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Informed Consent Must Be More Than a Clerical Task

Informed consent is a fundamental part of the healthcare process. Risk managers know the risks that can come with failing to adequately educate patients and document their consent. But the procedure is so common and performed so often that there is potential for it to become routine and less thorough.

Risk managers should constantly guard against that kind of relaxation of the informed consent process. That means emphasizing to clinicians what can happen when they let their guard down.

It is important to differentiate between the informed consent exchange with the patient and the documentation of that discussion, says **David Feldman**, MD, chief medical officer with The Doctors Company, a medical malpractice insurer in Napa, CA. Documentation of the informed consent process is important and necessary, but it is not the primary goal, he says. "People often conflate the two, and it is important to keep them in perspective," Feldman says.

> IT IS IMPORTANT TO DIFFERENTIATE BETWEEN THE INFORMED CONSENT EXCHANGE WITH THE PATIENT AND THE DOCUMENTATION OF THAT DISCUSSION.

The actual conversation with patients and families sometimes can be hurried and less than ideal in terms of content and a good back-and-forth with the patient, Feldman says. That is usually because of time constraints rather than the clinician thinking a more effective discussion is not necessary.

However, the time constraints can combine with a sense of routine so that clinicians do not recognize that their

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informed consent process has deteriorated, Feldman says.

"In the practice of medicine in 2019, time is a battle. With all the distractions and time pressures from electronic medical records [EMRs], and vanishing resources in the face of more complicated patients in a hospital environment, it creates time pressures for clinicians to spend the appropriate amount of time discussing the risks and benefits," Feldman says. "That becomes tricky when it's a procedure that the clinician does a lot of, but for the patient it's their entire world. The one operation that is routine for the surgeon may be a very big deal for the patient."

Most physicians are better at obtaining informed consent than they were 20 years ago, but the time constraints threaten to undermine that progress, Feldman says.

Can Be Key in Litigation

Informed consent is central to almost every case in which medical negligence is alleged, notes **Peter Kolbert**, senior vice president for claims with Healthcare Risk Advisors in New York City, which provides insurance and risk management advisory services. *(For more on the foundation of informed consent law, see the story on page 112.)*

"We do worry about cookbook processes where papers are presented to people and someone has to sign that consent has been done. It's a process, not a piece of paper," Kolbert says. "At the same time, it is in the self-preservation interests of every physician to adequately document it. If everything goes right, only clinicians read that document. But who reads it if something goes wrong? A lot of lawyers."

He agrees that the chief culprit in insufficient informed consent is the time pressure clinicians feel. "They are being asked to do more in the same amount of time, and the EMR has created some obstacles. Checkboxes and the lack of free narrative create a document that eliminates or removes free thought and the ability to write a narrative that includes the history and their thoughts about the patient," Kolbert says. "Informed consent can be a victim of that push to fill in the EMR."

Clinicians are keenly aware of the documentation needs for credentialing, accreditation, and the many aspects of patient care requiring records, Kolbert says, so much so that completing all the paperwork and checking all the boxes in the EMR can inadvertently draw focus away from what that documentation is supposed to represent.

EXECUTIVE SUMMARY

The informed consent process must be maintained as a valid and effective part of patient care. There is substantial risk in allowing it to become routine.

- Documentation is important but it is not the primary goal of the informed consent process.
- Electronic records can inadvertently degrade the process.
- Time pressures are the biggest challenge for physicians trying to inform patients.

Even if there was a truly meaningful informed consent discussion, it sometimes is not adequately reflected in the notes, Kolbert says. "I think every physician has the best intention and does discuss the procedure, but we need more than just a signature on a consent form. We need a narrative note written by the physician that they have had a conversation," he says. "The danger becomes that it is not a process, that we're just looking for a signature on a piece of paper. For the surgeon, it's Wednesday and just another appendectomy, but for the patient, it's the one time in their life they're going in to have an appendectomy and maybe the only time they have any surgery."

Patients Claim No Discussion

The danger comes when there is an adverse outcome and the patient claims, perhaps in good faith and perhaps not, that the conversation did not take place, Kolbert says. A simple signature and checkbox in the EMR is not much of a defense in that situation, but a good narrative note can be, he says.

"We've seen this in many lawsuits — not withstanding what actually happened — that the patient asserts no one explained anything to them. 'I was in the waiting room, someone presented a consent form to me and I signed it,'" Kolbert says. "The benefit of the narrative note is that it is a time capsule one can refer to later on to demonstrate that a conversation was held. Fingers were put on a keyboard or a pen was put to paper at that point in time, indicating a conversation occurred."

Fortunately, Kolbert says, EMRs are beginning to catch up with what physicians need to document. Modern EMRs allow and encourage physicians to include a narrative about the informed consent process, rather than relying so much on drop-down menus and checkboxes, he says.

Kolbert notes that malpractice claims often allege both insufficient informed consent and a technical error in how the procedure was performed. A thoughtful note about the informed consent process can defend against both claims, he says.

"Quite often the defense to the technical charge that something was done in error can be advanced with a note saying the physician discussed the possibility of this and it is a known risk," Kolbert says. "The good narrative note can support them in both the consent claim and the technical performance claim."

Audit Charts for Compliance

Time pressures may continue getting worse, Feldman and Kolbert both say. Risk managers may find it difficult to know how well their clinicians are performing the informed consent process and documenting it without actually witnessing it, which is impractical even to sample, Feldman says. However, a random audit of charts to look for adequate narratives may be possible.

Kolbert notes that research has shown an enormous disparity between what patients are told before a procedure and what they remember. That is good reason to take any allegation in a lawsuit of insufficient informed consent with a grain of salt, he says.

"It is still good practice to remind staff to never take this for granted, to emphasize that this is very important," he says. "Remind staff that although this is what they do every day, it's not for patients and they have to take their time, slow down, and explain this material in a meaningful way."

