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INSIDE



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# Crisis Management Requires Action Plan for Quick Deployment

Crisis management after a significant clinical event or other issue can thrust the risk manager into a sink-or-swim situation. A proper response can minimize the negative effect and a poor response can greatly magnify the fallout. Managing such an event requires preparation up front so an action plan can be activated when needed.

The well-being of patients and family should be the first consideration in a crisis event, followed closely by the staff, says **Leslie M. Jurecko**, MD, MBA, senior vice president for quality, safety, and experience at Spectrum Health, based in Grand Rapids, MI. Spectrum Health plans for crisis management by considering four buckets of concerns, she explains.

The first is concern for the patient and family. The second involves the frontline staff involved in the event. Only after those groups are taken care of does the health system address its own concerns, Jurecko says. The fourth group is the leadership and executive board of Spectrum Health.

"I have found that organizations tend to worry about how to communicate with the board of directors and leadership, and that takes the eye off what is most important: the patient and family involved in the event," Jurecko says. "We're very disciplined about not going on to those other groups before we really surround the patients, family, and frontline staff with what they need."

> THE WELL-BEING OF PATIENTS AND FAMILY SHOULD BE THE FIRST CONSIDERATION IN A CRISIS EVENT, FOLLOWED CLOSELY BY THE STAFF.

Jurecko and her colleagues usually learn of adverse events and crises through reports to the risk

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manager, who passes the notice on so that the health system can deploy its crisis management plan, she explains. An immediate response is crucial, she says.

"It helps us with disclosure to the family, and it helps us work through whether we need to be more transparent, whether we need to apologize, and determine whether we need to protect other patients from this happening again," Jurecko says. "When we move on to system issues, we're thinking about whether this can happen again tomorrow. Using the high reliability preoccupation with failure, we think about what things we need to control so that this doesn't happen again."

## Involve Patient, Family Early

Spectrum Health uses a crisis management checklist that concentrates on those four areas of concern. The checklist includes items such as who should be with the family when going through the disclosure process, appointing staff members to stay with the family or be available at any time, and providing family members a phone number for immediate access to someone familiar with the situation for updates or to answer questions.

Spectrum Health has learned the importance of involving the patient and family members as early as possible in crisis management, disclosing information as it becomes available in an effort at full transparency, she says.

"We also like to include their trusted providers in the process. If they have a primary care provider they know and trust, we will reach out to them and bring them into the process," Jurecko says.

The health system also performs functions that Jurecko says can be easily overlooked but are important in crisis management. For instance, Spectrum Health puts an immediate halt to all billing for the patient and family after an adverse event. For especially sensitive cases in which a loved one has died or been seriously injured, the health system halts all other mailings to respect the family's time to grieve and heal.

"We don't flood them with all the other information that can come from a health system and, in that circumstance, seem insincere and inappropriate," Jurecko says. "We're good about working with our communications team to think through all those extra things that you might not think about at first but which are important if you're going to respond in the best way to these events."

## EXECUTIVE SUMMARY

Crisis management in healthcare can determine how much an organization suffers from an adverse event. Risk managers should ensure there is an action plan for responding to a crisis.

- The well-being of patients and family members should be a top priority.
- Transparency and good communication are key to limiting the effects of an incident.
- Employ a crisis management team that is trained and ready to respond quickly.

Leadership at the health system hold a conference call within 24 hours, often on the day of the event, to go through the checklist and determine next steps. "We have to take a deep breath and not go into that call with the wrong attitude. The entire team will feed off any anxiety we express, and we cannot blame the humans involved in the incident," she says. "We immediately talk about not blaming the humans and looking for the systems failures. That's how we set the tone of these calls."

The leaders do not end the call until they have a plan for disclosure to the family and mobilizing the system's crisis incident response team for the staff involved, Jurecko says. That response team is headed by the pastoral care department and includes staff members from across the system who have been trained in helping others deal with stressful events.

