



HEALTHCARE RISK MANAGEMENT™

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Preoperative Assessments Can Be Weak Point, Increase Liability Risks

The preoperative assessment of patients is intended to uncover any potential health issues that could complicate surgery and threaten patient safety. Sometimes, the assessment can turn into a routine list of questions the patient answers without much thought. This can lead to complications and potential liability.

An effective pre-op assessment requires clinicians to carefully listen to a patient's responses and probe more when necessary.

Although many surgeries are conducted daily across the world without incident, undetected disease, known diseases, chronic illness, and other risk factors may increase the risk of surgical complications, notes **Kim Hathaway**, MSN, RN, CPHRM, CPHQ,

healthcare quality and risk management consultant with The Doctors Company, a medical malpractice insurer in Napa, CA.

A pre-op assessment is a standard element for accreditation and regulatory agencies. Many professional associations provide guidelines for conducting the assessment. Also, it is the key data point

to determine the safest

location for a surgical procedure, Hathaway says.

Potential surgical candidates with known conditions — ranging from minor upper respiratory illness or a cold to chronic conditions such as diabetes or heart disease — increase the risk of complications, she says. The procedure

and length of anesthesia

time must be evaluated in

the context of the individual's health. The pre-op assessment evaluates

UNDETECTED DISEASE, KNOWN DISEASES, CHRONIC ILLNESS, AND OTHER RISK FACTORS MAY INCREASE THE RISK OF SURGICAL COMPLICATIONS.

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EDITORIAL QUESTIONS
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whether conditions are controlled, thus lowering their risk, or out of control, which increases the risk of complications.

The surgeon's history and physical (H&P) should focus on whether the patient can undergo the surgery, Hathaway says. Patients with underlying comorbidities may be referred for clearance or surgical optimization by a specialist.

When a surgery is planned and elective, there is time to optimize the patients' health status. "Generally, an H&P is conducted within 30 days of the procedure and submitted to the hospital for review by the surgical team, including the anesthesia provider. The anesthesia provider will often call the patient several days out and ask additional questions related to anesthesia to verify information and provide pre-op education," Hathaway says. "Included in that discussion are family members' reaction to anesthetic agents that may be hereditary to the patient, withholding food and liquids, what meds to take, the timing of the meds, and whether they should bring their meds to take immediately postoperatively."

Specific Risks

The anesthesia provider also will record an initial score based on the ASA Physical Status Classification

System, and will assess the patient again on the day of surgery. This score is helpful to suggest the setting of hospital vs. outpatient, Hathaway explains.

"The very young and very old patients have different risk factors, including frailty, than a healthy adult. Understanding normal anatomy and age-specific variations or anomalies may be detected in the physical exam and provide vital information for the surgical team," she says. "Assessing the length and shape of the neck and tongue helps the anesthesia provider know if there will be any challenges related to intubation."

Smoking is an independent risk factor for complications related to breathing and wound healing. It also may contribute to cardiac and other vascular events, Hathaway notes. The pre-op assessment performed several weeks before surgery can provide time for the patient to quit smoking, decreasing the risk by lowering blood pressure.

Patients with diabetes should undergo a hemoglobin A1c test. A high hemoglobin A1c may be grounds to reschedule an elective procedure, she says.

"A second assessment is also done, and is a regulatory standard, on the day of surgery just prior to induction. Nurses and the anesthesia provider will take vitals and ask

EXECUTIVE SUMMARY

Preoperative assessments are critical to patient safety and reducing liability risks. Some assessments are inadequate and fail to identify risks that could be avoided.

- Nurses may be more effective in conducting assessments than physicians.
- Do not rely solely on online questionnaires.
- Train nurses and physician assistants to probe deeper when patient answers are insufficient.

questions to determine if there have been any changes, and will answer any remaining questions the patient may not have had an opportunity to ask,” she says. “The surgeon also will review the record again and ask if anything has changed. If there is a left/right surgery, it is an opportunity to review that all records have the correct procedure, patient, side, and site.”

When surgery is urgent or emergent, a good assessment can assist the surgeon and anesthesia provider in formulating the best plan for the patient despite the fact they did not have a longer preoperative period to “tune up” the patient with pre-existing conditions or risk factors, Hathaway explains. It is especially critical because often there is no history with that patient and no time to obtain records from prior care, she says.

Research Shows Assessments Vital

The authors of a paper published by the American Society of Anesthesiologists found that adequate preoperative assessment and evaluation and communication are among the most common contributing factors to preventable adverse events. (*That study is available online at: <https://bit.ly/3fcYIC6>.*)

Similarly, The Doctors Company Anesthesia Closed Claims Study revealed inadequate H&P often led to improper management of patients under anesthesia. These complications were caused by comorbidities present before the patient was taken to surgery. (*The study is available online at: <https://bit.ly/30tQUCp>.*)

“We found in our study that 67% of the patients had at least one comorbidity. Obesity as a risk

factor impacted patients’ care in almost three times as many cases as other anesthesia cases,” Hathaway says. “Obstructive sleep apnea common in obese patients was six times more likely to impact the outcome. Hypertension was three times more likely to impact patient’s surgical results. The conditions were unrelated to the purpose of surgery, but ultimately, they were the cause of the patient harm.”

It appears many patients were unhealthy before surgery. A good preoperative assessment may have provided clues to where trouble may arise., she says.

These patients suffered high-severity injuries in 62% of cases compared with 16% of high-severity injuries in all other anesthesiology cases (excluding tooth damage cases).

H&P Guidance Available

The assessment is a focused, quality H&P, which includes review and analysis of all the information available that would apply to the procedure and the patient. There is substantial guidance from surgical, anesthesia, and other specialty organizations that describe the elements of a good assessment, Hathaway notes.

H&P is foundational to all healthcare professions, she says. “The key is to follow those recommendations and to assure the results are available in a timely manner for the healthcare team to evaluate the risks for each individual and construct the perioperative plan that is the safest. If there are cardiac issues, there are specific guidelines to optimize the patient’s condition. If they have diabetes, lung disease, or neurological disorders, the specialty will usually be consulted prior to surgery to minimize the

risk, and perhaps follow the patient post-surgery,” she says. “There are tools that help to stratify the risk of patients. The ACS NSQIP [American College of Surgeons National Surgical Quality Improvement Program] Surgical Risk Calculator helps the physician evaluate the risk of complications or even death based on patient factors and type of surgery.”

