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Mergers and Acquisitions Activity Creates Safety, Liability Risks for Hospitals

The flurry of mergers and acquisitions (M&A) in healthcare recently should put risk managers on alert for threats to patient safety that can come with joining different corporations, facilities, staff, and cultures. Risk managers also should make sure they are involved in M&A negotiations early on so that patient safety issues can be factored in to the process.

M&A activity has held steady over the past few years, with more than 70 deals per year recently. Consolidation has occurred mostly in midsize systems, those worth between $1 billion and $5 billion, but hospitals also are acquiring physician practices and other healthcare lines on a smaller scale. *(More information on M&A activity is available in a report from a healthcare consulting and analytics firm at: https://mck.co/2Iq8uf0.)*

The threat to patient safety exists no matter how small the merger or acquisition, and larger transactions carry significant risk, says **Susan Haas**, MD, MSc, co-principal investigator on the Project on System Expansion Risks to Patient Safety with Ariadne Labs, Brigham and Women's Hospital, and the Harvard T.H. Chan School of Public Health in Boston.

> THE THREAT TO PATIENT SAFETY EXISTS NO MATTER HOW SMALL THE MERGER OR ACQUISITION, AND LARGER TRANSACTIONS CARRY SIGNIFICANT RISK.

"This is all about anticipation, what you want to scan the environment for and plan so you can mitigate before these problems arise," she says.

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"The approach should be all about proactive awareness, looking for where trouble might occur."

Haas recently co-authored an article in *JAMA* that highlighted the three primary patient safety risk areas from M&A: new patient populations, unfamiliar infrastructure, and new settings for physicians. *(The article is available online at: https://bit.ly/2NDwKjq.)*

A change in patient population — demographics or volume — can result from well-meaning efforts to combine previously separate clinical groups, Haas says. The health system may wish to put all obstetrics patients in the same building, for instance, or consolidate EDs.

"A hospital in Boston consolidated two services and one facility that had low prevalence of substance abuse in their obstetric population, suddenly saw a significant jump in those patients and had to adapt to provide care to those patients," Haas says. "Any kind of different population than the hospital is used to treating will present a challenge, partly because that new patient population may come in a sudden influx rather than a gradual increase that gives the hospital time to learn how to accommodate their needs."

Another example involves a sudden influx of pediatric patients to an ED. Pediatric dosing is different and more sensitive to error than adult medication dosing, so there would be an increased risk to patients from clinicians not used to treating children as often, Haas says. It is not that clinicians would be wholly unfamiliar with pediatric dosing, but that it is not a part of their typical workflow, she explains.

New Settings Mean New Risks

Unfamiliar infrastructure is one possible result of the push to standardize elements within the newly formed organization, which is usually one of the primary goals in the effort to reduce costs and eliminate clinical variation, she notes.

New settings for physicians can be a patient safety issue. For example, when a hospital does not have enough volume to support a specialist, like a pediatric cardiologist, but after the M&A the new affiliation gives them access to one. The hospital can call on the specialist from the larger facility to visit and provide care closer to the patient's home.

That is a benefit of a smaller or rural facility affiliating with a larger hospital or system, but Haas says it introduces safety risks.

EXECUTIVE SUMMARY

Mergers and acquisitions can create patient safety risks as disparate cultures merge and clinicians face new working conditions. There also are opportunities to improve safety during the transition.

- Clinicians may face unfamiliar physical surroundings, patient populations, and care protocols.
- Different cultures of safety can clash as people mix with those from another organization.
- Risk managers should work to involve themselves in the process from the earliest opportunity.

"The doctors are now practicing with an unfamiliar infrastructure, often alone, unfamiliar with local rules and responsibilities, and especially the local culture. We had one doctor say, 'I know the medicine, but I just didn't know how to get things done around here,'" she recalls. "Providing care is both making the clinical decision but also having it executed. If you don't know how to get it executed, it doesn't matter what you decide."

New settings and infrastructure can mean clinicians are practicing in unfamiliar environments, and Haas says that alone can introduce patient safety risks.

"That is an enormous, uncounted, unmeasured, unstudied field of study. We've had stories of physicians being assigned to a new hospital and unable to get to a code because they couldn't figure out how to get to the bridge that takes them to that wing of the hospital," she says. "A basic orientation for those new physicians is crucial."

Similarly, clinicians may be unfamiliar with the equipment they are using after M&A. For instance, defibrillators and ultrasound machines are not standardized; they have different interfaces that could slow an emergency response or yield the wrong results.

The human side of hospital operations is just as important, Haas says. Clinicians in new settings may not know who is available to assist in an emergency or difficult case, or they may know who but not how to reach them, she says.

"When they're making a decision about whether to hospitalize someone or transfer, who is upstairs at 2 a.m. on a Sunday? Maybe you knew who that was and how to contact them quickly at your other facility, but now you don't," Haas says. "That's an incredibly important resource you need to be familiar with."

Information on liability related to M&A is scarce because malpractice insurers only release information on closed claims, and they do not code cases related to system expansion, Haas says.

Risk managers should look at those three categories in any M&A activity, assessing what is going to be different with any location after the transaction. She cautions that the patient safety risks can go unrecognized by administrators and clinical leaders until patients are harmed.

"We had nurses and doctors say they didn't know what to call it, but they recognized this risk at their level. The network development people who put this together at a business level aren't going to see these clinical things," Haas says. "They're not going to anticipate and plan for these potential problems that are sneaking up on them."

Get Involved Early

That means risk managers, if not invited from the outset, must inject themselves into the M&A process, she says. Even when involved in M&A negotiations, risk managers may be asked to assess only financial and legal issues rather than patient safety concerns.

Alert health system leaders to the potential patient safety risks and make a case for why you should have access to the necessary data and people to research them, she says. Lobby for involvement in the decision-making process of the M&A if possible.