## Debrief for Emotional Well-Being

The crisis incident response team conducts a debrief with staff members involved with the incident, but the focus is entirely on the emotional well-being of the staff, Jurecko explains.

"It is not a root cause analysis debrief. This is for the team to start their healing process," she says. "Getting to the stage where people are comfortable with that idea has taken time. After one of these events people are very stressed about people being blamed and what is going to happen to them. They need to be reassured that our first concern is their emotional and physical health, and that any investigation into what happened will focus on system issues rather than individual blame."

The conference call also includes the risk manager providing some initial harm coding that makes it possible to start formulating a root cause analysis, Jurecko says. An executive also is named as a sponsor for the health system's response to the incident, she notes.

The response plan can run into problems if the organization loses contact with family members after the event, Jurecko says. That is one reason it is crucial to immediately assign a staff member as the family's contact and encourage a bi-directional line of communication, she says.

Hospitals and health systems should build crisis management plans that embrace transparency and concern for those most affected, Jurecko says. Timidity based on fear of litigation or media exposure will only hamper the effort and backfire in the end, she says. *(See the story on page 124 for more on why it is detrimental to minimize public comments.)*

"Don't be scared. Be bold on this," she says. "A lot of healthcare organizations and their team members feel scared about talking about things that don't go well at the hospital. We have to remind them that this is a complex system and taking care of your patients, family, and frontline staff is the best thing you can do. It always ends up better than keeping patients, family, and staff out of it, which just makes for a harder journey."

## Some Organizations Fearful

Some healthcare leaders are becoming more fearful, resulting in poor crisis management decisions, says **Matt Friedman**, co-owner of Tanner Friedman Strategic Communications, a public relations and strategic communications firm based in Farmington Hills, MI, with crisis management experience in healthcare.

"It can be fear of executive wrath, litigation, reputational damage," Friedman says. "I encourage them to do the right thing because, especially in healthcare, just doing the right thing goes a long way. You're supposed to be in the business of helping people, providing life, saving lives, so doing the right thing should be a guiding principle."

Risk managers and other healthcare leaders should be prepared to address challenges head-on, Friedman says. Healthcare entities are too high profile to think they can get away with hiding bad information, no matter what the lawyers say, Friedman explains. They are often the largest employers in their communities, and often are owned and governed by their local communities, making it especially difficult and ill-advised to try to hide bad information, he says.

"Fear of litigation often forces healthcare entities to not say anything or not say enough. They are in the people business, so issuing statements alone can't get them through every situation," Friedman says. "A client has told me that sometimes you have to push people, not paper. There are trusted individuals inside every healthcare organization, and they often make the best possible spokespeople who can talk to audiences with authority, credibility, and provide reassurance, along with concern for people affected."

## Respond Quickly, Clearly

Speed of response is key, Friedman explains. The longer it takes to respond, the greater chance that the

crisis will rise in news prominence and dominate news coverage and public discussion, whether or not that is warranted, he says.

But quality of response also is key. Empty and hollow does not work for healthcare, he says.

Friedman recalls working with a hospital that realized it may have performed procedures with gastrointestinal scopes that were not properly sterilized. The risk to patients was very low, but the hospital decided to send notification letters to patients. A few dozen patients were affected.

"That definitely fell under doing the right thing, but I encouraged them to go a step further. They had a physician call each patient, alerting them that the letter would be arriving soon," he says. "The physician described the situation, said the risk was very low, but that the hospital wanted them to know and to answer any questions they might have. There were only positive responses from the patients, no litigation, and no media coverage at all."

Risk managers should work closely with the organization's public relations department for crisis management, Friedman says. Involve them as early as possible in crisis management.

Do not make the mistake of thinking the role of public relations is only to talk to the media and take complaints from the public, he says. "Sometimes, public relations can be the conscience of the organization, if they're doing their jobs well," Friedman says. "They should be able to look at the organization from an outsider's perspective, seeing how the hospital is being perceived and what people need from it at that moment, and they should be able to connect with their audience in a personable way."