Still, pre-op assessments can fall short. The Doctors Company Anesthesia Closed Claims Studies revealed that “production pressures often limited testing and input from attending or referral physicians. These pressures also limited anesthesia professionals’ opportunities to recommend safer locations for anesthesia care (e.g., hospital operating room vs. ambulatory surgery, GI, or cardiac labs) or to prepare for complications that might occur as a result of multiple comorbidities or complicated health histories.”

Patient assessments were closely linked to allegations related to failure, delay, or wrong diagnoses, Hathaway says. The physical examination (PE) always has been an integral part of medical practice. But new technologies, widespread use of electronic health records, and changes in medical school curricula are contributing to its rapid decline, she says.

“It is paramount that at the time there is a determination to proceed with an elective procedure, the proper attention must be given to the length and depth of the pre-op assessment. The surgeon’s H&P is one factor, but the optimization of the patient’s physical state is paramount to a successful outcome,” Hathaway explains. “Understanding the patient’s exercise ability, to walk without getting winded, or functional capacity is inversely

related to complications. Therefore, it is extremely important to tune up a patient's health status, particularly when comorbidities are present."

Hathaway points out the questionnaires provide preliminary data that must be validated at several levels. It is not a standalone document or data point. A questionnaire is given in the surgeon's office, and the hospital or surgery center also will require a health history questionnaire at admission. This typically is the first document used to capture data for a physician's H&P, and it always should be clarified and reviewed with the patient, she says.

"This H&P examination is a regulatory requirement. If it is not done or not present, it needs to be completed and on the medical record before the patient can go to the OR suite," she explains. "Everyone involved in the case usually reviews that document and the patient's self-reported history, asks clarifying questions, and then adds or amends the medical record to include any missed information. It is vital that discrepancies be communicated and clarified among the surgeon, anesthesia provider, and nurses who care for the patient."

Probe Deep for Useful Answers

The pre-op assessment should be completed at the surgery center or hospital rather than relying on the information supplied by the physician's office, says **Catherine Ruppe**, RN, associate principal with ECG Consultants in Seattle.

"We got the history and physical that the physician's office sent to us, but also did our own, side by side," Ruppe says. "We talked to

every patient ahead of surgery and would ask thorough questions, head to toe. Sometimes, we would find that the surgeon would do a cursory assessment and not delve into the details, whereas I found that the nursing staff was good about digging deeper."

For instance, a patient may reply to a question about blood pressure by saying he or she has no hypertension issues. But then the nurse can follow up by noting the patient is taking three different blood pressure medications, and seek clarification, Ruppe says.

"The doctor may ask that question, and when the patient says no, the doctor might just move on," Ruppe says. "We'd like to think everyone is doing a thorough job every time, but we did see a difference in how nurses approached that task. That proved critical in getting meaningful pre-op assessments."

At her surgery centers, nurses focused specifically on family history issues that could suggest a risk of malignant hypothermia, which would require moving the surgery to a hospital setting or altering the anesthetic plan, Ruppe says.

Ruppe notes she worked closely with the surgery centers' risk manager. Any patient safety incidents prompted an incident report, and they would review the significant incident reports together. Often, the risk manager's first question was about the pre-op assessment.

"We always wanted to know if we missed anything. Was there anything that could have been detected in the pre-op assessment that could have flagged this particular issue?" Ruppe says. "That was not always the case, but she was always very interested in taking a look at the pre-op assessment as a primary way of seeing if this issue could have been avoided."

The ability to conduct a good pre-op assessment comes with time and experience, Ruppe says. The key is to listen carefully to what the patient is telling you and putting that together with what you are seeing with the patient, or what you have reason to suspect might be true despite what the patient is saying or not, she says.

Nurses must engage with the patient in a meaningful way rather than just asking rote questions and recording their answers, she says. That does not always happen when physician offices ask patients to go online and complete the same health questionnaire a nurse would give, Ruppe says.

The online questionnaire is efficient, saving time over asking patients to complete the survey on site. But it is only a starting point for the pre-op assessment, she says.

"We found that if we relied on just the patient and not having the nurse review and ask some of the questions again, the online answers were not enough. You forget things that didn't seem significant to you until someone probes more, like a family history that didn't seem pertinent until the nurse asks," Ruppe says. "A few minutes on the front end can save a whole lot of misery on the back end."

Train to Listen

Nurses should be regularly trained on the importance of a thorough pre-op assessment, Ruppe says. She notes that physician assistants (PAs) conduct assessments in some practices, so they should be trained, too.

"We worked with the PAs of an orthopedic practice we worked with regularly. By training them to listen with kind of a different ear, their

assessments were much better, much more thorough,” she explains.

Risk is relative, and the mortality risk will differ substantially among various procedures, notes **Charles Dinerstein**, MD, MBA, FACS, FSVS, medical director at the American Council on Science and Health in New York City, and a former vascular surgeon.

For example, the 1-5% mortality risk associated with vascular surgery is far too high for the 1% or so risk associated with cosmetic surgery or orthopedic surgery, he says.

“That said, you try and identify the salient risks that can be modified. Being massively overweight carries risks but cannot effectively be managed in a short time frame. Smoking can, and many physicians require smoking cessation for six weeks before elective treatment,” Dinerstein says. “The other classic problems would include stable management of chronic conditions such as hypertension or diabetes. You do not want to operate on a patient whose blood sugars are out of reasonable control. You also want to identify real but unidentified risks — the greatest being cardiovascular disease, especially coronary disease — because the stress of surgery may result in a perioperative myocardial infarction, which carries a greater mortality risk.”

Preoperative assessment also is a time tradeoff, Dinerstein says. In his experience, referring a patient for cardiac evaluation meant delaying surgery by four to six weeks. While that may be reasonable for some elective surgery, some urgent surgery cannot be delayed that long.