Clinicians also should be reminded that a signed consent form is not a perfect defense, Feldman says. In virtually every lawsuit alleging the patient did not receive appropriate informed consent, there is a form with the patient's signature saying otherwise, he says. Not all those cases are dismissed or won by the defendant, Feldman notes.

Kolbert points out that when a patient has been injured and claims not to have given informed consent, U.S. law does not require the plaintiff to say "If had I known the risks, I would have refused." Instead, they rely on "If a reasonable a person would have known, a reasonable person would have refused." The difference is significant, Kolbert says.

"The plaintiff does not have to prove that he or she would have refused, but that a reasonable person in that situation would have refused," he says. "That can be a lower bar than proving that individual would have made a different decision."

State Laws Vary

Informed consent law is state-specific, so physicians must understand the particular requirements of their own states, says **Amy S. Flanary-Smith**, JD, special counsel with Parker Poe in Columbia, SC. The legal obligation to obtain informed consent falls on the physicians, even though hospitals usually maintain the documentation because they need it to receive payment and to meet the Medicare

Conditions of Participation, she notes.

State statutes on informed consent typically outline categories of information that must be conveyed, Flanary-Smith explains. They include the professional standard of what other physicians would disclose, and then the standard of what the patient would want to know. Some states use a modified version of the second, requiring disclosure of what a reasonable patient would want to know.

"We have seen movement toward physicians taking the informed consent more seriously, with many surgeons completing the informed consent process before the patient comes to the hospital," she says. "If the informed consent process were to become a matter of just handing the patient a document to sign, without a true exchange of information, that would be a problem. Fortunately, that is not something we encounter very often."

Readability and understanding of printed information can be a concern, Flanary-Smith says. Physicians should be certain that a patient can read and comprehend the information, obtaining translation to another language when necessary and explaining terms in a way the patient can understand, she says. The same concerns can occur with verbal conversations, so it is important to ensure that the patient understands and is not just listening politely, she adds.

Some physicians are using video presentations of the potential risks associated with a particular procedure in addition to the personal conversation, Feldman notes. He used such videos when he practiced as a plastic surgeon.

Kolbert notes that the videos can be linked to the patient record and even shown to the jury if there is a claim involving informed consent. "We need to take informed consent to the modern age," Kolbert says. ■

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1914 Case Established Informed Consent Principles

A 1914 case from the New York Court of Appeals established some of the foundation for what the healthcare community now thinks of as the informed consent process.

In *Schloendorff v. Society of New York Hospital*, 1914, the court addressed the lawsuit brought by Mary Schloendorff, also known as Mary Gamble. In January 1908, she had been admitted to New York Hospital for evaluation of a stomach disorder. The house physician diagnosed a fibroid tumor, explains **Peter Kolbert**, senior vice president for claims with Healthcare Risk Advisors in New York City.

She agreed to undergo ether anesthesia for examination of the tumor but did not agree to its removal. The surgeon determined that the tumor was malignant and removed it.

"She suffered some type of clotting anomaly, a vascular insult, and developed gangrene that necessitated the amputation of several fingers," Kolbert says. "She brought a lawsuit claiming not that the surgery wasn't indicated, but that she never would have consented to the procedure because of the inherent risks and she didn't give permission."

The court determined that she could sue the charitable institution and that performing the procedure without her permission constituted assault and battery against her, Kolbert says.

"That case led to the codification across many states of the laws of informed consent, saying that even if the procedure is indicated and done properly and a known risk develops, patients have a right to not subject themselves to those known risks," Kolbert says. "Being subjected to risks that a reasonably prudent person wouldn't subject themselves to becomes a compensable event."

Justice Benjamin Cardozo explained that reasoning in the court's opinion:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained." *(The court's opinion can be found online at: https://bit.ly/2lQmasY.)* ■

Provider Stress Can Trickle Down to Affect Patient Safety

The healthcare industry can be stressful for everyone involved, with clinicians sometimes suffering greatly from the workload, time demands, bureaucracy, and the emotional nature of their work. Minimizing stress is important for the health of the caregivers, but also to maintain patient safety.

When staff are exhausted, experiencing depersonalization from their work and feeling less effective, they are more likely to fail to follow practices that support high-quality, safer care, says **Robert Morton**, BA, ARM, CPHRM, CPPS, assistant vice president of patient safety and risk management for The Doctors Company in Napa, CA.

A common example of how this happens is with nurse understaffing, which has been linked to higher healthcare-associated infection (HAI) rates since Florence Nightingale first reported and demonstrated this in the 1850s, Morton says. Understaffed working conditions and inadequate support by leadership to deliver high-quality care erodes nurses' vigilance and adherence to infection control practices.

"Work overload, interruptions, inefficient systems, and administrative overburdens create chaos and increase errors, some leading to patient harm. Chaos also diminishes the situational awareness needed to check yourself and ensure other members of the healthcare team are strictly adhering to infection control and other safe practices," he says. "A widely recognized example of this is reduced observance of hand hygiene and sterile technique practices by overstressed staff, leading to higher patient HAI rates."

WHO Recognizes Risk

The World Health Organization (WHO) has identified burnout as an occupational phenomenon (not a medical condition) in the International Classification of Diseases (ICD-11), Morton notes. The syndrome, which results from chronic workplace stress, is characterized by feelings of exhaustion, increased mental distancing from one's work or cynicism about work, and reduced professional efficacy.

These symptoms can manifest in many ways in and out of the healthcare workplace, he explains. Some of these include higher rates of error and infections, increased staff turnover, more sick days, lashing out at work, disruptive behavior, complaints from staff and patients, and home-life problems.

"To begin to address the issue, hospitals should first measure it using a valid survey instrument. Once the scope and severity of the dilemma are better understood, hospital leaders should roll up their sleeves and invest in the areas of greatest need for their clinical staff," Morton says.

They should round with staff and ask them, "What's not working?" and for ideas about how to make things better, Morton says. Invest in staff wellness, quality improvement, and workplace efficiency.