"This is not something you can jump into at the last minute, after all the plans have been made and the deal is done. That is exactly how we are in the spot we are in today," Haas says. "Get involved early. These things are often done quietly, so when you first get word that it is being considered, go to your leadership and tell them if it's happening or might happen at some time, you would want risk management involved from the very beginning."

(The Project on System Expansion Risks to Patient Safety offers a free toolkit to address these issues. It is available online at: https://bit.ly/2p7JlOv.)

Culture Clash

Patient safety risks often materialize when cultures clash in M&A, says **Kerin Torpey Bashaw**, MPH, BSN, RN, senior vice president in the Department of Patient Safety and Risk Management with The Doctors Company, a liability insurer based in Napa, CA. The culture of safety can be significantly different at hospitals, and trouble can arise when those facilities suddenly come under one umbrella and people with different approaches start working together.

The organizations' scores on the Agency for Healthcare Research and Quality (AHRQ) Hospital Survey on Patient Safety Culture could signal the degree of risk over clashing safety cultures, Bashaw suggests.

If those scores are far apart, that could portend difficulty in merging the two groups when it comes to patient safety issues, she says. *(Information on the AHRQ survey is available online at: https://bit.ly/2IdjlZK.)*

"If the culture at hospital A is such that a nurse can pull an attending out of the room because she noticed he didn't perform hand hygiene, the physician might thank

that nurse for having his back when he was distracted," Bashaw says. "At hospital B, the physician might berate the nurse, the nurse shuts down and never challenges a physician again, and she might get reported by the physician. Those are very different cultures, and when you suddenly mix them, you're more likely to get negative effects — at least in the short run — than to see the good culture win out."

Bashaw notes that health systems use different models for transformation in M&A, such as the eight steps in the model by John Kotter, and they usually incorporate an assessment of risk. Risk managers would be well advised to study the different risk models and be able to discuss them with leaders when trying to direct attention to the potential patient safety risks associated with M&A, she suggests. *(Information on Kotter's model can be found online at: https://bit.ly/2nB6msb.)*

The risk manager can contribute to prioritizing and removing barriers to patient safety improvement during the M&A process, Bashaw says.

"When you're merging two cultures with different policies, procedures, electronic health records, and personalities, barriers will arise. Having a coalition that is watching for those barriers and willing to remove them is paramount to a successful M&A," she says. "Some of those barriers can be identified early on and dealt with before a patient is harmed or before existing safety practices are undermined. Those short-term wins are important to giving people reassurance that this M&A can be successful and add value."

Remember also that there are opportunities to improve patient safety in M&A, says **Leah Binder**, CEO of The Leapfrog Group in Washington, DC. Any process of change affecting the entire organization represents an opportunity to introduce new concepts and to address existing problems, she says.

"If you don't pursue the opportunities presented, you will experience the worst of the risks," Binder says. "The opportunities are to standardize care across organizations and bring all the facilities up to the safety level of the facility with the highest standards. I've seen mergers where that happens, with one very high-performing hospital bringing their standards and procedures to the other hospitals involved in the merger and ultimately they improved their safety."

Standardization is the key to patient safety, and a health system expansion is the perfect opportunity to standardize to a higher level of safety, Binder says. Standardization also is necessary to simply prevent the overall safety level from sliding down.

"The risk is that there's just chaos, with everyone having a different idea how care should be delivered. Physicians going from institution to institution with their own ideas of how things should be run," Binder says. "That is the height of an unsafe environment for patients. M&A can reduce patient safety by undermining standardization, unless that is made a priority in the merger process."

Medication reconciliation is one opportunity for potential improvement, with one hospital bringing its superior processes to the merger, she notes.

Another opportunity involves surgical volume standards. Research indicates that patient safety improves with certain procedures when surgeons perform a minimum number of cases regularly, so merged systems can direct more patients to surgeons to ensure safe patient volumes, Binder says.

"We've seen that happen in mergers, with good results. The newly merged system says this is now the hospital that does this procedure, and that hospital is the one that does this other procedure," she explains. "They do not allow surgeons to just do one of these procedures once a year, for example, when we know that is unsafe. That is an example where safety can be vastly improved with a systematic approach."

Binder points out that the Centers for Medicare & Medicaid Services (CMS) reports hospital quality by Medicare provider number, and sometimes an entire system uses only one number. That means the variation in performance by different facilities will not always be apparent within one system. Risk managers need to be aware of that and make sure they are digging deep enough to get the data that show variability within the system, she says.

M&A a Distraction From Daily Tasks

M&A also can distract clinicians and hospital leaders from their daily activities, notes **John O. Chesley**, JD, an attorney with the Ropes & Gray law firm in San Francisco.

"The distraction arises because management often is pulled away to the demands of the M&A process and there are just so many hours in the day," Chesley says. "The consequence can be that those in a supervisory function can take their eyes off the ball. It's natural; just the result of being pulled in different directions."

For example, M&A requires extensive due diligence before the deal closes, and that usually requires a great deal of document

requests. Personal interviews also may be involved, but feeding the beast of document requests can come to dominate the time of many healthcare leaders — including risk managers, he says.

"That can include a download of patient care policies, statements of deficiency, and plans of correction, for instance. If there are any Medicare deficiencies, the parties will gather around that and want to know what is out of compliance, what the plan of correction is," Chesley says. "All of that demands a huge amount of attention from not just managers but also nurse supervisors and others involved in the patient care safety process. This is a time when things can be missed with patients."

Unfortunately, there may be some limitations in how much a risk manager can be involved in the M&A process, at least in the first phase before the expansion goes public. Before that point, the discussions are typically confidential, involving only the top leaders of each organization, he says. That means risk managers will be brought in — if they are included at all — only after some preliminary decisions and plans are made.

Keep in mind how the announcement of a potential merger will affect employees and physicians at all of the involved facilities.

"Everyone who works at these organizations will start wondering how it affects them and if they might lose their jobs. So there is another element of distraction," Chesley says. "Work to keep them informed as much as possible so that you can minimize that fear and keep them focused on their work."