“The ultimate risk manager is frequently the anesthesiologist who completes a preoperative assessment and may delay surgery by not providing anesthesia services until they are

satisfied it is safe. What is ‘safe’ can sometimes be gray,” he says. “Preoperative assessment is a fertile area for medical malpractice hindsight. Many surgeons request preoperative clearance from primary care physicians or specialists hoping to both deflect possible responsibility and provide, in a fee-for-service world, a form of thank-you for referring the patient.”

There is a lot of pushback from primary care physicians who have to perform many clearances, Dinerstein says. These physicians often complain they are not clearing the patient for surgery, only reviewing their current medical status.

There also has been a push to standardize these assessments with preoperative evaluation programs, Dinerstein says. These programs were developed, in part, as a cost-saving measure because of routine testing that had no value.

“The poster child here is the chest X-ray, which rarely provides any information to assess risk or improve care,” Dinerstein says. “The same holds for cardiac evaluation in patients without risk factors.”

Preoperative assessments should be designed to provide a comprehensive view of the patient’s health history and status, detect any unknown conditions, and help create the best treatment plan for their procedure, says **Jennifer Kim**, product manager at Casetabs, a company based in Irvine, CA, that provides technology for surgery coordination. Further, the assessments should be easy for patients to complete, and efficient for clinicians to review and share among care teams to provide the highest quality of care.

The transition to online questionnaires improves efficiency at some hospitals and surgery centers. If carried out properly, they can improve patient safety, Kim says.

“The COVID-19 pandemic is forcing these health systems to practice new protocols to minimize risk of exposure, including how information is obtained from patients in advance of a procedure,” Kim says. “This is good news, as taking the preadmission process online enables patients to complete histories at a time that is convenient for them, which yields more thorough and accurate histories.”

Furthermore, in a post-COVID world, it is critical to ensure the patient experience is not overlooked, Kim says. Physicians must recognize preassessment as not just a routine process but as actual medical care, putting the patient at the center of the entire continuum of care.

“Engaging patients meaningfully and streamlining the process for staff through a more thoughtful preassessment experience ensures the best patient outcomes, as well as higher completion rates, shorter stays, and fewer cancellations,” Kim says.

Less comprehensive assessments can lead to major adverse reactions for the patient, including morbidity, mortality, or hospital admissions, Kim explains. All factors of the patient experience should be considered throughout the patient’s stay to deliver the highest quality of care, and not just in the operating room.

“Older patients, for example, can be at fall risk at the facility,” she says. “As health systems adopt more digital health solutions in a post-COVID world, it’s critical now more than ever that assessments are not only comprehensive in capturing all potential risk factors, but are simple for patients to complete and clinicians to access.”

Some physicians may view certain procedures as low risk, and therefore conduct less thorough assessments,

Kim notes. When this happens, it is easy to miss underlying and undetected conditions.

Risk managers can encourage better assessments by recognizing and communicating that assessments are not just a process, but are equivalent to actual medical care and set the stage for a patient's overall care experience, Kim says.

“Engaging patients meaningfully at a time when they are not rushed

and have all necessary information on hand minimizes the chance of risk factors being overlooked — factors which could have major implications on the patient's outcome,” she says. ■

SOURCES

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Some Attorneys Vow Not to Sue Over COVID-19 Care

Risk managers are bracing for what some fear will be a wave of malpractice claims related to COVID-19 care. However, some attorneys say they will not take these cases, arguing the treatment standard is unclear, and substandard care claims cannot be substantiated.

One attorney refusing to take COVID-19 claims is **Jack E. McGehee**, JD, founding partner at McGehee, Chang, Landgraf, Feiler in Houston. The firm focuses on representing plaintiffs in medical malpractice cases.

His experience in suing hospitals across the country has made him familiar with their risk management programs. McGehee says he is sympathetic to their position in the pandemic.

“For the first time in my life, I found myself aligning with what the healthcare providers are going through. We are fighting this enemy, and I know better than anybody that there is no standard of care for this pandemic in our hospitals,” he says. “I’m acknowledging that and I’m telling all my brethren that we need to be true to our word and bring lawsuits only when there is a clear departure from the standard of care. Since there is no standard of care for this, we have no business suing hospitals for COVID-19 cases.”

That does not mean that patients were not damaged during the pandemic, McGehee says. The question is how to prove that healthcare providers should have been expected to do more.

“There are going to be mistakes made and people will be hurt from those mistakes, but the question is whether those mistakes were made recklessly and whether they were made negligently,” McGehee says. “The definition of ‘negligence’ is a departure from what a reasonable person would do in the same or similar circumstances. We’re in uncharted territory and I don’t think there is a place for lawsuits in that territory.”

Other Attorneys Support Moratorium

McGehee was joined in the moratorium by Charles Brown, JD, managing partner with Brown Christie Green in Houston. Both firms posted notices on their websites and encouraged other plaintiffs’ attorneys to join them in refusing COVID-19 claims. The response from other law firms has been positive, McGehee says.

“We would like to pioneer the idea that we should stand down against these folks that we’re used to suing. We only sue them when they’re wrong, and I have more healthcare

EXECUTIVE SUMMARY

Some plaintiffs’ attorneys are vowing not to take cases related to care provided for COVID-19. Other attorneys may be eager to take those claims.

- The standard of care for COVID-19 is unclear.
- Do not automatically cave to claims that care was substandard.
- There may not be many lawsuits related to the pandemic.

providers on my side serving as my experts than I do on the other side that we're chasing," McGehee says. "The community needs to recognize that we're not enemies in this and share the same kindred spirit."

Some attorneys have replied with skepticism about the moratorium, but McGehee says their criticism always goes beyond the boundaries of what he supports regarding COVID-19.

"When I have fellow trial lawyers describe situations where the moratorium is bad, they're describing something that is a grossly negligent, callous disregard that goes beyond what I'm calling for in the moratorium," he says. "If healthcare providers all start writing prescriptions for hydroxychloroquine, I would have trouble with that. But as far as the standard of care cases

that I have spent a career pioneering, those cases don't belong there when they are based on COVID-19 care."

Lawsuits May Not Appear

McGehee says he does not expect a huge wave of COVID-19 lawsuits against healthcare providers. Some plaintiffs' attorneys will be tempted, particularly the younger ones who tend to lower their screening criteria when offered a case that involves death or a sensational aspect, he says. But McGehee expects most attorneys will realize the challenge of providing a deviation from the standard of care and will be reluctant to fund COVID-19 claims.