"Give staff the authority to make changes that improve care quality and enhance safety. Then, recognize and reward them when they achieve it," he says. "Repeat these steps. It's a journey."

Physical Demands Increasing

In addition to all the emotional stressors, the physical demands of nursing are increasing, says **Bette McNee**, RN, NHA, clinical risk management consultant at Graham Company in Philadelphia. The increased size of the typical patient puts more physical stress on nurses and other employees, she says.

"There also are the increased distractions, all the bells and alarms, which adds to the daily demands of the job," McNee says. "We're also hearing more complaints about aggression and physical violence from patients and even family members. All of that compounds the stress of

EXECUTIVE SUMMARY

Stress can affect physicians, nurses, and other healthcare staff, but it also can affect patient safety. Overstressed caregivers are more likely to make errors and lower the quality of care.

- Understaffing is a major cause of stress.
- Watch for physical and emotional signs of stress.
- Create a culture that allows people to acknowledge their stress and take steps to relieve it.

what has always been a demanding job."

A stressful environment makes it difficult to concentrate and pay attention to the details of patient care, McNee says, which leads to medication errors and other problems. Increased stress also can lead to a decrease in caring behavior by nurses, she notes.

"They're so busy and so stressed that they don't have time for that dialogue and good bedside manner that we hope to see from our nurses. That really affects quality of care," McNee says. "Nurses don't have the time we used to have before to spend with the patient and family, and we know that increases patient anxiety. We may see an increase in patient falls and other adverse outcomes like tube dislodgement because the patient is so much more anxious and knows the nurse doesn't have time."

Direct Effect on Care

Stress and burnout can be directly associated with adverse levels of care, says **Mary Bemker-Page**, PhD, a core faculty member with Walden University's MS in Nursing program.

Stress and burnout in healthcare settings have been linked to decreased productivity, reduced vigilance and attention to detail, and a higher level of employee turnover, Bemker-Page says. Staffing shortages, provider errors, adverse events, and mortality all can result from provider stress, she says.

Bemker-Page provides this list of symptoms of individuals experiencing high levels of stress and burnout:

Physical

- Fatigue for no apparent reason;
- Nervousness, anxiety, or general upset;
- Changes in eating and sleeping patterns;
- Less self-care.

Psychological/Emotional

- Pessimistic and cynical;
- Avoidance of decision-making;
- Anger or irritability in the workplace;
- Questioning ability to make a difference; hopelessness.

"When symptoms are noted, it is important for leadership to reach out individually and collectively. Creating a culture where staff is supported significantly mitigates stress generated during the normal course of work," she says. "Offering relevant in-service education and developing procedures that promote structure and minimize stress can help. It also is important to continually assess the environment for additional stressors and address them when found."

It is important for hospitals to acknowledge the profound impact of workplace stress on individual clinicians and to expand access to confidential, nonpunitive mental

STRESS DECREASES ABILITY TO FOCUS, INCREASES ERRORS

Stress can lead to two distinct types of attention problems with clinicians, says **Curtis W. Reisinger**, PhD, corporate director for the employee and family assistance program at the Zucker School of Medicine at Hofstra/Northwell in Manhasset, NY. Reisinger also is an assistant professor of psychiatry.

When under a great deal of stress, some people will focus intently on the one task viewed as primary, such as a surgeon who concentrates so much on the surgical activity that the bigger picture of the patient's status is neglected, Reisinger explains. Others may go in the opposite direction and try to divide their attention among so many tasks that none receive adequate attention, he says.

Stress brought on by an abundance of tasks or an unforeseen problem during surgery interferes with the person's problem-solving ability, Reisinger says. "When you have fatigue and burnout, your higher cognitive functions decrease," he says. "At a certain point, your brain just doesn't have the resources to do the best you could in a different circumstance."

The use of physician extenders, such as scribes to enter notes in the medical record, can be helpful in reducing some of the stress of modern healthcare, he says. Most healthcare professionals will respond well to organizations trying to take meaningful steps to reduce stress.

"There may be some old-school types who insist that stress has always been part of this life and we should just keep going, but the newer generation tends to be very receptive to having down time to take care of themselves and to take care of colleagues who need the help," Reisinger says. ■

SOURCE

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healthcare for doctors and nurses, Morton says. This should be part of an organizational strategic priority for well-being, supported by leadership arising from the recognition that patient safety cannot fully be realized without a safe and optimally healthy workforce.

Burnout Leads to Apathy

Healthcare always has demanded more from its workforce than perhaps any other field, notes **Helen Hrdy**, senior vice president of customer success with NRC Health in Lincoln, NE. The work is unrelenting, it requires the utmost emotional sensitivity, and often, the stakes are literally life and death.

"Add to that the trappings of modern healthcare work — time-consuming EHR systems, complex care protocols, long shifts, and heavier patient loads — and it's no wonder that 51% of doctors and 41% of nurses report feeling burnt out and unengaged. If left unchecked, working in healthcare can make even the most empathetic of clinical staff feel completely removed from the human impact of their roles," she says. "Burnout makes clinicians increasingly apathetic during care interactions, leading to an inability to fully engage with patients."

When the patient-provider relationship is jeopardized, communication is sacrificed, Hrdy explains. That is when mistakes happen that put patients at risk.

The signs of burnout closely mirror chronic stress and other illnesses, Hrdy says. Some specific symptoms include increased sickness, chronic headaches and pain, increased or decreased sleep and appetite, feelings of self-doubt, helplessness, feeling trapped, or a sense of failure, emotional detachment and feelings of isolation, lack of motivation, decreased satisfaction in once-pleasurable activities, withdrawal from social obligations and personal responsibilities, negative attitude and increased frustration, and using food, drugs, or alcohol to cope.