Risk managers also can become involved with managing situations that could influence M&A negotiations, Chesley says. For instance, if a report cites the hospital for a high number of falls, the resulting media reports could influence the parties negotiating the deal, he explains.

"Paying attention to everything that a state agency can evaluate and apply penalties to should be on somebody's checklist," he says.

Struggling Hospitals Can Improve

The good news is that M&A can address issues in struggling hospitals that might compromise patient safety, says **Diane Rafferty**, managing director of the Healthcare Industry Group with the consulting firm Alvarez & Marsal in Los Angeles.

"Mergers and acquisitions of health systems remain strong, with little change in momentum. When properly executed, mergers can improve the survivability of struggling hospitals by helping to keep patient access local, enhancing leverage with the payers and vendors, increasing access to capital, and advancing the standardization of patient care protocols," Rafferty says.

Keeping up with the process may be one of the challenges for risk managers. The business side of an M&A needs to move quickly and effectively to achieve the promised financial benefits, Rafferty says. But merging the business office, revenue cycle, and contracting is very different than merging clinical staff, patient care protocols, policies, and procedures, she says.

"The upfront work required to merge different care delivery cultures is important to understand and to manage. Larger systems see themselves as taking over the smaller system, as they believe they bring the better way of doing things," she says. "Minimal time is spent understanding what the acquired has to offer, which can be incredible best practices or a specific culture that benefits their patient population, which has taken years to develop."

It is important to be realistic about expectations when working with clinicians to address potential patient safety concerns, Rafferty says. Not all clinicians and employees will be happy and may feel that decisions are being made by those far removed from the work.

"Addressing these concerns in an upfront and transparent manner is critical," she says. "Unhappy employees may result in decreased patient satisfaction, which in turn can affect the cost benefits of the deal and cause a delay in the work required to make it a success." ■

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Consciousness Guidelines Affect Continuation of Care

New guidelines on how to determine consciousness could affect how healthcare organizations address legal questions regarding intensity of care, discontinuation of care, and end-of-life decisions. Risk managers should be familiar with the changes and anticipate challenges from family members.

New research suggests that chance for recovery for some of these patients is better than previously thought.

The guidelines update the 1995 American Academy of Neurology (AAN) practice parameter on persistent vegetative state and the 2002 case definition on minimally conscious state (MCS) and provide care recommendations for patients with prolonged disorders of consciousness (DoC). Developed by the American Academy of Neurology in association with other professional organizations, the guidelines were published recently in the journal *Neurology*. *(An abstract is available online at: https://bit.ly/2B5pacp.)*

Initial Diagnosis Is Key

The guidelines are divided into four subsections: diagnosis, prognosis, natural history, and treatment. Each section contains information that is pertinent to decisions regarding withdrawal of care, says lead author **Joseph T. Giacino**, PhD, director of rehabilitation neuropsychology and research associate at Spaulding Rehabilitation Hospital in Boston.

"It is essential to get the diagnosis right. We know that about 40% of people with disorders of consciousness are misdiagnosed," he says. "That means someone has made the diagnosis that this person is not conscious, but this person does retain some level of conscious awareness. We also know that patients in minimally conscious states, relative to those in vegetative states, have significantly more favorable outcomes, particularly when they are diagnosed early."

However, the difference between those two states can be very subtle. The signs can be missed and the patient easily can be misdiagnosed as being in a vegetative state. Understanding that is key to ensuring proper care and the accuracy of future decisions regarding continuation of care, Giacino says.

"It's complex, not an easy differential diagnosis to make," Giacino says. "These patients in a minimally conscious state do not show consistent signs of consciousness, so one might do a one-off examination and not show any signs of consciousness. But if one were to return to the bedside an hour later, you might find signs of consciousness."

That is why the new guidelines call for "serial examinations" to assure the diagnosis is accurate, he explains. They also call for the use of standardized assessment scales, getting away from the current practice in which two different examiners may assess the patient with their own preferred tests and criteria using their own judgment to determine what qualifies as a response from the patient, he says.

"These standardized tools remove that subjectivity, to some extent, because they determine what tests should be administered and the criteria for what qualifies as a response," he says.

Better Prognosis Than Before

Regarding prognosis, the guidelines note that the most recent research indicates the potential for late recovery is substantially better for patients with prolonged DoC than was previously understood.

"About 20% of those who have traumatic disorders of consciousness — a head injury from car accidents or falls, for instance — regain functional independence between two and five years post-injury," Giacino says. "They get substantially better over a longer period of time than was previously understood. We now know

EXECUTIVE SUMMARY

New guidelines on assessing consciousness indicate a better prognosis for some patients than previously thought. This information could change how decisions on continuation of care are made.

- Twenty percent of traumatic brain injury patients could recover consciousness.
- A large majority of these patients die from discontinuation of care.
- Risk managers should anticipate challenges from families in light of the new guidance.

that one in five people in that group are going to get a lot better."

The question is which one, he says, and research has not yet pinned down the characteristics that could identify him or her.

"It's essential to avoid statements dealing with family members of patients with prolonged disorders of consciousness suggesting a poor prognosis for these patients. There is still an air of nihilism around these individuals," he says. "They remain minimally conscious for that period of time and people view that as the point of no return, but that is clearly not the case, particularly with traumatic brain injury."

Those new facts are particularly important given that research from one study shows that, for traumatic brain injury patients, 70% of the deaths in the ICU were related to withdrawal of life sustaining therapy, Giacino says. *(The study is available online at: https://bit.ly/2Mvd5xE.)*

"The really compelling finding was that for about 65% of the patients who had care withdrawn, the decision to do so was made within 72 hours of admission," he says. "You put those two things together and have these high rates of withdrawal of care alongside the knowledge that one in five of them will, with proper care, get to the point that they can function independently at home. That's a problem for us now to deal with."