"That means hiring experts first, and that's not cheap," he says. "If you

just do a cost analysis, that argues against a wave of lawsuits being filed over COVID-19."

For risk managers who do face COVID-19 claims, McGehee offers strong advice: Do not automatically cave to COVID-19 claims just because they seem intimidating.

"I know a great many risk managers, and my message to them is to do nothing different, and continue to be motivated by the prospect that you're trying to help people," he says. "You're going to find problems, and you should own those problems to do better for the next patient. If you do that, I think you're going to be safe in the civil justice system." ■

SOURCE

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Compliance Oversight Necessary with COVID-19 Relief Funds

The federal government is providing billions of dollars in relief to hospitals affected by the COVID-19 pandemic, but risk managers must ensure compliance plans are adequate to oversee the money. Failure to comply with the government's require-

ments will leave hospitals at risk of substantial liability.

The funds from the Coronavirus Aid, Relief, and Economic Security (CARES) Act are not like the \$1,200 stimulus checks that many Americans received because that money came

free and clear of any requirements. The CARES Act funds come with a lot of strings attached.

The CARES Act provided more than \$175 billion in relief funds to hospitals, physicians, and other healthcare entities, notes **Peter Urbanowicz**, JD, managing director with Alvarez & Marsal in Dallas. Previously, he was principal deputy general counsel at the Department of Health and Human Services (HHS) with President George W. Bush's administration, and he was executive vice president, general counsel, and secretary of Tenet Healthcare Corporation.

The regulatory language for the funding specifies the funding should be used for costs related to COVID-19 treatment, and for any

EXECUTIVE SUMMARY

Funds provided to hospitals through the Coronavirus Aid, Relief, and Economic Security Act require careful compliance efforts to avoid substantial liability. The money comes with many strings attached.

- The government enacted substantial restrictions on how the money can be used.
- Funds not used for appropriate reasons must be returned to the government.
- The Department of Health and Human Services Office of Inspector General is expected to audit hospitals receiving the funds over the next two years.

lost revenues associated with the pandemic, Urbanowicz explains. All healthcare entities accepting the money must accept those conditions, which are spelled out in greater detail, he says.

HHS also requires the hospital or other entity to keep records specifying how the money was used. “There also are specifications on how the money may not be used. For example, they cannot use it for highly paid executives, using it to give them a big bonus,” Urbanowicz explains. “There are prohibitions that you typically find in federal grants, such as not using it for lobbying. As you accept these monies you need to have a process in place, create separate accounts in your general ledger, so that when you draw down this money, you know where it’s going. At some point there will be an accounting for this.”

Document Lost Revenues

Pay attention to using the funds for lost revenues, he says. There should be clear documentation of lost revenues for March and April 2020, with an explanation of those figures — a year-over-year comparison, against budget, or another method.

“Commit to a methodology so that one or two years from now when the Office of Inspector General [OIG] does audits of this money you have a methodology that you followed, and you can demonstrate what your losses were. You won’t have to do it after the fact, or even worse, try to do it at the time of the audit,” he says.

There is danger in accepting the HHS funds too casually, Urbanowicz says. The healthcare entity cannot just deposit the funds in general revenue

and continue to run the business normally with no special accounting of those funds, he explains.

“Whether it is \$10,000 or \$10 million, you must have a careful accounting system that demonstrates where you transferred all that money,” he says. “That is the No. 1 pitfall — not having an accounting system in advance to show where that money is going.”

The funds are restricted in ways that will be familiar to academic institutions that receive federal grant money, Urbanowicz says. For instance, grants from the National Institutes of Health specify many ways in which the money cannot be spent — executive pay, lobbying, gun control advocacy, embryonic research, marijuana advocacy.

“It’s also similar to receiving Medicare or Medicaid money. There,

you are providing a service; here, it is more open-ended. In both cases, you are signing something that potentially sets you up for a violation of the False Claims Act,” he explains. “If you were to take the money, sign the terms and conditions, and then violate them because you didn’t spend the money on something related to COVID-19, or the money you kept wasn’t equal to your losses, that can set you up for all kinds of violations of the False Claims Act with civil penalties and fines.”

Smaller Hospitals at Risk

Urbanowicz suspects larger organizations are better prepared for compliance with CARES Act requirements. Smaller hospitals may not be as prepared because they have less experience with government grants and may mistakenly assume

HHS DISTRIBUTING \$175 BILLION IN CARES ACT PROVIDER RELIEF FUND

The Department of Health and Human Services (HHS) is distributing \$175 billion to hospitals and healthcare providers to compensate for their coronavirus response. Through the Provider Relief Funds, \$50 billion is allocated proportional to providers’ share of 2018 net patient revenue.

“The allocation methodology is designed to provide relief to providers, who bill Medicare fee-for-service, with at least 2% of that provider’s net patient revenue regardless of the provider’s payer mix,” HHS explained. “Payments are determined based on the lesser of 2% of a provider’s 2018 (or most recent complete tax year) net patient revenue or the sum of incurred losses for March and April.”

Another \$50 billion is allocated for providers in areas hard hit by the pandemic, rural providers, providers of services with lower shares of Medicare reimbursement or who predominantly serve the Medicaid population, and providers requesting reimbursement for the treatment of uninsured Americans.

HHS also provided an additional \$15 billion in distributions from the Provider Relief Fund to eligible Medicaid and Children’s Health Insurance Program (CHIP) providers that participate in state Medicaid and CHIP programs.

More information is available online at: <https://bit.ly/3cNZSx0>. ■

their smaller grants require less oversight.

“Some healthcare organizations that don’t deal with government funding as much may not realize there are so many strings attached. They may have gone into the portal, got a sum of money, and attested to the terms, and that’s all they did,” he says. “Those are the ones that are really at risk, whether it’s six months from now or two years now. The OIG says, ‘Where did you spend that money? Were your losses really equal to the amount of the money we gave you?’ They will ask, ‘If you did not have legitimate use for the money, why didn’t you return it?’”

That is another important point, Urbanowicz says. Just because the CARES Act provides a certain amount of money, you do not necessarily get to keep it all. The hospital or other healthcare entity must justify how much was needed and used appropriately; the rest must be returned.