It is essential to assemble a crisis management team that is ready to respond quickly, says **Mary Patrick**, CEO and managing partner with Jasculca Terman Strategic Communications, a Chicago firm that handles crisis management for healthcare organizations. That team should include internal communications, legal counsel, risk manager, and outside communication agencies if internal communications is inexperienced or too busy, or if the crisis is too big to handle internally, she says.

The team also should include a decision-maker, possibly the CEO or another high-ranking executive who can make decisions quickly, she says. Once the crisis management team is mobilized, you should add team members relevant to the incident, such as the head of the clinical department involved.

Patrick offers this list or priorities for crisis management:

- Support the victims;
- Fix the problem;
- Ensure all stakeholders know how you are handling the event;

## 'NO COMMENT' IS NEVER THE RIGHT RESPONSE

When something has gone wrong and your hospital or health system is under scrutiny, it may seem the simplest response is to say nothing. But that can be a huge mistake, because "no comment" never looks good. Healthcare organizations sometimes mishandle crises by buttoning up, issuing terse statements through public relations, and encouraging the public to think they have something to hide, says **Matt Friedman**, co-owner of Tanner Friedman Strategic Communications.

That can result from people thinking that they must follow internal procedures to the letter, fearing that any deviation will cost them their careers, he says. That is one reason the internal procedures must be constructed so that people can be transparent and communicate effectively.

"Some healthcare organizations like to talk through heavily lawyerized statements, in the name of protection and safety, without thinking of direct communication with their audience," he says. "I worked with one hospital that was about to settle with government over a marketing issue, nothing to do with patient care. I wrote a message from the CEO to the public that was forthright about the matter, trying to get ahead of any publicity. The attorney for the hospital that handled the settlement with the Department of Justice completely rewrote all the materials and made them sound like lawyerized stuff that would be submitted to a government bureaucrat."

Friedman had to negotiate with the lawyer to balance the legal message with the information the hospital wanted to convey to its audience.

"If only the legal message got out, the community may have been confused and unnecessarily nervous," he says. "It's a good strategy to negotiate this on the front end so that the message getting out is effective and limits how long the bad news is out. Otherwise, you can have lawyers overruling whoever wrote the original message, and only the legal message makes it out to the public." ■

- Mitigate damage;
- Engender sympathy or trust;
- Build back positive reputation.

## Be Careful With Social Media

One of the most common mistakes or oversights in crisis management is moving too slowly, because trouble fills a vacuum, Patrick says. Other mistakes include neglecting to communicate to staff and internal audiences, acting or looking defensive, and not apologizing when warranted.

Engaging early or wrongly on social channels can be another big mistake, she says. Sometimes, just entering the conversation elevates it because a big health system has now weighed in, Patrick says. Engaging with social media needs to be a strategic decision.

"A lot of times, people focus a lot on the digital media and trying to figure out how to respond on those platforms, but you have to back up and think about the other audiences that matter to you," Patrick says. "People forget to communicate with their staff, so focused on external audiences that they forget about the people around them. They can be your best ambassadors for you when people stop them at the grocery store or bus stop to ask what's going on, but they can't be helpful if you haven't told them anything."

It is important to have one voice speaking for the organization in a crisis, says **Stephen A. Timoni**, JD, an attorney with Lindabury, McCormick, Estabrook & Cooper in Westfield, NJ. The media and attorneys will look for inconsistencies, seizing on them to allege impropriety, he notes.

"That spokesperson should have a clear and consistent message regarding the incident, which should be developed by a team that includes your lawyer. The message should be completely truthful," Timoni says. "This is a difficult position to put someone in because they have to perform well under pressure. That might not be your CEO, because that person might be a great manager but not necessarily the best person to communicate this message in the most effective way."

It also can be important in some situations to notify your insurance carrier, Timoni notes.