Review Hospital Guidance

The new guidelines also call for abandoning the term "permanent vegetative state," which was introduced in the 1995 guidelines. The term "chronic vegetative state" is less absolute and less likely to discourage continuing care.

For these patients, the guidelines say families should be told that the person is not fully conscious and there is a time period in which that could change, but they also should be told that there will be a point when there is a higher level of certainty that the condition will not change.

Giacino suggests that the new guidance could necessitate a review of a hospital's or health system's policies or guiding principles on how to make decisions regarding continued care for patients with DoC.

"These guidelines should prompt a lot of careful consideration now on how to make these decisions. We still don't know how to identify which patients will recover with the proper care, but the approach needs to be systematic," Giacino says. "A team working the ICU should be approaching this the same way." ■

SOURCE

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Malpractice Nursing Claims Rise With Experience

Data on malpractice claims involving nurses indicate a somewhat surprising trend: The more experienced a nurse is, the more likely he or she is to have malpractice claims.

This may be attributable to several factors. They may get too comfortable in their environment and let their guard down, older nurses often take on more complicated cases, or they may be mentoring younger nurses, which can leave them vulnerable.

Years in practice at the time of the incident are associated with malpractice claims, says **Jennifer Flynn**, CPHRM, risk manager with the Nurses Service Organization (NSO) in Warrington, PA. The most recent NSO data indicate that none of the surveyed nurses who had been working for up to two years experienced a malpractice claim, she notes.

However, nurses who have been in practice for at least 16 years are more likely to have a claim, she says, and the largest average indemnity payment ($70,171) was for nurses in practice for three to five years. *(The most recent research is available online at: https://bit.ly/2oYRfcB. It is updated every five years.)*

EXECUTIVE SUMMARY

The likelihood of a malpractice claim increases with a nurse's years of experience, contrary to some expectations. There are several possible explanations and solutions.

- The average payout on claims also increases with experience.
- Experienced nurses should be encouraged to maintain their skills and education.
- Risk managers should use the data to alert experienced nurses to their risk.

"In addition to the increase in claims, we also see that the average paid indemnity increases with experience. Not only are we seeing increased likelihood to experience a claim as a nurse's experience increases, but the payment made to that injured third party also increases," she says.

The first likely explanation is that more experienced nurses are treating more seriously ill patients with complex care needs, Flynn says. They also may be taking on more patients than less experienced nurses and mentoring less experienced colleagues.

"If you ask a nurse who is more likely to be sued, they might say it's definitely the newer nurse because they're not as familiar with policies and procedures, or they're taking longer with patients and not recognizing signs of distress as easily as someone who is more experienced," Flynn says. "These results were interesting to us because it flips that mentality and says to the experienced nurse that because of all the things you might be doing in your unit, you are more likely to face a malpractice lawsuit."

Risk managers can use this information to encourage more experienced nurses to keep up with trends in the industry and not rely on their years of experience to protect them, Flynn suggests. The NSO research also indicates that nurses who took continuing education and risk management courses had lower incidence of malpractice lawsuits, and the payouts on claims were lower, she says.

"The risk manager can encourage experienced nurses not to get complacent and to keep up with their continuing education, but if the nurse is going to be held accountable, then the healthcare organization needs to invest in those nurses' training in the same way they would for nurses new to the practice," she says.

Flynn also suggests risk managers might implement a peer review process to ensure that all nurses, including those most experienced, are compliant with policies and procedures, as well as best practices and clinical standards. ■

SOURCE

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Stark Law Could Be Eased, but Compliance Still Difficult

Efforts to move away from the fee-for-service model may lead to changes in the Stark anti-kickback law, an attorney explains. Expect more exceptions and exclusions that will in some ways make the law less onerous but no less difficult when ensuring compliance.

The House Ways and Means Committee met recently to discuss the need to modernize the Stark Law — federal legislation that aims to prohibit physicians from making referrals for certain health services payable by Medicare to an entity with which they (or their family members) have financial relationships.

The Centers for Medicare & Medicaid Services also sought public comment on how to address undue regulatory burden as a result of this physician self-referral law. Changes to the Stark Law will affect how risk managers guard against potential liability related to kickback allegations, says **Ron Lebow**, JD, senior counsel in the Health Law Group with the Greenspoon Marder law firm in New York City.

The effort to reduce reliance on the fee-for-service payment model could loosen some Stark restrictions, which would be good news for some healthcare organizations, he says.

"If there was a financial incentive to order more testing or services, it cost the government more money, and so the Stark Law has been in place a long time to discourage the kind of payments that result in excess services," Lebow says. "The Stark Law worked in the sense that it prevented incentives to make more money, but it sometimes got in the way of medically necessary services because certain

EXECUTIVE SUMMARY

The Stark anti-kickback law may be changed as the healthcare industry moves away from fee-for-service. It is not likely to be scrapped altogether.

- New care models lessen the need to monitor orders for possible kickbacks.
- The government is likely to add more exceptions to the law.
- Compliance may become more challenging as the exceptions grow.

parties couldn't do things unless they fell in line with every bit of criteria to make it legal. Even the legislators who championed Stark regretted how it just became this monster."

Reducing the use of fee-for-service could make Stark less important to protecting the government's interest, and therefore the law could be made more palatable to healthcare providers, he says.

"If you don't get paid per click for everything you order, then why does anybody care how much you order, at least as it concerns about getting kickbacks? If we're going to transfer to bundled payment models, risk-sharing models based on capitated payments, or courses of care models, then they should be able to order anything they want because it's not going to cost the government more money," he says.

However, do not expect the government to just say the Stark Law is no longer needed.

"They are so afraid of scrapping the whole thing that I'd expect them to just keep adding more and more exceptions and criteria related to consumer protection," Lebow says.