When a provider is showing one or more of these symptoms, it can put a healthcare organization at risk for lower satisfaction and quality of care, higher medical error rates, and malpractice risk, she says. Higher staff turnover, alcohol and drug abuse or addiction, and clinician suicide also are serious repercussions of burnout, Hrdy notes.

"Innovative healthcare organizations know that the quality of their care depends on engaging their employees before burnout occurs, and they're doing everything possible to preserve that vital spark of empathy in their staff by implementing programs that reduce stress," Hrdy says.

Some hospitals have launched internal social networks specifically designed for intercolleague praise, she says. Earning compliments from colleagues helps bring staff together and motivates performance. Other organizations are instituting real-time feedback solutions to bolster and maintain employee morale, Hrdy says. *(See the stories on page 114 and page 117 for more on how some hospitals address stress.)*

"Provider scorecards, for example, provide patient insights on the care experience in a snapshot to help doctors see what they are doing well and where they can improve," Hrdy says. "And for many providers, getting this kind of encouragement directly from patients is more meaningful than any bonus incentive or staffing arrangement."

Address Burnout Head-On

Hospitals need to address burnout head-on by offering solutions that bring joy and well-being back to healthcare staff, Hrdy says.

For example, Hrdy says physician engagement should be fostered in the healthcare setting because it does not always happen on its own. A simple way to start is by setting up board-administration and administration-provider co-commitments. This helps reduce feelings of hierarchy and embraces these relationships as a partnership, she says.

"Hospitals must also find healthy ways to allow for decompression. Some organizations have adopted what's termed a 'code lavender,'" Hrdy says. "This can be called by anyone when there are times of extreme stress such as a patient death."

In addition to making errors more likely, stress also can affect the other variables that are essential for a safe work environment and the delivery of safe, innovative care, notes **Herman Williams**, MD, MBA, MPH, managing director in The BDO Center for Healthcare Excellence & Innovation.

For example, imparting stress when communicating with others can discourage open and honest communication and undermine the culture of empowering everyone on the team to speak up, he says. This can lead to a stressful hierarchical environment that stifles communication from the workers who know the system best.

Additionally, provider stress can encourage a "renegade" culture

where clinicians depart from policies and procedures and improvise to accommodate a stressful situation, he says. This also can support individual thinking while under pressure, which can have a dangerous effect on the reduction of variation and create a poor, negative, scared, hurried provider attitude prone to errors, he says.

Identify Symptoms, Form a Plan

The common causes for stress in a healthcare environment — financial pressure on the organization, staffing shortages, equipment failure or substandard conditions, poor leadership, mismatched fit of staff with the positions held — lead to symptoms of provider stress that are extensions of these contributors, Williams says.

"When looking to manage risk and ease symptoms, an astute leader should look for indicators of provider stress in areas like employee attitudes, patient satisfaction feedback, and financial performance, and then work to develop a strategic plan that addresses and combats the core factors contributing to this anxiety," Williams says. "Once a plan is formed, it is then immensely important for hospitals and health systems to keep open lines of communication with providers to accurately track and execute on the progress and success of their efforts."

The best way to limit provider stress is to create a formal safety program that raises awareness around the effects of stress on patient safety, Williams says. He encourages use of The Joint Commission's Speak Up program, the Situation-Background-Assessment-Recommendation (SBAR) technique, and other communication practice standards to promote an organizational culture where patient safety is the founding principle.

"To properly manage the risks associated with provider stress, leaders must be able to model safe behaviors under demanding conditions and should have a toolkit for combating anxiety and focusing on safety principles," Williams says.

Hospitals can reduce stress by offering proactive intervention techniques that promote health and well-being among providers, Bemker-Page says. Activities such as tai chi, walking clubs, meditation, and nutrition courses can be presented at the hospital or supported elsewhere at little to no cost to the employee.

Structured activities, like nursing huddles and journal clubs, can include information on stress reduction activities and solutions for problems commonly encountered by staff, she suggests. Cumulative stress debriefings and support rounds also can be helpful. A quiet room where staff can listen to music, sit in a massage chair, or read a book can be another useful resource, Bemker-Page says.

However, McNee cautions that self-management is only part of the solution. Patient safety is best served by assessing the hospital environment to determine what is interfering with high-risk patient tasks, she says.

"It is known that the more tasks a person is responsible for at the same time, the less you can concentrate on any one thing. Go to a unit and understand everything a nurse is responsible for all at once," McNee says. "The alarms, medications, monitors, recordkeeping, and maybe keeping track of who's going to lunch and when. Eliminate as much of that as you can and you'll see the nurse improve her real job and protect patient safety."

Complexity Adds to Pressure

Provider stress and burnout are worsening in healthcare, but not because clinicians are weaker in any way than they were in the past, says **Thomas H. Lee**, MD, chief medical officer with Press Ganey,

headquartered in South Bend, IN. Rather, it is the increasing complexity of medical care that is contributing to rising stress levels.

"There has been so much scientific progress and we can do so much more, but the result is that there are so many more people involved and the risk of poor coordination and dropped balls goes up exponentially," Lee says. "There is an obligation to be in touch with everyone involved, and that leads to the fear of screwing up, the idea that you didn't touch base with everyone, or they didn't understand what you meant."

That fear comes to the forefront when clinicians are talking to the patient and it is clear that not everyone is working together, he says.

"That's the kind of thing that is dispiriting. Even if patients aren't actually hurt by it, patients lose their trust that everyone is working together and clinicians lost that psychological reward of people feeling grateful for what they've done," Lee explains. "The root cause of the challenge is medical progress, more people, and more complexity. There is more chance for error and an emotional drain that results."

Lee authored a paper with a colleague on understanding burnout in healthcare professionals, concluding that a key solution is to help them spend more time actually caring for patients and have more pride in their work.