Some government relief funds are made specifically to hospitals that treated COVID-19 patients. Urbanowicz says hospitals must be careful in documenting that qualification. The amounts provided for this reason can be significant, he says, and the compliance requirements are strict.

“It has to be someone you can document actually had COVID-19, and not try to code a patient who came into the facility for something else and you can’t really determine if they died from the coronavirus. You can’t count up all those patients and lump them in so that you qualify for more funds,” he says. “There is a risk that some hospitals may have done that. It can come back to hurt them if the OIG audits turn up numbers that cannot be substantiated.” ■

SOURCE

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OSHA Enforcement Prioritizing Hazards Related to COVID-19 Response

The Occupational Safety and Health Administration (OSHA) stated it will prioritize investigations of complaints, referrals, fatalities, and hospitalizations related to the COVID-19 pandemic. That means risk managers should prepare to respond effectively to employee complaints or OSHA queries.

Allegations of workplace safety hazards, such as a lack of personal protective equipment (PPE), could prompt a full OSHA inspection, says **Joseph W. Dorr**, CIH, CSP, CHSP,

assistant vice president with The Graham Company in Philadelphia.

Although the agency does not use a standard specific to infectious disease, compliance officers could cite several other requirements, such as bloodborne pathogens, PPE, respiratory protection, or the general duty clause, Dorr says. OSHA also has emphasized that employers cannot retaliate against employees who allege unsafe work conditions related to COVID-19, he notes.

“Any employer-reported fatality,

inpatient hospitalization, or any complaints alleging high exposure risk without adequate PPE may warrant an on-site inspection or Rapid Response Investigation [RRI],” Dorr says. “While practicing social distancing as advised by the Centers for Disease Control and Prevention, OSHA compliance officers may conduct inspections using video conferences, phone interviews, and video recordings from the workplace. Conversely, complaints asserting medium- to low-risk tasks — from those in roles that do not have high potential for exposure — likely will be addressed through an informal process not involving on-site inspections.”

OSHA also has issued a directive to compliance officers, instructing them to consider employers’ good-faith efforts to comply with standards regarding annual training, auditing, inspections, and more, Dorr says. Because the agency realizes many

EXECUTIVE SUMMARY

The Occupational Safety and Health Administration (OSHA) has vowed to take a hard look at complaints and referrals related to employee safety during the COVID-19 pandemic. Healthcare employers should prepare to answer concerns about employee safety.

- OSHA may respond to complaints with a full inspection.
- Inspections may be performed remotely if social distancing is still in effect.
- The agency will consider employers’ good-faith efforts to protect employees.

employers are operating under unique and challenging conditions, this directive allows them some leeway with routine items, as long as the employer has made its best effort to comply and use alternative methods to ensure employee safety, he says.

OSHA is constantly updating its enforcement criteria and efforts as more is learned about the disease and its transmission, Dorr says.

“Healthcare facilities should be looking out for complaints from staff who feel they do not have access to proper PPE during this crisis, as it is imperative that employers provide proper PPE to protect against exposures to the virus,” Dorr says.

Some Risks Related to COVID-19

Employers are required to make a work-related determination of employee reports of COVID-19 illness, he says. This includes reporting fatalities and hospitalizations if determined to be work-related because of the coronavirus. OSHA had previously stated employers not in healthcare, corrections, or emergency response would not be required to record employee reports of COVID-19 infection because of its community spread unless they are aware of a workplace exposure, Dorr explains. But OSHA changed its enforcement guidance in May to require this reporting.

“Most importantly, if an organization receives Notice of an Alleged Safety or Health Hazard from OSHA, risk managers should carefully consider their response and immediately engage resources from their insurance broker to assist with answering the complaint,” he says. “A complete and detailed response can help satisfy a compliance officer’s request and

prevent the need for an on-site audit of the facility and program.”

Some compliance risks may be strictly COVID-19-related, but they are unlikely to disappear soon. Even if the pandemic subsided, some COVID-19 hazards will persist.

“The unfortunate reality of the situation is that COVID-19 is not going away any time soon. The healthcare industry and society in general will experience lasting effects, such as the continued use of face masks, increased handwashing, social distancing, and more, for the foreseeable future,” Dorr says. “While the path of the virus may subside, the risk associated will not. It is critical to learn from these experiences.”

The pandemic has served as a wake-up call for many organizations in all different industries, Dorr notes.

Many pandemic risk management programs were established for a hypothetical situation, proving difficult to follow in reality. Now, risk managers have to develop and implement them on the spot, then later refine and streamline, he says.

“Risk managers should take note of what challenges their organizations are currently experiencing so they can identify solutions to be better equipped in the future, should another pandemic or similar emergency situation arise,” he says. “Learning valuable lessons from this situation will ensure programs are well-documented and ready for rapid deployment in the future.”

Supply Scarcity a Challenge

One of the first challenges with the pandemic was the scarcity of necessary supplies, including PPE and cleaning chemicals. While most facilities had pandemic policies in

place, many were based on general infection control. As a result, the facilities did not have the supplies on hand to actually execute their emergency plans, Dorr notes.

“For risk managers preparing for similar situations or future pandemics, slowly building a reserve of necessary equipment and supplies will be key to prevent the fear and price gouging that arose in the face of limited supply following the COVID-19 outbreak,” he says. “In addition, all healthcare facilities should maintain a rotating stock of emergency supplies so as not to run into issues with expiration dates of supplies.”

Risk managers also should revisit the policies and procedures they currently have in place related to the COVID-19 pandemic to evaluate their effectiveness, Dorr suggests. This includes policies related to cleaning procedures, proper disinfection methods, employee personal hygiene practices, communication protocols with stakeholders, procedures for contact tracing, and screening of visitors.

“It’s important to also remember that this does not only apply to internal policies. Risk managers must also ensure any third-party contractors and service providers, such as equipment suppliers, janitorial services, and food manufacturers, are properly equipped to handle the facilities’ respective needs,” he says. “It is not just whether they have the appropriate supplies, but also whether they have the right protection and policies on their end to safely serve providers, residents, patients, and staff.” ■

SOURCE

- Joseph W. Dorr, MS, CIH, CSP, Assistant Vice President, The Graham Company, Philadelphia. Phone: (215) 701-5250. Email: jdorr@grahamco.com.