"It will become a boondoggle of regulatory compliance, but without clear guidance that account for these changing models of care, everyone is going to be too fearful to jump in these new arrangements with the fear of huge civil liability hanging over them. The government is going to keep taking on exceptions to make people feel they're safe in what they're doing, even though it would be cleaner to scrap the whole thing." ■

SOURCE

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Hospitals Face ADA Lawsuits Over Websites

Serial plaintiffs have been filing lawsuits under Title III of the Americans with Disabilities Act (ADA), alleging that private businesses — from hospitals to small restaurants — were not physically accessible to persons with disabilities, but now a new version of this lawsuit is appearing.

A new wave of ADA lawsuits has emerged in the past few years claiming that businesses' websites are inaccessible to visually impaired individuals who rely on special software, says **Adam Chotiner**, JD, shareholder with Shapiro, Blasi, Wasserman & Hermann in Boca Raton, FL. Many large companies have already been hit with such a lawsuit, and hospitals are vulnerable to this threat, he says.

In 2017, more than 800 ADA website accessibility cases were filed in U.S. federal courts.

"ADA website lawsuits are particularly challenging because the U.S. Department of Justice has never issued regulations specifying the criteria or standards for determining whether a private business's website is accessible. A couple of website cases have been dismissed on that basis, and some other judges have found that a business's website does not count as a 'place of public accommodation' and thus is not covered by the ADA," Chotiner explains. "But those trial court decisions — which are not binding on any other judge or court — are clearly the minority. Most judges confronting the issue have found that a business's website can constitute a place of public accommodation provided the website has some nexus to an actual physical location."

Only one ADA website accessibility case has gone to trial in the entire country so far, Chotiner says. That case was tried in 2017 in south Florida, and the defendant, a grocery store chain, lost and was ordered to make its website accessible, Chotiner says.

The judge adopted the Web Content Accessibility Guidelines (WCAG) 2.0 as the accessibility standard that the chain must meet to make its website accessible. Chotiner explains that WCAG 2.0 AA is a set of guidelines developed by a private group of accessibility experts and has been incorporated into many consent

EXECUTIVE SUMMARY

Healthcare facilities are being sued by plaintiffs who allege that facility websites are not in compliance with the Americans with Disabilities Act. The lawsuits can be difficult to defend.

- One lawsuit has gone to trial and the defendant lost.
- Defendants can face copycat lawsuits.
- A plan of improvement in the first lawsuit can deter others.

decrees and settlement agreements. It is the standard the U.S. Department of Justice referenced in its rulemaking process for state and local government websites under Title II of the ADA.

The judge did not consider the $250,000 cost of making the website accessible to be an undue burden, Chotiner says. The judge said that the cost '"pales in comparison to the $2 million [the grocery store chain] spent in 2015 to open the website and the $7 million it spent in 2016 to remake the website."

"Moreover, the judge found [the chain] responsible for the entire website's lack of accessibility even though parts of the website are operated by third-party vendors," Chotiner says.

The judge said "many, if not most, of the third-party vendors may already be accessible to the disabled and, if not, [the company] has a legal obligation to require them to be accessible if they choose to operate within website."

The case is now on appeal at the 11th Circuit Court of Appeals, Chotiner says, and when the appellate court finally rules, it may provide some much-needed clarity to this area of the law.

The 11th Circuit recently provided guidance involving copycat lawsuits in which a company settles one ADA website accessibility lawsuit but then gets hit with another lawsuit before the company has implemented changes pursuant to the settlement of the first case, Chotiner says.

"In short, a company can still be sued if it hasn't yet implemented accessibility changes pursuant to an earlier settlement, but the company's chances of having the second lawsuit dismissed will be significantly enhanced if the earlier settlement requires ongoing monitoring/compliance and the court retains jurisdiction to enforce the settlement," Chotiner says. ■

SOURCE

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Key Components of a Drug Diversion Program

Diversion risk points include preparation, administration, and waste

Although drug diversion may be considered a rare event, investigations reveal that the practice could be going undetected in facilities that do not have a proactive prevention program, warns **Kimberly New**, JD, BSN, RN, executive director of the International Health Facility Diversion Association.

"Having a formal program is essential. If you are treating this as a one-off, you are going to be inconsistent and have an incomplete response," she said recently in Minneapolis at the annual conference of the Association for Professionals in Infection Control and Epidemiology.

In the most basic terms, the program should increase transparency and develop a culture of accountability. "If you are not open within the organization about drug diversion, then people are not going to believe it's a risk," she said.

> IN THE MOST BASIC TERMS, THE PROGRAM SHOULD INCREASE TRANSPARENCY AND DEVELOP A CULTURE OF ACCOUNTABILITY.

"Make sure you have a good auditing surveillance program in place. Risk rounding is essential to prevention."

Employee health professionals looking to establish or improve a drug diversion program at their facilities may want to consider some of the measures taken by **JoAnn Shea**, ARNP, MS, COHN-S, director of employee health and wellness at Tampa General Hospital.

Diversion Prevention Guidelines

Shea and colleagues are following Guidelines on Preventing Diversion of Controlled Substances, issued last year by the American Society of Health-System Pharmacists (ASHP).[1]

The ASHP recommends forming a drug diversion committee that should include members from employee health, pharmacy, nursing, risk management, security, and other departments. Another key

step is hiring a diversion specialist who can dedicate his or her time to detecting and preventing drug theft and tampering.

All of the Tampa General specialist's time is devoted to identifying diversion, Shea says.

The ASHP recommends that the diversion officer should have a license and a college degree in pharmacy or nursing, with at least five years of healthcare experience. At Tampa General, a pharmacy nurse specialist has been hired as the drug diversion point person.

"We actually created that position for her," says Shea, who co-chairs the hospital's Controlled Substance Diversion Prevention Committee. "She reports to me and to the pharmacy director. It's kind of a 'dotted-line' relationship."

Duties include education, diversion identification, audits, and conducting a gap analysis based on ASHP best practices. The diversion committee meets quarterly and is currently conducting a gap analysis of drug use and controls throughout the facility. The hospital IT team developed software that can show graphs and detailed drug use by unit.

