming those barriers, and a plan to engage with staff to ensure and encourage compliance. Hospitals should consider creating an implementation team tasked with overseeing effective implementation.

Experts are critical in any medical malpractice case as they are required to discuss the standard of care and what physicians should do under the same or similar circumstances. In this case, experts opined about the cardiologist's failure to order a cardiac catheterization. The defendant's own expert indicated that he would have ordered

a cardiac catheterization given the infarction showed by the second ECG. Cardiac catheterization is a useful tool to determine whether a patient suffers from heart disease, and the failure to use such an effective procedure when circumstances justify its use may fall below the standard of care.

Treatment always must be tied to each specific patient's symptoms and conditions, yet a wide variety of methods may be available to treat a single condition. Myocardial infarctions, which caused the death in this case, often are caused by heart disease. In treating heart disease, physicians have multiple options, including angioplasty with or without stent placement, closing holes in the heart and addressing congenital defects, repairing or replacing heart valves, or using balloon valvuloplasty. In this case, the first ECG result was enough to indicate that further observation and testing was urgently needed. An ECG would indicate abnormalities in the structure of the heart and heart valves and the ejection fraction or ability of the heart to pump blood, which would diminish following damage to heart muscle after an infarct. To make a diagnosis of unstable angina and discharge the patient with a noncardiac diagnosis likely does not satisfy the applicable standard of care. Unstable angina is a cardiac diagnosis that requires treatment with medication designed to prevent constriction of the cardiac arteries that supply blood to the walls of the heart. Without using these critical and readily available diagnostic tools, this patient was not afforded the appropriate standard of care that he deserved. ■

REFERENCE

Decided on March 21, 2017, in the Florida Circuit Court, Sixth Judicial Circuit, Pinellas County; Case No. 14-009201-CI.