Assessing Malpractice Coverage for Improvements

Medical malpractice insurance is a vital part of any risk management program, but it is easy to assume that whatever coverage you have had for a while is adequate. It may not be, and a regular review of your insurance policies is a good way to avoid nasty surprises.

Hospital risk managers should review coverage regularly and assess whether it will be sufficient, says **Rachel Nudel**, JD, partner with Lindabury, McCormick, Estabrook & Cooper in Westfield, NJ.

“A common mistake is to have enough coverage for the facility or healthcare entity, but not enough for the physicians, nurses, and other clinicians who work there and will be covered by the employer. That’s basic, but it’s a No. 1 concern,” Nudel says. “There is sometimes the misconception that ‘If I have enough coverage for the entity, that should be enough to cover everyone.’ That is not the case.”

Individual policies typically impose a limit of \$1.3 million per occurrence and \$3 million in the aggregate, but hospital policies will have greater limits, Nudel notes. Whatever the limits, the policyholder must understand that it is liable for anything beyond that, she says.

“Particularly with physician groups, we see the mistaken assumption that they don’t have to worry about payouts because they have coverage. That is not necessarily the case,” she says.

The type of coverage also is important. The most common policy is a claims-made policy, she says. This insurance policy provides coverage only for claims made or reported during the time the policy is in effect. It

costs less than other options, with the premium starting low and gradually climbing for the first few years, then levelling off.

“The problem with this type of policy is that if a claim is made after the policy is terminated, the insured would not be covered even though there was coverage in place at the time of the incident,” she explains. “Tail coverage can be purchased for extended coverage, but those policies are super expensive, about two-and-a-half times the yearly premium of the primary policy. When you’re talking about clinicians who are at higher risk, that can be a lot of money.”

Another option is the occurrence-based policy, which includes coverage for service provided during the term of the policy, but also whenever the claim is reported or made, including after the policy is terminated. This type of policy is more expensive than a claims-made policy, but it eliminates the need for tail coverage, Nudel notes.

“Everyone likes that option, but few insurers offer them because it is difficult to predict the risk of claims made in the future for services provided today,” she says.

The least-common policy is the claims-paid policy, in which the premium is based on the claims settled in the previous year and the claims anticipated in the next year, Nudel says. The policyholder can be charged extra fees with this type of policy that go beyond the premium.

Also, consider the consent to settle. If the insurer pushes for that against the doctor’s wishes, some policies have a “hammer clause” that allows the insurer to settle without the doctor’s consent, Nudel notes.

But if there is no consent-to-settle provision, the insurer cannot settle.

Consider Defense Costs

Defense costs are an important point, with some policies specifying defense costs are inside the policy limits and others saying they are outside, Nudel explains. Inside means that if you have a \$1.3 million limit per occurrence and you spent \$300,000 on defense costs, you have only \$1 million to pay the claim.

Exclusions also will be spelled out in the policy. Typically, intentional acts and sexual abuse will be excluded, but policies also may exclude duties carried out as medical director of a hospital, Nudel says. That will require a separate policy.

The amount of coverage is a critical factor, of course, and Nudel says it is theoretically possible to be overinsured. One argument is when plaintiffs see the defendants have an abundance of insurance coverage, they will seek all of it, whereas they may have settled for much less.

“I think not having enough coverage is more of a problem. The only real downside to having too much insurance is the cost of the premium,” she says. “It comes down to a cost-benefit analysis of whether you want to risk overpaying for too much insurance or risk having not enough insurance for a serious claim, which can be scary.” ■

SOURCE

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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

- 1. What does Catherine Ruppe, RN, recommend regarding pre-op assessments?**
 - a. They should be completed in the surgeon's office before the date of surgery.
 - b. They should be completed at the surgery center immediately before the procedure.
 - c. They should be completed at home by the patient and the documents filed by the hospital or surgery center.
 - d. They should be completed online, with no need for further review at the hospital or surgery center.
- 2. Why does Jack E. McGehee, JD, refuse to accept plaintiff claims for care related to COVID-19?**
 - a. The potential payouts are too small.
 - b. There is no established standard of care for COVID-19.
 - c. Hospitals will be overwhelmed with lawsuits and will reach their policy limits quickly.
 - d. Government regulatory relief will make the cases difficult to pursue.
- 3. What does Peter Urbanowicz, JD, say is a key component of compliance with the Coronavirus Aid, Relief, and Economic Security Act?**
 - a. The hospital or other entity must keep records specifying how the money was used.
 - b. The funds must be distributed evenly across a health system's facilities.
 - c. Funds must be used within six months.
 - d. The hospital or other entity must publish a report on how the funds were used.
- 4. What is one benefit of an occurrence-based policy?**
 - a. It is less expensive.
 - b. It eliminates the need for tail coverage.
 - c. It includes fewer exclusions.
 - d. It is offered by more insurers than some other policy types.



LEGAL REVIEW & COMMENTARY

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

\$30 Million Award Upheld for Negligent Treatment of Kidney Disease

By **Damian D. Capozzola, Esq.**
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Elena N. Sandell, JD
UCLA School of Law, 2018

News: A patient underwent a pre-employment physical examination at an urgent care center. The exam revealed the patient suffered from hypertension and required medication. The patient attended two follow-up visits, then did not follow up again for two years. A nurse failed to fully inform the patient about his condition and the need for further treatment. The patient eventually was found to have suffered extensive kidney damage and stage 4 chronic kidney disease, which ultimately required a kidney transplant.

The patient filed a medical malpractice suit and was awarded \$29.7 million in damages. The defendant appealed, alleging the patient was negligent for missing appointments and failing to take his medication. Upon review, the court ruled the patient acted reasonably, and any negligence on his part did not cause the injury.

Background: In 2008, a 28-year-old patient went to a federally funded urgent care center to complete a pre-employment physical examination, which revealed the patient suffered from hypertension and needed medication.