"It is an internal database that we can look at to review diversion issues," Shea says.

More Education, Methods Needed

The diversion specialist and members of the team also are creating a controlled substance workflow checklist to be used in unit audits. In reviewing drug use practices, Shea says she is seeing medication overrides granted too routinely.

"That is not really a best practice, but once it is accepted it becomes the norm," she says. "We have had some diversion issues with discrepancies. One of the nurses will go to the charge nurse and say, 'I miscounted — the count's off.' And instead of doing a look-back [investigation], the nurse signs off."

The committee decided to ramp up education and training on diversion and drug-wasting, which prior to that had been a 30-minute program for new hires.

"We realized there is a lot of training and education involved," she says. "We needed education on diversion, discrepancies, and waste."

During an audit, the diversion specialist may pull charts and documentation to see if, for example, any leftover drug was wasted within 30 minutes of administration.

"Did they administer the drug within 30 minutes or an hour of signing it out?" Shea adds. "Those are the kinds of things we are looking at."

The audit checklist is a work in progress, with Shea and colleagues still identifying components to be assessed. Those may include establishing some benchmark for the number of discrepancies a given unit should have.

"Why does this unit have 100 discrepancies and every other one has 10?" she says. "We are still building that part of the program. We based our gap analysis on what the ASHP recommended — their [guidelines] are very well put together."

Given the diverse challenges of a large hospital system and a single diversion specialist, interventions will have to be prioritized.

"We can't do everything at once with one person," Shea says. "We have to look at our inpatient pharmacy and our flow of drugs between our ambulatory facilities and inpatients. We have a freestanding ER and a surgery center. We want to make sure the chain of custody is being followed when we are moving controlled substances to the hospital."

Risk Points

The ASHP warns that there are multiple risk points for drug diversion as controlled substances move through healthcare systems. These include the following at various phases:

- procurement;
- preparation and dispensing;
- prescribing;
- administration;
- waste and removal. ■

REFERENCE

1. Brummond PW, David F. Chen DF, Churchill WW, et al. ASHP Guidelines on Preventing Diversion of Controlled Substances. American Journal of Health-System Pharmacy 2017, ajhp160919; DOI: https://doi.org/10.2146/ajhp160919.

CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

1. describe the legal, clinical, financial, and managerial issues pertinent to risk management;
2. explain the impact of risk management issues on patients, physicians, nurses, legal counsel, and management;
3. identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **What does Susan Haas, MD, MSc, recommend regarding mergers and acquisitions?**
   a. Risk managers should strive to be involved in the process as early as possible.
   b. Risk managers should resist attempts to involve them in the business expansion.
   c. Risk managers should be involved only in the last stage, after most decisions have been made.
   d. Risk managers should be involved only in providing patient safety and liability data regarding their own organization.

2. **Why does Leah Binder urge caution in using reports from the Centers for Medicare & Medicaid Services on hospital quality during a merger or acquisition?**
   a. The data are reported by Medicare provider number and sometimes an entire system uses only one number.
   b. The data are not a useful measure of quality or patient safety.
   c. The data often are outdated by the time the facilities are negotiating a deal.
   d. The data can be compromised by the other organization involved in the negotiations.

3. **In new guidelines on assessing consciousness, what is one of the key findings?**
   a. The prognosis for patients with prolonged disorders of consciousness is worse than previously thought.
   b. Twenty percent of traumatic brain injury patients could recover consciousness.
   c. Twenty percent of traumatic brain injury patients are certain to never recover consciousness.
   d. More patients should be diagnosed with a "persistent vegetative state."

4. **Which of the following is *not* cited by Jennifer Flynn, CPHRM, as a possible reason nurses with more experience have a higher rate of malpractice claims?**
   a. They may get too comfortable in their environment and let their guard down.
   b. Older nurses often take on more complicated cases.
   c. They may be mentoring younger nurses, and that can leave them vulnerable.
   d. Older nurses may suffer from physical ailments that impair their caregiving.

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

Negligent Knee Replacement and Postoperative Care Result in Amputation, $8.35 Million Verdict

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News: An elderly man presented to an orthopedic surgeon to undergo a total replacement of his right knee. However, the surgeon failed to identify circulation problems that previously resulted in a stent insertion. This failure, combined with inadequate postoperative care, resulted in circulation problems requiring an above-the-knee amputation.

As a result of the amputation, the patient's life dramatically changed. He was unable to work, and his wife of more than 20 years became his full-time caregiver. The patient and his wife sued the surgeon and his medical practices, alleging malpractice and seeking damages for pain and suffering and loss of consortium. After a seven-day trial and one day of deliberations, the jury awarded the patient and his wife $8.35 million in damages.

Background: An 82-year-old man suffered from arthritis in his right knee, requiring several years of physical therapy and injections. Despite the patient's age and condition, he lived an active and full life, was a former professional athlete, and worked full-time as a security guard. In 2011, the patient underwent surgical insertion of a stent in the right leg.

In 2013, the patient presented to a surgeon for a total replacement of the afflicted right knee. However, the surgeon failed to analyze the patient's medical history, including the stent. Due to blood circulation complications and a crumbling femoral bone, the knee replacement was not successfully completed; instead, the surgeon used a temporary bone graft and then placed the leg in a whole-leg cast. During the procedure, the surgeon used a tourniquet for two hours at 350 mm and for another two hours and 10 minutes at 400 mm, which the patient later alleged was excessive in pressure and duration.

ACCORDING TO THE PATIENT AND MULTIPLE EYEWITNESSES, THE SURGEON DID NOT EVEN TOUCH THE PATIENT'S LEG DURING SEVERAL FOLLOW-UP VISITS.