They wrote that "organizations should reinforce individual clinicians' ability to find meaning in their work, reduce clinicians' work that is external to patient care, and define an organizational culture with values that make clinicians proud." Even without definitive answers to what causes burnout and how to avoid it, organizations "can act now

HOSPITAL ADDRESSES STRESS WITH HEALTHY HEALER PROGRAM

A Colorado hospital is addressing stress by reminding clinicians that it is OK to take a moment for themselves and focus only on the patient care at hand.

The idea may seem simple but it has a profound effect on people, says **Diane Reinhard**, DNP, MBA, MSCIS, RN, CRRN, NE-BC, vice president for patient for care services and chief nursing officer at Craig Hospital in Englewood, CO. "If we don't protect our physicians and other caregivers from the effects of stress, then we are in some ways responsible if that results in harm to patients," Reinhard says. "Our physicians at the bedside are working faster and longer than they have in many years, and there are shortages in some clinical domains that are predicted to only get worse, not better, in coming years."

Craig Hospital created its Healthy Healer program two years ago to help nurses address their stress in a positive way, encouraging them to be more at ease during patient interactions and better able to focus on providing proper care. The program has been expanded to include physicians and other clinicians.

One aspect is a designated quiet room for staff who just need a few minutes to get away. "They can walk in to this space and there's a chalkboard where they can write inspiring comments to each other," Reinhard says. "There's a yoga mat for stretching. It's intentionally a very simple, quiet, calming place that only our staff have access to. It's to reinforce that we recognize their work is hectic and we give them this really sacred space where they can take a moment to recenter."

The Healthy Healer program also encourages physicians and staff to pause before entering a patient room and take a moment to clear their minds, purposefully orienting themselves to the patient's needs at that moment. The hospital has long used a chime system that rings throughout work areas at 10 minutes before the hour, originally to alert staff that the hour was almost up and they should wrap up therapy sessions and similar work. Now, the hospital also uses that chime to remind staff to pause for a moment to clear their heads.

"There are so many things going on in their minds that the risk comes when they're just trying to juggle too much. They need to be present with that patient when they walk into the room, not thinking about all the other things that bring them stress," Reinhard says. "We've heard from our staff that it makes a difference for them know it's OK to just stop, take a minute before getting on with work."

The hospital also offers yoga and meditation sessions twice a week for staff. After its inception, the program was taken over by the human resources department and turned into a 360-degree culture group that works to relieve stress and reward employees with things like spontaneous recognition of a department.

"It's to constantly remind people that they have permission to stop and take a breath. We want to do whatever we can do in the moment to help with that," she says. ■

to counter the forces that worsen burnout and work to enhance the reasons for clinicians to find pride in their work." *(An abstract of the report is available online at: https://bit.ly/2jXh5P4.)*

High Cost of Burnout

Clinician burnout also can lead to high turnover rates, which bring additional patient safety risks, Lee says. The rule of thumb in healthcare is that the economic hit to the organization when a staff member or physician leaves is equal to 1.5 times that person's salary, he explains. Enough people leaving can have a financial effect on the organization that also can affect safety.

Healthcare organizations must pursue three major methods to address stress and burnout, Lee says. First, they must eliminate unnecessary work burdens and impediments to the workflow. Second, organizations have to reinforce the internal satisfaction of providing healthcare to others, the reason that people go into this line of work, Lee says. The third focus should be improving the resilience of people, the ability to adapt to the unexpected and the unpleasant.

"People are able to do that when they feel they are part of an organization that makes them proud," Lee says. "It has the right values and is trying to do the right things." ■

SOURCES

- Mary Bemker-Page, PhD, MS in Nursing program, Walden University, Minneapolis. Phone: (844) 768-0132.
- Thomas H. Lee, MD, Chief Medical Officer, Press Ganey, South Bend, IN. Phone: (800) 232-8032.
- Bette McNee, RN, NHA, Clinical Risk Management Consultant, Graham Company, Philadelphia. Phone: (215) 701-5429. Email: bmcnee@grahamco.com.
- Helen Hrdy, Senior Vice President, Customer Success, NRC Health, Lincoln, NE. Phone: (800) 388-4264.
- Robert Morton, BA, ARM, CPHRM, CPPS, Assistant Vice President, Patient Safety and Risk Management, The Doctors Company, Napa, CA. Phone: (800) 421-2368.
- Herman Williams, MD, MBA, MPH, Managing Director, The BDO Center for Healthcare Excellence & Innovation, Chicago. Phone: (312) 856-9100.

Oncology Unit Improves Safety and Culture With Focus on Relationships

An oncology unit at a Washington, DC, hospital has improved patient safety by focusing on "relationship-based care," a model that aims to help nurses focus more on caring for and connecting with other people.

The 5E Medical Oncology/Hematology Unit at MedStar Washington Hospital Center recently received AMSN Premier Recognition In the Specialty of Med-Surg (PRISM) Award. It is co-sponsored by the Academy of Medical-Surgical Nurses (AMSN) and the Medical-Surgical Nursing Certification Board.

The unit had made strides in recent years in improving quality and safety on the unit as well as the overall culture, explains **Rebekah Groff**, RN, BSN, OCN, patient care manager on the 5E unit.

"We were establishing relationship-based care with each other and with our patients," Groff says. "Oncology patients are a vulnerable population, with lots of issues associated with infections. The hospital helps us address those infection risks, but as a unit we wanted to band together as a team and strive to prevent infections in these patients with whom we've established these wonderful relationships."

The relationship approach resulted in reduced infections and falls, and staff retention rates climbed, says **Jane McGee**, MSN, RN, CMSRN, RN-BC, senior nursing director for medical and behavioral health services at MedStar Washington Hospital Center. She was the senior nursing director for 5E at that time.

As part of the improvement efforts, McGee and Groff realized that they needed more certified nurses on the unit. MedStar Washington Hospital Center created a program that presents review courses on several certification exams, and staff can take the exam for free. The oncology unit urged nurses to participate.

The unit also sought to improve the education of techs and other staff besides nurses.