No other physical problems were noted. After failing the physical, the patient sought further examination and treatment. He was diagnosed by a nurse practitioner as suffering from hypertension and obesity. The nurse practitioner ordered routine lab work and scheduled the first follow-up visit. During the first visit, the patient was diagnosed with severe hypertension (his blood pressure measuring 210/170), high cholesterol, and obesity. Based on the patient's factors, including his young age and severe hypertension, he was at severe risk of developing kidney disease.

The patient's kidney function appeared normal during the first examination. The nurse gave the patient clonidine, which lowered his blood pressure. The patient's medical notes indicated the nurse provided several samples of blood pressure medication to take at home, and instructed the patient to engage in "healthy eating habits." However, there was no indication the patient was adequately informed of the details and effects of his hypertension and the potential risk of developing kidney disease. Instead, he was cleared to go to work.

The patient did not follow up for two years, until he failed another work-related physical. According to the patient, during the two-year period, he reported no symptoms of high blood pressure. Records indicated the nurse prescribed a blood pressure medication to take at home and noted in the patient's chart that he was "noncompliant." However, no new lab work was ordered, even though tests were two years old and the patient had not taken any blood pressure medication for an extended period.

Between August 2010 and July 2011, the patient returned to the same clinic six times. During this time, the

THERE WAS NO INDICATION THE PATIENT WAS ADEQUATELY INFORMED OF THE DETAILS AND EFFECTS OF HIS HYPERTENSION AND THE POTENTIAL RISK OF DEVELOPING KIDNEY DISEASE.

nurse and the clinic did not order any new labs, even though the patient's blood pressure still was above normal and posed danger. The patient's medications also were changed frequently. The patient reported he believed the medications were causing him pain. The patient's chart did not indicate notes that he received any education on his condition and the potential risks associated with not taking his medication.

In July 2011, new lab work was ordered for the patient. Results indicated abnormal kidney function, but these were never seen or reviewed by the nurse. Because of this lapse in review and notification to the patient, he did not return to the clinic for 15 months. When he returned, his blood pressure was within a normal range at 140/60, but he was complaining of dizziness. Results of new lab work revealed extensive kidney damage, and that the patient suffered from stage 4 chronic kidney disease. However, these lab results were not discussed with the patient and he was not referred to a specialist.

Two months later, the patient felt extremely ill. He was transported to a hospital, where he was determined to be in hypertensive crisis. His blood pressure was 275/180. During this visit, the patient was informed for the first time that "hypertension" is synonymous with "high blood pressure," and he was suffering from stage 5 chronic kidney disease. He was readmitted a few months later to have a fistula surgically inserted so he could begin receiving hemodialysis regularly. Two years after beginning treatment, the patient received a kidney transplant which, although successful, requires him to take immunosuppressive and anti-rejection medication.

The patient filed a medical malpractice suit against the clinic,

alleging the clinic's and nurse's failure to read and review tests, failure to adequately inform him about his condition and the necessity of taking his medication, and failure to diagnose and treat or refer him to treatment for the kidney disease constituted malpractice. The clinic denied liability, and claimed that the patient's failure to seek treatment for his hypertension and failure to take medication constituted negligence that caused his injuries.

Following a bench trial, the judge ruled in favor of the plaintiff and awarded him \$29.7 million. The defendant appealed, arguing the court failed to apply the correct standard for the patient's alleged comparative fault. While the appellate court agreed, the trial court eventually found the patient acted reasonably and was not at fault for his injuries, despite his few lapses in attending appointments and refilling medications.

What this means to you:

Although unsuccessful in this matter, the defendant care provider raised an important defensive tool in medical malpractice actions: comparative negligence. States employ different applications of this legal principle. In Illinois, where this matter took place, if a party is more than 50% responsible for the injury, then the party is not entitled to any recovery, even if the care provider was 49% responsible. Other states apply a percentage-based reduction, such that if a party is 25% responsible for their own injuries, the party's damages award is reduced by 25%.

Regardless of the specific application, this principle can allow for physicians and care providers to reduce or eliminate an injured patient's recovery when the patient bears some responsibility for his or her own injuries. This case provides an example of how such arguments may be raised, and

how courts and juries evaluate such arguments.

In this case, the defendant clinic argued the patient's noncompliance and failure to follow up in a timely manner contributed to at least 50% of his injuries, thus precluding him from any entitlement to damages. The patient claimed that his behavior was justified because the nurse practitioner failed to educate him on his condition and possible consequences, and his delayed follow-ups and refilling of his medication did not contribute to his injuries. Here, the court agreed with the patient and found he acted as a "reasonable person" would have in the same or similar circumstances. The court acknowledged the patient's delays, but noted he was only 28 years old at the time and otherwise was in good health. It was reasonable for him to only seek medical attention when he felt ill.

Additionally, the patient stated that he first learned that "high blood pressure" and "hypertension" had the same meaning after he was transported to the hospital. This shows the patient clearly was uneducated on his condition and likely was unaware of the health consequences related to the disease. This also is confirmed by the notes, or lack thereof, kept in the patient's file by the nurse practitioner. In fact, other than indicating "healthy diet," the nurse did not keep a record of any conversation she had with the patient explaining the severity of his condition and the potential consequences. The nurse instructed the patient several times to return to the clinic "as needed," rather than on any specific schedule, such as within six months, for regular follow-up visits. These circumstances supported the court's finding the patient lacked the knowledge to act differently

because the care provider failed to adequately inform the patient.

Several expert witnesses testified at trial for both the patient and care provider. All witnesses agreed on one fact: The patient's blood pressure readings were among the highest they had ever seen. Given the severity of the patient's results, the experts agreed the case was complicated for a nurse practitioner to handle. They agreed the patient should have been referred to a physician, and monitored closely. Several instances of the patient's treatment in the clinic provide clear examples of care below the applicable standard: failure to perform lab work for more than two years or obtain lab results from the emergency care center, failure to follow up on the lab work that was ordered but never reviewed, and failure to disclose to

patient the progression of his kidney disease and order a specialist visit.

The high award in this case was calculated based on the experts' testimony on what dialysis entailed in terms of the physical toll, economic loss, and ability to work. Experts agreed the duration of a kidney transplant is 10-12 years. Based on the patient's life expectancy, he would need additional kidney transplants, which require years of dialysis in preparation and would cost the patient between \$10-\$14 million. Most experts also agreed the patient's kidney disease was caused by uncontrolled hypertension.