## Get Facts Quickly

A crisis management plan also must allow participants to gather facts quickly, says **Janey Bishoff**, a crisis management expert in Boston. Gathering the facts can be challenging, but is critical in any crisis, she says.

"There are only minutes, not hours or days, to understand what happened. Leaders should ensure that they have a way to immediately gather all of the information necessary about the situation," she says. "In a crisis, information is paramount, yet it often is like peeling back an onion to obtain all of the facts necessary to effectively manage the crisis."

Preparation ahead of time is key, she says. The team must know their roles in a crisis and have a crisis playbook, a plan that can be implemented almost instantaneously.

"It is not a binder with hundreds of pages, or even tens of pages, that sits on a shelf. It should be a living document with checklists," Bishoff says. "Today's preparation must include discussing and preparing for all types of reputational crises as well as emergencies. Most healthcare organizations are well prepared for a patient or facility emergency, but few organizations are focusing on all of the different types of issues that can throw even the most well-respected organization into crisis."

## Public Wants Transparency

Understand that the public demands transparency, Janey says. If it becomes clear that leadership did not know what was happening in the leaders' own organization, that can add to or become the crisis, she says.

Do not make the mistake of thinking that a crisis will never hit your organization, Janey says. Many healthcare organizations prepare for emergencies caused by natural disasters, but not for human errors, lapses of judgment, and the many other incidents that can become a crisis, she says.

Never trust that there are some individuals, including those on the leadership team, who do not need to undergo training for issues such as sexual harassment, Janey says. "Another common mistake is trying to think that something won't become public," she adds.

The key elements that will determine how well the organization fares after the event are how quickly the organization responded, and how forthright the organization was in the response, Janey says.

"If an apology was needed to regain trust, the outcome also will be determined by whether the organization promptly accepted responsibility and if they apologized," Janey says. "The public is amazingly forgiving when leadership quickly acknowledge and

take responsibility for a mistake, a lapse in judgment, or a rogue player, and when they make an apology that is sincere and authentic. The apology should not only acknowledge the need to make changes, but demonstrate how the changes have been or will be made quickly." ■

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# 2020 to Bring More Focus on Patient Safety, Technology Solutions

Patient safety will be the primary concern for risk managers in 2020 as government regulators and accrediting bodies continue to raise their expectations in this area for healthcare organizations, several experts predict.

Regulatory requirements concerning patient safety will continue to expand in the coming year, says **Bette McNee**, RN, NHA, clinical risk management consultant at insurance broker Graham Company in Philadelphia. Healthcare organizations are beginning to look for ways to make better use of nurses and other staff, helping them to work at the top of their abilities rather than handling menial tasks, she says.

McNee notes that some hospitals are even experimenting with the use of robots that can fulfill minor tasks such as delivering items to a patient. This can help address a growing concern over the patient experience, in which a hospital can be downgraded for nonclinical concerns such as a family member unhappy with how long it took a nurse to bring a requested item, she notes.

Improving the patient experience is important because it can reduce liability risks, McNee says. Disgruntled patients and family are more likely to press for litigation, she says, even when their source of dissatisfaction is relatively minor and not associated with patient care.

"One of the things we expect to be a priority for risk managers is using technology to improve efficiency. That can increase patient safety and reduce nursing burnout," McNee says. "We have this increased scrutiny on patient safety. If we can save the staff and nursing time for what matters most to the patient's safety, that's an improvement for everyone."

## Also Threats From Technology

But at the same time, McNee notes, healthcare organizations are becoming increasingly wary of patient safety threats from malfunctions of machines and medical devices.

"When you have a cool IV pump that is tied to the call bell system and does all these other things, a failure in any of those machines can increase the liability risk," McNee says. "For risk managers, it will be a huge concern to make sure that maintenance and failsafes with existing technology are addressed with this new technology."

The prudent deployment of technology should be a goal for 2020, says **Tracey Kilcullen**, Esq., vice president of claims services with Graham Company. Work toward using technology to reduce the staff's work burden of menial tasks requiring no special skill or training, allowing nurses to focus on patient safety and improving the patient experience, she says.