"We wanted to make sure we were retaining our staff because that allows you to cultivate and maintain those really good relationships on

the unit that ultimately helps to reduce infections because everyone is working together," Groff says. "We also made sure that everyone on the unit, down to our unit techs and clerks, were involved with reducing falls and infections. If our unit clerks hear a bed alarm down the hall, they may get up from their desk and go check on that patient and call the appropriate people in."

The unit also sent nurses to participate in the hospital's central line-associated bloodstream infection committee, Groff notes. They also re-educated staff members on fall prevention to make sure they were conducting proper fall assessments, checking bed alarms on hourly rounds, and proactively toileting patients.

After those changes, the unit went six months without a fall and has maintained a very low fall rate. McGee attributes that largely to the unit staff's policy of taking patients to the bathroom whenever they are in the room, rather than waiting for the patient push a call button or try getting out of bed on their own.

"We also emphasized that we are responsible for all of the patients on our unit. A patient is not Jane's patient or Susie's patient, but rather we all collaborate. If you hear an alarm, you go in and assist the patient," Groff says. "The central theme was developing relationships with each other and with the patients, which ultimately will help keep the patient safe." ■

SOURCES

- **Rebekah Groff**, RN, BSN, OCN, Patient Care Manager, 5E Unit, MedStar Washington Hospital Center, Washington, DC. Phone: (202) 877-7000.
- **Jane McGee**, MSN, RN, CMSRN, RN-BC, Senior Nursing Director, Medical and Behavioral Health Services, MedStar Washington Hospital Center, Washington, DC. Phone: (202) 877-7000.

MSU Expands Risk Management, Adds Additional Safeguards

Michigan State University has expanded its risk management program after the arrest and conviction of Larry Nassar, a former USA Gymnastics national team doctor and osteopathic physician at the university, for the sexual abuse of minor patients.

MSU has been upfront about its improvements, issuing public statements about its progress, but declined interview requests from *Healthcare Risk Management*.

MSU recently signed an agreement with the U.S. Department of Health and Human Services to make further improvements. The university has made these changes:

• In April 2017, the university established a policy requiring chaperones for "sensitive treatments and when minors are involved." *(The new MSU chaperone policy is available online at: https://bit.ly/2kubrUX.)*

• MSU developed a standardized consent-to-treat form that acknowledges the chaperone policy and other permissions. *(The form is available online at: https://bit.ly/2lGt8Rh.)*

• MSU expanded the role of the risk manager. Based on recommendations from an independent review conducted by Willis Towers Watson, the university created new committees, including the Steering Performance Committee, Wellness and Patient Experience Committee, Quality and Patient Safety Committee, and Credentialing Certification Committee. *(The Willis Towers Watson report on improving patient safety at MSU is available online at: https://bit.ly/2jZG8B6.)*

• Health clinics at MSU implemented a triage protocol to review all allegations of inappropriate interactions between providers and patients or students. A multidisciplinary team reviews allegations. If there is any concern, the university immediately removes the provider from patient contact while investigating.

MSU plans to assign a new "civil rights specialist" to all buildings containing health clinics. This person will serve as a first point of contact for complaints, as well as a monitor of policy compliance. ■

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CME/CE QUESTIONS

1. **What does David Feldman, MD, chief medical officer with The Doctors Company, say is a key contributor to the breakdown of the informed consent process?**

   a. Time constraints
   b. Physician apathy
   c. Patient disinterest
   d. Complex hospital requirements for documentation

2. **What does Peter Kolbert, senior vice president for claims with Healthcare Risk Advisors, cite as another threat to the informed consent process?**

   a. EMRs do not require documentation of consent.
   b. Physicians may focus so much on documenting consent in the EMR that they lose track of the real purpose of informed consent.
   c. Risk managers do not put enough emphasis on documentation of consent.
   d. Risk managers do not adequately maintain consent records.

3. **What is one reason stress is increasing for nurses and other healthcare employees, according to Bette McNee, RN, NHA, clinical risk management consultant at Graham Company?**

   a. Hospitals are limiting their work hours.
   b. Hospitals are requiring more overtime and weekend hours.
   c. The increased size of the typical patient puts more physical stress on nurses and other employees.
   d. More nurses are employed with a lower level of training than in years past.

4. **What was the common theme in the quality and patient safety improvements made in the 5E Medical Oncology/Hematology Unit at MedStar Washington Hospital Center?**

   a. Relationship-based care
   b. Zero mistakes
   c. Patients belong to only one nurse
   d. Innovation trumps tradition

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

Negligent Thyroid Surgery Results in $2.2 Million Verdict

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News: A patient underwent total thyroidectomy as treatment for papillary thyroid carcinoma. During the surgery, the patient's left recurrent laryngeal nerve was severed and the physicians significantly removed or damaged her parathyroid glands. A lead physician handled the right part of the nerve and permitted a far less experienced resident to handle the left nerve. The patient requires a permanent tracheostomy and suffers from constant psychological and emotional distress related to her medical conditions.

THE PATIENT REQUIRES A PERMANENT TRACHEOSTOMY AND SUFFERS FROM CONSTANT PSYCHOLOGICAL AND EMOTIONAL DISTRESS RELATED TO HER MEDICAL CONDITIONS.

The patient filed suit against the government because the surgery occurred at a military hospital under her husband's Navy healthcare plan. After a three-day bench trial, a federal judge agreed that the physicians were negligent and awarded the plaintiff the state's statutory maximum of $2.2 million while acknowledging that the patient's damages greatly exceeded that maximum.

Background: In 2015, the 37-year-old patient, a wife of an active-duty Navy servicemember and a mother of four, was found to have an enlarged thyroid gland, according to an MRI. A subsequent ultrasound revealed a mass in the area of her right thyroid and smaller lobe nodule. The patient was referred to an otolaryngologist at a hospital operated by the U.S. Department of Defense, which provides healthcare to military servicemembers and their families. The physician scheduled a fine needle aspiration (FNA) biopsy to determine whether the mass was malignant, and opined that the patient would likely have to undergo surgery. The biopsy indicated that the patient tested positive for papillary thyroid carcinoma.