During postoperative visits, the surgeon suspected a venous clot in the right calf. The patient presented to a hospital shortly thereafter based on the surgeon's advice; however, according to the patient and multiple eyewitnesses, the surgeon did not even touch the patient's leg during several follow-up visits. The surgeon failed to document any ischemic changes to the leg in notes at two postoperative visits, while other providers noted a blackened, insensate, and partially mummified foot as well as other signs of long-existing ischemic injury. Based upon the severity of the patient's condition, the leg was amputated by a different surgeon above the knee. A pathologist noted that the leg had extensive gangrenous changes, including a hard, black, reddish-black and mummified heel and partial mummification of two toes.

The patient and his wife filed suit against the surgeon and his medical practices, alleging that the physician failed to meet the applicable standard of care, harming the patient and causing his wife loss of consortium. The patient claimed that, at the time of the surgery, he had a number of indications of potential problems that would complicate the surgery due to prior arterial flow issues in his legs. The

patient alleged that the surgeon never documented any examination of the adequacy of the arterial flow in the right leg and was not aware of the components of a vascular examination of the leg. The surgeon apparently relied on the warmth of the leg, which is an improper indicator of good arterial flow.

According to the patient, the standard of care would have been to seek approval from a vascular surgeon, who would have required various intraoperative measures to avoid harming the flow to the leg and would have assisted with postoperative surgical clearance. While the surgeon did consult and receive clearance from a cardiologist, he did not seek the approval of a vascular surgeon.

The defendant surgeon claimed he was not negligent and testified that he asked the patient to return to a vascular surgeon, but that the patient failed to do so. The surgeon further argued that the patient recognized the high-risk nature of the surgery, that this was sufficiently discussed with the patient, and the patient willingly chose to proceed.

After one day of deliberations, the jury awarded the plaintiff $8.35 million: $6.75 million for the patient's pain and suffering, and $1.6 million for the wife's loss of consortium. The defendants sought a new trial, but the court denied the request. The court noted that the surgeon's violations of the standard of care were egregious and caused a significant effect on the patient, changing an outgoing, active 82-year-old man to a reclusive, solitary man who rarely left his own bedroom. The court further commented on the wife's conversion to a full-time caretaker who was unable to enjoy the marital relationship she was entitled to, and who was independently unable to live her own life to a meaningful extent.

What this means to you: This case illustrates the critical need for attention to a patient's details at all stages of treatment and care, not simply during a procedure. The surgeon here failed to look beyond the procedure: He did not adequately consider the patient's history of circulation problems in the right leg and did not adequately monitor and evaluate the patient during postoperative care when the leg continued to deteriorate. Patient evaluation and care is important at all times, and a physician who is focused solely on a surgical procedure or other singular incident may fall below the applicable standard of care if surgeons similarly situated would not do so.

Every patient has a unique medical history which care providers must understand and consider prior to engaging in a course of treatment for the patient. In this case, although the patient lived an active life, he had a history of circulation problems in his right leg and required a stent. At the time of the surgery, the patient reportedly had other indications that complications were likely. During trial, the patient alleged that the surgeon did not understand the components of a vascular examination of the leg and relied upon an improper indicator — leg warmth — during his evaluation.

In this situation, the surgeon should have exercised additional precautions by closely examining the patient and by seeking specialized assistance beyond his own expertise. As both parties discussed during trial, a vascular surgeon's review, approval, and assistance would have prevented a dangerous surgery or facilitated the surgery's success. The surgeon here argued that he asked the patient to return to a vascular surgeon, but the patient refused. But when dire consequences may result from the patient's own refusal, a more cautious course of action dictates that the physician may insist that the consulting physician be brought in, if a reasonable physician would do so under the same or similar circumstances.

Alternatively, if a patient is adamant and refuses no matter what, thoroughly documenting the patient's rejection is important to protect from future malpractice claims where patients may claim that they were not fully informed or were not offered the option.

As with preoperative considerations, postoperative attention and treatment remains essential. Physicians must ensure that their patients are recovering in a manner consistent with what would be standard under the circumstances. When a patient undergoes a particularly difficult procedure, or complications are encountered along the way, additional postoperative attention and care may be warranted.

In this case, critical complications arose that prevented the surgery from proceeding as planned, and the surgeon reported crumbling of the femoral bone. A reasonable physician under the same or similar circumstances should have noted that as a result of these issues, the patient was at higher risk for severe injury to the leg from insufficient bloodflow.

However, this surgeon failed to provide the standard of care necessary by failing to correctly evaluate the patient's leg and by failing to document restricted blood flow and resulting injury. By the time the patient received proper attention, the patient's leg was injured beyond recovery. This could have been prevented if the surgeon met the

standard of care and addressed the patient's needs as they arose.

Physicians have the ability and the right to refuse to continue to treat patients who will not follow their recommendations and instructions. It is prudent to do so if the patient's refusal might affect the outcome of a treatment or procedure. It is imperative that physicians recognize potential risks to patients, but they also must recognize risks that can arise when patients refuse to participate in their medical plan of care.

It is incumbent upon the physician to assure that the patient fully understands the reasons for these recommendations and that this understanding is documented in the patient's medical record. If the need arises to refuse care, it is the responsibility of the physician to assure continuity by cooperating with the patient to find an alternative provider and handing off care formally to the new physician. Often, a patient may rethink his or her decision during this process and acquiesce to the primary physician's requests.

A final lesson from this case is that while a patient's age is often connected with the amount of a medical malpractice award, it is not always the case that an older patient recovers less. When, as in this case, the injuries are devastating and life-changing, an elderly patient may recover significant sums, just as a younger patient would. This 82-year-old man and his wife had their life permanently changed as a result of the surgeon's failure to meet the standard of care, and the verdict of $8.35 million reflected that. Patients of all ages are entitled to care within the applicable standard, and a care provider's failure to provide that subjects him or her to medical malpractice. ■

REFERENCE

Decided on June 15, 2017, in the Superior Court of the District of Columbia; Case Number 2015 CA 008980.