"If you are trying to use technology to do things that in the past trained clinicians have done and you're doing it perhaps too fast or not in the best way, you might just create more fodder for plaintiffs' attorneys claiming profit over patients," Kilcullen says.

## Improve Root Cause Analyses Now

McNee also encourages risk managers to look at how well they have been performing root cause analyses. If you have let yours become routine exercises, now is the time to improve, she says.

"Some people do a great job at

root cause analysis, and sometimes it is more of a perfunctory, checkbox kind of thing. If hospital risk managers have not truly engaged all staff in good root cause analysis and robust process improvement, doing it on a high level and getting by without engaging frontline folks, your successes are going to be short-lived," McNee says. "If you haven't implemented that just culture and pulled people from the floor to engage in the analysis of an adverse event, near miss, or good catch, now is the time to do that. You will not be able to survive the coming changes if you haven't."

The medical community will see an increased effort to reduce adverse events in 2020, says **Albert Wertheimer**, PhD, MBA, adjunct professor of social, behavioral, and administrative sciences at the Touro College of Pharmacy in New York City. In addition to the concern for patient safety, healthcare organizations increasingly are aware of the costs associated with an adverse event, he says.

"ln 2020, we will see several avenues employed to reduce risks. One is through what has come to be called customized or personalized medicine. By genotyping patients, prescribers will have a far better idea about which drugs can be more safely and effectively used in different patients, depending on their metabolic characteristics, enzyme production, and other physiologic parameters," Wertheimer says. "This includes customizing the dosage."

The FDA also has contracted with large health insurers for signal detection services, Wertheimer notes. This initiative is aimed at addressing how, if a single doctor in Boston sees only one adverse event with a specific product, he or she probably does not worry about it. But if similar individual reports of that same problem come to light in Seattle, Los Angeles, and Chicago, the FDA and the manufacturer can investigate the situation before it becomes huge and causes needless harm.

The signal detection services are intended to warn physicians so they can use an alternative product, he explains.

## Drug Interactions Targeted

Medical education is focusing more on adverse event avoidance, Wertheimer says. For instance, pharmacists are providing medication therapy monitoring services to help patients taking multiple medications to prevent drug-drug interactions and related problems, and insurers are reimbursing for these services as they have proven their worth, he says.

Another technique to reduce adverse event risks or to prevent less-than-desirable outcomes is by using technology assessment principles. ln the United States, new drug products are tested against a placebo to learn whether a drug is effective and safe, he notes, but those clinical trials are limited in what they can reveal.

"In the European Union, they conduct head-to-head clinical trials, testing the new drug candidate against the usual and customary current drug of choice," he says. "This latter method tells us not only if the new drug is safe and effective, but whether it is superior, equal, or inferior to the existing product. That is a huge improvement."

This health technology assessment is called comparative effectiveness research when it involves pharmaceuticals, he explains. Wertheimer also notes that patient safety may improve with the FDA's upcoming Tack and Trace system. Every individual bottle of medication would be assigned a unique faculty number, he explains.

"This list will be kept in a huge database. lf someone offered a hospital in Cleveland some drug products, one would be able to see that this drug is shown as being in inventory at a wholesaler in Denver and the product offered in Cleveland must be counterfeit, or a bad batch that was supposed to be destroyed," he says. "This should eliminate most subpotent counterfeits." ■

### SOURCES


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## EXECUTIVE SUMMARY


Risk managers should expect patient safety to dominate their work in 2020. Increasingly, regulators and accreditors are focused on patient safety.

- Use technology wisely to free up nurses for more skilled work.
- Technical malfunctions that threaten patients need attention.
- Changes to pharmaceutical management may reduce adverse events.