Based on the patient's preoperative scans and the result of the FNA biopsy, the patient's physicians recommended that she undergo a total thyroidectomy, followed by postoperative radioactive iodine treatment. While the physician claimed to have advised the patient about the risks involved with the total thyroidectomy, the patient claimed that she did not remember whether the physician actually provided any of the counseling and there was no evidence that the physician explained the risks.

During the procedure, the physician was assisted by a chief resident in his fifth year who was approximately two months from completing his residency. The resident had not treated the patient before surgery. The lead physician began to dissect around the patient's right lobe, and the physicians observed that the mass was invading the right recurrent laryngeal nerve. However, the lead physician permitted the resident to work on areas around the patient's left nerve. Because of the patient's condition and the right nerve's impact from the cancerous mass, the preservation of the left nerve was critical: If the left nerve also was compromised, the injuries would be catastrophic. The resident attempted to dissect the left thyroid lobe,

but the lead physician discovered that the resident transected the left recurrent laryngeal nerve. Thus, the patient requires a permanent tracheostomy, constant medical care, and attention.

The patient filed suit, alleging that the physician failed to provide care consistent with the applicable standards by permitting the resident to lead at a critical time and by failing to consider a partial removal, which would have avoided the left nerve completely. During the trial, five lay witnesses, including the patient and her husband, and seven expert witnesses testified. The patient testified about her extreme psychological and emotional distress related to her medical conditions, including living in a state of hypervigilance to keep her tracheostomy clear and functioning correctly. A life care plan expert testified that the physical medical care alone would cost more than $3 million.

Following a three-day bench trial, the judge agreed that the physicians were negligent and that the patient's damages exceeded the statutory maximum of $2.2 million.

What this means to you: One of the primary lessons from the case for physicians and care providers is that assistant physicians, including residents, may be subject to liability for failing to provide services within the standard of care as well, and that standard does not change for a resident still in training. Surgery on or around the thyroid always is high risk. Intense training, supervision, and proctoring are required before a surgeon is considered competent enough to be credentialed for that procedure. If possible, the physician should ask an experienced surgeon available to step in when complications develop or to perform the more critical parts of the procedure for which the primary surgeon may not be fully prepared.

While it is expected that physicians in training, particularly surgeons in training, will participate in procedures, the trainee must be properly supervised and provided the opportunity at the appropriate time. That responsibility and liability falls to the supervising physician, and in this case, the injured patient alleged that the physician was negligent by permitting the resident to take the lead at a critical time in the procedure.

It is unusual for a resident, medical student, or others in training to be named in legal action or financially responsible for damages unless they are found to have acted outside of their scope of practice with intent to harm. The patient also must be informed, in writing and consent, that there will be others participating in the surgery. Participants must be named by level of expertise, such as residents, medical students, and technicians.

Another important lesson for physicians and care providers concerns providing thorough information to patients about the nature and purpose of a specific course of treatment or procedure, the potential risks, and alternative courses of treatment. Absent emergency circumstances where there is not sufficient time to provide information, providing this information is necessary as patients are entitled to make a fully informed decision about their medical treatment.

By its very nature, informed consent must be individualized to the specific patient and that patient's circumstances. Typically, the "informed consent" standard is that a physician must disclose whatever information is "material" to the patient's decision. There are no hard and fast rules about percentages of risks, such that a physician must inform the patient if there is an X% risk of significant injury, the physician must inform the patient. Instead, the standard is more flexible, and physicians and care providers may opt to be overly cautious and inform patients about risks with low probabilities (especially if the corresponding harm from such a risk is great).

In addition to providing the information to patients, an equally important part is contemporaneously documenting the provision of information. It is important for physicians and care providers to tailor the information specifically to each patient and their course of treatment. Standardized consent forms that are not customized are not recommended. A form may be used, but should be individualized to the specific patient and the specific information provided.

Physicians and care providers must be mindful to document thoroughly the circumstances of the patient's consent, as a patient may subsequently not recall whether or when the physician provided the information. In this case, the physician claimed to have advised the patient about the procedure and risks, but there was insufficient evidence other than the physician's own testimony to support the claim. A written document created contemporaneously goes a long way in defending claims about a lack of informed consent, and getting a patient's signature on a written consent form is ideal. If a medical malpractice case arises, it often will be tried years after the underlying events and the memories of all the individuals involved will be less

reliable than contemporaneous written documentation. It also is prudent for the physician to document that the patient understands and can verbally repeat the information presented to him or her. This brings informed consent full circle because the patient must take an active part in the discussion, and not just be a passive listener.

Fortunately for the liable defendant in this case, a statutory maximum limited the amount that the injured patient was permitted to recover — and the court even opined that the injuries greatly exceeded that maximum. While jurisdictions treat these issues differently, many states set maximum amounts that injured patients are permitted to recover; these maximums are legislative policy decisions designed to reduce the ever-increasing costs of insurance for physicians and care providers. Such maximums should not be considered when providing underlying care to patients, but in the event that a medical malpractice claim is subsequently brought, physicians and care providers should review these maximums, if applicable. Knowledge that the claim is capped may facilitate strategic considerations or influence settlement discussions, permitting physicians to resolve disputes more efficiently with injured patients while avoiding additional legal expenses incurred defending a malpractice action. ■

REFERENCE

Decided on July 23, 2019, in the United States District Court for the Eastern District of Virginia, Case Number 1:18-cv-821.

Physician Not Liable for Alleged Complications After Gallbladder Removal

News: A patient was admitted to a medical center with complaints of abdominal pain and gallstones. A physician removed the patient's gallbladder via laparoscopic cholecystectomy. The patient was discharged three days later, but returned to the medical center three days after that with difficulty breathing, syncope, and hypotension. The patient presented to two other medical centers, receiving different diagnoses and treatments, and she underwent multiple procedures, including removal of her spleen.