Most determinative for the court was the testimony of a primary care physician who noted that although the nurse practitioner categorized the patient as "noncompliant," he

believed the patient was simply not educated by the nurse. If he fully understood the risks involved, he would have complied. In fact, the patient's nephrologist noted the patient was willing and able to follow all medical advice in the years leading up to his kidney transplant. Further, he successfully monitored his blood pressure by himself once he understood the risks and consequences of his disease, and the necessary preventive steps he needed to take. The court found this evidence supported the claim the patient was reasonable and did not contribute to his injuries. ■

REFERENCE

Decided on April 22, 2020, in the United States District Court for the Southern District of Illinois, Case Number 3:15-cv-00124.

Failure to Diagnose and Treat Infection After Surgery Results in \$2.75 Million Award

News: A 15-year-old patient underwent a coccygectomy and was not closely monitored. The physician missed an infection that caused the patient severe, permanent injuries. According to the patient, the physician was aware of the risks but failed to investigate the infection.

The patient filed a medical malpractice suit and was awarded \$2.75 million in damages. The defendants appealed, arguing the evidence was insufficient to support the verdict, and the patient's expert should not have been permitted to testify by video. However, the appellate court found the evidence sufficient, and affirmed the award.

Background: A 15-year-old patient underwent a coccygectomy, or tailbone surgery, which was performed by an experienced

spinal surgeon. Following surgery, the wound seemed to have healed well; however, the patient started to develop symptoms consistent with a postoperative infection, including intermittent draining and pain, which worsened over time. Two months after the surgery, the pain was persistent and increasingly severe. Additionally, the incision site now presented hypergranulation, red tissue, and extreme tenderness. The patient attended two follow-up visits with the surgeon, who failed to identify the signs of an infection. While the surgeon took a culture from the patient that tested negative for infection, this was not sufficiently reliable to rule out infection, as false-negatives occur.

The patient alleged the surgeon should have taken further steps

because of the new wound draining and the extreme tenderness. A few days after the first follow-up visit with the surgeon, the patient saw his primary care physician, who suspected an abscess. An MRI was ordered and revealed a large fluid collection, consistent with an abscess. A radiologist documented the MRI results.

Although these MRI results were available before the patient's second follow-up visit, the surgeon failed to review the results. The results were not necessarily conclusive to demonstrate an infection, but the presence of fluid was another symptom of a potential infection, which should have prompted the surgeon to investigate further.

At trial, the defendant care providers claimed there was no

record of the patient experiencing draining after the surgery. However, the patient's medical records revealed intermittent draining had been documented two to four weeks after the surgery. These findings were consistent with the patient's statements and indicated the patient reported drainage before he was diagnosed with an abscess or had been made aware of the significance of an abscess.

Because of the infection, the patient suffered permanent nerve and tissue damage, permanent loss of function, and severe pain. The patient's neurology expert further testified the patient would live a poor quality of life and would be required to modify his life to cope with the significant pain.

The patient filed a medical malpractice action against the surgeon and hospital, alleging both were negligent for failing to monitor the surgery and failing to timely diagnose and treat the infection. The defendants denied liability. A jury found in favor of the plaintiff and awarded him \$2.75 million: \$1.5 million for pain and suffering, and \$1.25 million for lost earning capacity over a 45-year expected work life. The defendants appealed, but the appellate court affirmed the award.

What this means to you: This case demonstrates the need to carefully monitor patients during the relevant times, particularly during and after surgery, and to investigate abnormal conditions. The primary basis for the medical malpractice liability in this case was the surgeon's failure to diagnose and timely treat the infection, which escalated and caused severe, irreparable damage and pain to the patient.

As with many medical malpractice cases, this one turned into a battle

of the experts, where the patient's experts and the care provider's experts offer conflicting opinions — and the jury is required to evaluate those experts and decide which opinions to believe. Under such circumstances, it is common for parties to try to challenge not only the substance of the opposing party's expert's opinions, but also the procedure by which the expert offers his or her opinions.

In this case, the care providers argued the court should not have permitted the patient's expert to testify by video after he was needed longer than expected. The plaintiff's attorney indicated its expert was busy and provided a limited time during which he could testify. The expert remained available for the entire time during the pre-arranged period and answered all questions presented. The defendants did not raise any issue about insufficient time to cross-examine or any other relevant fact. Only the defendants' attorney could have known how long their own cross-examination would take. Nevertheless, the defendants argued that presenting the cross-examination via recording was detrimental to their case because it lacked the same effect as an in-person examination, and it hampered the jury's ability to assess the expert.

The trial and appellate courts rejected this argument because the jury was instructed to treat the recording as a live, in-court testimony. Almost a full hour of the recording was played for the jury, giving jurors sufficient time to assess the expert. The courts found the video presentation was not prejudicial. As the current health crisis has caused significant disruption to in-person activity, in courts and otherwise, it is instructive that this court recognized the propriety of permitting video testimony of a

medical expert. Such testimony by remote means is likely to benefit the court, the parties in litigation, and the experts themselves, as it reduces costs and time for travel, and simplifies scheduling and availability issues that may otherwise arise.

On appeal, the defendants also argued the patient's attorney improperly attempted to introduce a new theory of liability during trial. However, the courts disagreed and found the activity was proper impeachment of the defendants' witness through prior inconsistent statements by citing data the witness published in clinical studies that directly contradicted his testimony. In particular, the witness testified only 15-20% of his patients developed wound problems, including infections, after surgery. However, studies he authored placed that same figure at 28-36%, establishing the complication rate for his patients was toward the higher end.

The court concluded this was a proper manner for the patient's attorney to challenge the defendant's expert. Ultimately, the patient's expert and undermining of the defendant's expert was more convincing to the jury and resulted in a verdict against the care providers. If named in a medical malpractice action, care providers should work closely with counsel in identifying and retaining qualified experts, and in determining the best methods for challenging an opposing party's experts. Such efforts are likely to be valuable in presenting a successful defense. ■

REFERENCE

Decided on April 23, 2020, in the Commonwealth of Massachusetts Appellate Court, Case Number 18-P-1589.