# New Approach Needed to Address Workplace Violence

Workplace violence occurs at rates more than four times higher than in other industries, says **Scott Cormier**, vice president of emergency management, environment of care, and safety with Medxcel, a healthcare facilities management company based in Indianapolis. Patients and family are under stress, and often take it out on the physicians, nurses, and other employees.

"We are seeing that what we've been doing for decades in healthcare — taking de-escalation cases and writing policies — doesn't work. Organizations will have an incident in which someone is injured, they'll throw some money at it to do some training and write another policy, then they move on until the next incident," Cormier says. "We need a paradigm shift. We need a sustainable process that actually helps protect our workers rather than just going through the motions after an event."

Eighty percent of workplace violence in healthcare comes from patients, but the rest involves coworkers and outsiders such as vendors, Cormier notes. Any solution must begin with collecting data on how violent incidents occur, he says. That should include near misses.

Cormier recalls working in an ED where it was an accepted part of the job that patients and family members would occasionally become violent. People swung fists at him regularly, but unless the blow landed and caused injury it wasn't reported. If he ducked and the punch missed, that was a good day and there was no report.

"We need to collect that data, and we have to make it easy to collect that data," he says. "If your employee has to spend 10 or 15 minutes on a website reporting that incident, they're not going to do it."

Once data are collected for a baseline, the paradigm shift can begin, Cormier says. The first step is training, but not just a handful of high-risk employees, he says. "We should be training the whole hospital. Everyone needs to be trained in how to recognize the potentially violent person and how to respond in a constructive way," Cormier says. "Think of all the people a patient encounters on a visit to the hospital — the volunteers, registration people, triage nurses. All of those people are typically not trained in workplace violence, but they should know what to do when they see someone in the waiting room who is escalating and how to respond quickly before it gets worse."

The training must not be burdensome, Cormier says. An intense, full-day seminar not only takes the employee away from job duties, but it also overloads them with information that they will file and try to remember months later when needed, he explains.

"A better approach is to use shorter classes of maybe two hours, with monthly updates," Cormier says. "A team huddle also is a good opportunity once a month to talk about what we learned about workplace violence and how to prevent it. That way, it's kept at the front of your mind and you don't have to dig back so deep when something occurs to try to remember the right response."

Cormier recommends a team approach that includes risk management, human resources, behavioral health, critical care, and surgery leaders, as well as representatives of the workers who have day-to-day interaction with patients but typically are not considered frontline caregivers. Those include housekeepers and administrative clerks.

The plan should involve developing a threat assessment team that can respond at any time, around the clock and on weekends, to situations in which staff are concerned that someone may become violent.

"You also should get your local law enforcement involved with this team because if an incident escalates to violence and they respond, you want them to be familiar with your process," Cormier says. ■

# Cyber Risks Will Continue to Grow in 2020

With cybersecurity, one of the biggest patient safety threats is ransomware, says **Anthony Chadd**, global sales vice president with Neustar, a technology and analytics company based in Sterling, VA.

"It looked like ransomware attacks were on the decline in healthcare last year, but attackers have adjusted their tactics and we've seen several new variants emerge that have impacted all levels of the industry," Chadd says. "In just the past few months, ransomware attacks hit the DCH Health System in Alabama, Omaha-based CHI Health Lakeside Hospital, the Premier Family Medical physician group in Utah, and the Campbell County Health system in Wyoming."

Ransomware attacks have become easier to launch, and attackers increasingly are targeting smaller healthcare organizations where cyberdefenses may be less sophisticated and employees less savvy about how to spot threats, Chadd says. While small providers and practices may have basic cybersecurity protections in place, they typically lack a mature cyber response plan and do not have the resources and expertise needed to initiate a successful recovery process, he says.

For example, a recent attack against one California provider caused it to permanently close its doors after attackers encrypted and destroyed servers containing all EHR data, as well as backup hard drives, Chadd says. Attackers rightly recognize ransomware as an easy, effective way to garner financial gain. This dynamic is exacerbated by organizations that opt to pay the ransom — which perpetuates this cycle and leads to more attacks, he says.