The patient filed suit, alleging that the first physician negligently contacted the wall of the patient's artery and cut into the patient's liver. The physician denied any liability and brought a motion for summary judgment, arguing that the patient could not establish causation. The court agreed and granted the physician's motion. The patient appealed, but the appellate court upheld the ruling.

Background: In 2013, a patient presented to a medical center complaining about abdominal pain and gallstones. A physician removed the patient's gallbladder using a procedure known as a laparoscopic cholecystectomy. The patient was discharged three days after the procedure. However, the patient returned to the same medical center three days after discharge, suffering from difficulty breathing, syncope, and hypotension.

The same physician evaluated the patient and admitted her to the ICU. The patient was provided with blood products and electrolyte and fluid support based on the evaluation. Two days later, the patient was transferred to a different medical center; she underwent an exploratory laparotomy and evacuation of a hematoma by a second physician.

Eleven days later, the patient returned to the second medical center and received a CT scan that revealed a pseudoaneurysm of the splenic artery. The next day, the patient went to a third medical center, suffering from abdominal pain and syncope. She was diagnosed with possible pancreatitis and underwent multiple procedures, including an attempted splenic artery embolization and an exploratory laparotomy during which her spleen was removed.

The patient filed suit against the first physician, medical center, and others. The patient claimed that the initial physician's instrument came into forceful contact with an artery supplying blood to the patient's spleen, and that the physician cut into the patient's liver. The patient initially alleged that the physician's postoperative conduct was negligent, including negligently prescribing blood-thinning medications, but abandoned that claim on appeal.

The defendant physician deposed the patient's expert witness on the standard of care and causation, two important elements necessary for medical malpractice claims. After the deposition, the defendant contended that the patient could not establish causation that the physician's actions actually caused the patient's injuries. The defendant brought a motion for summary judgment, which is a

motion that seeks adjudication by the court when there is no dispute of material facts or when a plaintiff cannot satisfy a necessary element of a claim. The defendant relied on the plaintiff's expert's deposition, in which he testified that bleeding is a risk associated with a laparoscopic cholecystectomy, even when the procedure is performed correctly.

The court agreed with the defendant physician and found that the plaintiff's expert failed to demonstrate causation, and that the legal doctrine of res ipsa loquitur, which implies negligence based on an injury, did not apply. The plaintiff appealed, but the appellate court upheld the lower court's ruling.

What this means to you: This successful defense case reveals potent methods for defeating medical malpractice claims. On the substance, the defendant physician successfully challenged one of the necessary elements that an injured patient must prove when alleging medical malpractice: causation. Causation includes factual and legal aspects, where the physician's actions must have been a "substantial factor" in contributing to the patient's harm, but there may be an intervening action or event that cuts off the physician's liability. If the risk of injury exists, even when a procedure is performed correctly, then simply because an injury occurred does not mean that the physician was negligent.

The legal doctrine of res ipsa loquitur provides for a "common sense" inference of negligence when there is no direct evidence of the defendant's conduct, but an injury occurred and the specific injury does not occur in the absence of negligence. However, for a jury to consider this doctrine, the injured patient must produce sufficient evidence to draw the common sense inference — evidence that the kind of injury only occurs when a physician has been negligent.

Laparoscopic procedures are advantageous because the incisions are tiny and the patient recovers quickly with less pain. The physician can view the operative area using instrumentation that enlarges the visual field. A disadvantage of the laparoscopic approach is that the physician may be unable to visualize a larger area surrounding the surgical site and thus be unaware of a surgical injury, such as a laceration of a blood vessel or puncture of a nearby organ. The operative report, which must be completed as soon as possible after surgery, will not mention any untoward event occurring during the procedure and no rescue interventions will be taken at the time the injury occurs. The problem will not be identified until the patient seeks medical attention due to the injury. This may be days, weeks, or even months after the injury. To mitigate any possible litigation, the physician must ensure that the patient is aware of the risks inherent in the laparoscopic procedure and immediately return to the hospital if any symptoms, such as fever, excessive pain, weakness, dizziness, or other more obvious signs of bleeding, occur.

Expert testimony commonly plays a critical role in determining whether the causation element has been satisfied, among other standards. Therefore, the selection and retention of an expert may make or break a party's case, as may the expert's deposition. In this case, the patient disclosed a single expert who opined on the standard of care and on causation, and the defendant physician deposed the expert. Depending on the expert's familiarity with the legal process and depositions specifically, the expert may be adept at providing savvy answers that skirt the line and satisfy the applicable legal standards. But it may be the case that the expert's answers are patently insufficient, as here, and an expert's opinion that a required element is merely "possible" may be an appropriate avenue to challenge the patient's allegations. It is important for physicians and care providers to work closely with their own retained experts as well as counsel in preparing for a thorough and calculated deposition of a patient's expert to evaluate all potential methods for challenging the patient's claims.

An important lesson from this case revolves around the particular procedural challenge that this defendant physician raised. Here, the physician brought a motion for summary judgment, which seeks adjudication by the court before the matter proceeds to a jury. This motion is appropriately brought when there is no dispute of material facts or when a plaintiff cannot satisfy a necessary element of a claim. In this case, the defendant physician challenged the patient's ability to prove causation because of the deposition from the patient's expert witness. The patient's expert testified that he was "not certain what" the defendant did that caused the damage and wavered by claiming that the instrumentation was a "possible" cause of injury. The expert was unable to say whether the injury was actually caused by the defendant physician's use of a trocar, or by postoperative pancreatitis. The court found that this uncertain testimony was insufficient to permit a jury to infer that the patient's injury would not have occurred absent negligence. ■

REFERENCE

Decided on July 30, 2019, in the Arizona Court of Appeals, Case Number 1 CA-CV 18-0444.