Catastrophic Brain Damage After Delayed Treatment, Respiratory Collapse Results in $26 Million Verdict

News: A female patient presented to a hospital for neck fusion surgery. The day after the surgery, the patient complained of difficulty swallowing, severe neck swelling, and throat pain. She presented to the ED at a different hospital three days later and was admitted at 5:30 a.m. However, she was not seen by the physician until about noon.

The patient suffered respiratory failure, and two physicians — the admitting physician and a pulmonologist — attempted intubation. By the time she was stabilized, the patient had suffered significant brain damage resulting in blindness and loss of coordination and balance.

She sued the hospital and two physicians. The admitting physician settled prior to trial. A jury found that the admitting physician was 100% at fault, but liability was attributed to the hospital as the employer. The pulmonologist was found not liable. The jury awarded $26 million.

Background: A 52-year-old administrative assistant required a common neck surgery after running a 5k race in 2012. She underwent the surgery without incident. However, the following day, she experienced severe neck swelling, throat pain, and difficulty swallowing. A very large bubble appeared to be sitting on her windpipe, causing the difficulties. Three days after the surgery the issues had not subsided, and the patient presented to the ED and was admitted at 5:30 a.m.

According to the hospital's policy, admitting physicians are required to see patients within two hours. The admitting, on-call physician did not see the patient until nearly noon, allegedly because the patient had not complained about any breathing problems. Furthermore, the admitting physician did not review the patient's imaging results. During this intervening time, the patient's condition dramatically deteriorated, and eventually the patient suffered respiratory failure as a result of a postoperative neck hematoma, or blood clot, that closed off her trachea.

A pulmonologist was brought in to assist based on the severity of the patient's condition. The pulmonologist attempted to intubate the patient but encountered difficulty due to the neck swelling. By the time the patient was stabilized, catastrophic brain damage had occurred; the patient is now blind and has significantly reduced coordination and balance, resulting in confinement to a wheelchair. She has little function in her legs and has difficulty grasping with her hands.

The patient brought suit against the two physicians and the hospital, claiming that the hospital was liable for the employee physicians. Prior to trial, the patient and the admitting physician settled for an undisclosed amount. During trial, the patient alleged that the hospital and admitting physician failed to timely and properly treat the blood clot and that delays in imaging and examination resulted in the botched intubation. The patient's experts opined that the patient would not have suffered any brain damage if she had been sent to the hospital's operating suite for intubation under anesthesia in a timely manner. The patient's experts further claimed that the pulmonologist should not have sedated the patient and that he failed to properly intubate her.

The defendant hospital argued that the admitting physician was immediately available as required and that the patient was constantly monitored by other staff; the hospital claimed that any respiratory distress signs would have been noted immediately. The pulmonologist alleged that he was brought into an already crisis situation, and under those circumstances his care was appropriate. He further argued that he requested, but did not timely receive, assistance from hospital staff.

The trial lasted two weeks, with about two dozen witnesses and multiple experts opining for all parties. After seven hours of deliberations, the jury determined that the hospital was liable for the negligence of the admitting physician, and that the pulmonologist was not negligent at all. The jury awarded $26 million in damages to the patient. Another surprise followed the verdict: The hospital agreed to forgo all appeal rights and pay the full judgment in exchange for the patient withdrawing a request for attorney's fees.

What this means to you: Delayed diagnosis and treatment are common circumstances that give rise to medical malpractice claims. As with this case, the medical issues involved were not complicated or uncommon. What resulted in a finding of medical malpractice was instead the physician's failure to treat the patient in a timely manner. While this seems obvious to most physicians and care providers, it is critical to attend to patients, evaluate them, and provide treatment. ED settings such as with this case necessarily include the juggling of multiple patients, each of whom may require immediate action; physicians are not superhuman and cannot be in multiple places at once, so there are times when some delay is unpreventable.

One of the important items discussed in this case was the hospital's policy for ED admissions and physician review. The hospital's policy required that admitting physicians see patients within two hours. While such a policy is not determinative of whether malpractice occurred, a physician complying with the policy will appear much more reasonable to any potential jury.

By contrast, the admitting physician in this case reportedly did not see the patient until approximately 6.5 hours after admission. That glaring failure to satisfy the hospital's policy undoubtedly weighed against the physician, and a reasonable physician given the same or similar circumstances would have seen and treated the patient much sooner to prevent the eventual respiratory emergency and distress.

It is not unusual for hospitals, in an attempt to create policies and procedures that meet regulatory and licensing requirements, to box themselves into a corner by creating restrictive policies that go well beyond minimum requirements. Rather than determining the number of hours required in which a new patient must be seen by the attending, it may be better to use phrases such as "within a reasonable amount of time not to exceed four hours" or similar statements that allow flexibility while still meeting requirements.

Physicians are not the only care providers in hospitals. In fact, most of the time patients are in the hospital, they are under the watchful eye of trained, licensed nurses who act as the eyes and ears of the physicians. These RNs are trained to assess and intervene when patients' conditions change. Rapid response teams are now required in acute care hospitals. Calling a rapid response code brings high-level expertise to the bedside, including respiratory therapists and intensive care nurses and physicians. Patients with potentially life threatening injuries or illnesses can be quickly assessed and transferred to the appropriate service or level of care even if their attending physician is not available.

Finally, while the admitting physician was found to be liable, the pulmonologist was cleared of all fault. Medical malpractice does not occur simply because of a devastating outcome for a patient. Rather, it occurs when a physician fails to meet the applicable standard of care — that is, when a reasonable physician under the same or similar circumstances would not have acted as this physician did.

For the pulmonologist in this case, he satisfied this standard: He entered into exceedingly difficult and emergent circumstances, but the care he provided was consistent with what a reasonable physician would have provided under those circumstances. ■

REFERENCE

Decided on Dec. 11, 2017, in the Muscogee County Court in Muscogee County, GA; Case Number SC14-CV884.