Neustar is seeing a concurrent trend in the rising number of multivector DDoS attacks and an increase in the number of very small-scale attacks, Chadd says. The company's latest Threats and Trends Report notes a 133% increase in the number of attacks (measuring Q2 2018 vs. Q2 2019) and a 158% increase in the use of smaller, less immediately identifiable attacks.

"These attacks are small enough to slip by normal attack mitigation thresholds and are becoming more targeted in their ability to degrade or disable specific infrastructure within the target," Chadd says. "Because such attacks can continue for days without discovery, attackers can degrade specific infrastructure targeting vital business functions."

## Breaches Originate Outside

Organizations are focused on taking the necessary steps internally to ensure patient medical data and other critical information is protected, but a huge number of breaches are the result of a violation by an external cloud partner or third-party managed service provider, Chadd says. A recent Neustar International Security Council study found that 89% of senior cybersecurity leaders are concerned about someone hacking their third-party managed service providers (MSPs), and 53% said they would change cloud providers if they could.

Most institutions work with multiple MSPs, and system compromises due to a third-party security violation will increase unless they take extra steps to secure their systems and ensure partners adhere to the same set of strict security standards, Chadd says.

"This includes developing a risk register to determine what their most critical assets are, and ensuring they have the appropriate DDoS protection in place to secure against a wide range of attack vectors," he says. "Proactively, healthcare organizations should ensure that any third-party MSP they work with adheres to a rigid set of security principles and practices. Ideally, these should be put into place in the negotiation phase before a partnership is struck."

## Patient Matching Often Fails

Patient matching and identification will continue to be a safety hazard in 2020, says **Andy Aroditis**, CEO of NextGate, a healthcare data management company based in Monrovia, CA.

"Moving into 2020, the healthcare industry continues to endure dramatic change and, in turn, evolving risk," he says. "With increased use of technology in relatively every aspect of healthcare, subsequent risk imposed on patient safety as part of digitization is only expected to grow."

Duplicate records often occur because of multiple name variations, data entry errors, and lack of data standardization processes, Aroditis explains. A typo or absence of a single digit in one's birth date, address, or phone number can result in the creation of a duplicate. Patients move, marry, divorce, and visit multiple providers in their community, where new records

are created and the potential for duplicates grows.

"While EHRs have become commonplace, the disjointed, competitive nature of systems contributes to an influx of duplicate and disparate medical records. The issue of poor patient identification becomes exponentially more problematic and dangerous as more data are generated and more applications are introduced into the healthcare environment," he says. "Without consistently and correctly matching individuals to their health data, patients and providers alike will continue to suffer the consequences."

Attention to accurate patient identification has accelerated in the past few years, with all sectors of the industry working to develop a better understanding of the issues and identifying potential solutions, Aroditis says. While healthcare's massive transformation is forcing federal officials to rethink current approaches for patient matching, the nation's longtime ban on a universal patient identifier remains intact, he notes.

"When Congress dismissed the concept of a national patient identifier in the early 1990s, healthcare's IT infrastructure was still relatively immature. Today, however, in the wake of digitization, healthcare organizations are inundated with data, and widespread information-sharing across settings remains a decisive goal," he says. "The absence of a unique identifier has forced regulators to engage the private sector to help develop a coordinated strategy that will promote patient safety by correctly linking patients to their healthcare data."

Patient matching functionalities within EHRs often lack the complexities to unify information from external systems, Aroditis says. Poorly designed systems that fail to integrate or communicate with one another exacerbate inefficiencies, generating millions of duplicate and incomplete records that lead to patient safety errors, skewed reporting and analytics, administrative burdens, and lost revenue, he explains.

"As healthcare becomes consumer-driven, it is equally critical to consider use of other identification mechanisms to ensure that patient demographic information is accurate and up to date," he says. "Use of personal smartphones, for example, to streamline registration and allow patients to play an active role in managing and updating their data can help improve patient matching efforts at key stages where data errors often occur: during enrollment and at registration."

One of the biggest cyber risks for 2020 will be the continued proliferation of malware attacks via business email compromises that inject malware designed to find vulnerabilities in the system and compromise sensitive data, says **Steve Leatherman**, managing director for healthcare with BlackRidge Technology in Reno, NV. The FDA recently issued a warning about cybersecurity vulnerabilities in some medical devices that connect to the internet, he notes.

The vulnerabilities, referred to as URGENT/11, allow a malicious actor to potentially take control of these medical devices and steal data, change the settings, or turn them off completely, he explains. As medical technology advances and more devices are connecting to the internet, the exposure of vulnerabilities such as those documented in URGENT/11 will become increasingly common, he says.

"The continued proliferation of insecure internet-of-things devices throughout healthcare networks is an urgent and pressing trend. This connectivity creates challenges across many fronts," he says. "The root of the problem is that security remains an afterthought in the development of many connected devices, as product developers and manufacturers prioritize speed to market. The faster you can get a new product in the hands of consumers, the more likely you are to capture market share, but this means many new connected devices lack anything beyond very basic security features."

In the case of medical devices, this can lead to compromises of sensitive medical data, vital equipment coming under cyberattack, and even the death of a patient, he explains.

Added connectivity poses a wide range of challenges, Leatherman says. Within a hospital/clinical setting, connectivity creates added vulnerability around the protected health information (PHI) of a patient, he says. Connectivity also creates risk within patients themselves. For example, smart implants like pacemakers contain vulnerabilities that, if exploited, can create a potentially life-threatening situation for a patient, he says.

Additionally, the rise of telehealth solutions to assist external patients creates new security challenges for hospitals and healthcare practices. The U.S. now has more than 7,000 designated Health Professional Shortage Areas — or healthcare deserts — affecting a geographic footprint that is home to 80 million people across much of rural America, Leatherman explains. Health tech companies are working to close this gap with a range of telehealth and remote patient monitoring solutions that can share real-time patient data

with remote doctors to eliminate the need for on-site monitoring and reduce readmission rates.

In terms of keeping patient data (and patients themselves) safe from malware attacks, one of the main areas of focus should be advocating for a shared responsibility model, Leatherman says. Addressing insecure medical devices and protecting PHI is the responsibility of both vendors and hospitals, he notes.

The implementation of a "zero trust" model that incorporates network microsegmentation and authenticated identity represents a smart, multilayered defense strategy — and is increasingly critical as the amount of interconnectivity increases, Leatherman says.

Zero trust requires authorization before any attempt at a network connection can be made, even for users already within the network perimeter. Microsegmentation divides the network into smaller and smaller nodes, creating additional access points to verify identity, Leatherman explains. Authenticated identity ensures that with every communication request, from the first connection to each move within the network, identity is re-verified before a connection is made.

"This approach can prevent malware attacks, or at least mitigate the damage that can be done once a bad actor is inside the network, confining them to the point of entry and ensuring they aren't able to create more damage," he says. "Solutions like this can be monitored by the vendor company, but must be advocated for by physicians, administration officials, and accreditation bodies on behalf of their patients."

Leatherman notes that the biggest direct risk to patients right now is not the hacking of PHI. Rather, it is at the patient care level, where test results are attributed to a patient.

"Think about a patient coming into the emergency room. That patient may get bloodwork and then possibly be rushed up to surgery," Leatherman says. "How can the surgeon be certain that the results from the bloodwork, which are guiding decisions about the surgery, have not been tampered with?"

One challenge is that a hospital's IT department is a non-revenue-generating department, Leatherman says. Unlike a new medical device or procedure that benefits the hospital because it saves time, money, or benefits the patient's outcomes, the IT department is an expense — one that typically is 10 years behind the curve in terms of implementing leading-edge technology, he says.

"Risk managers should be advocating for an adequately funded IT department. With the proliferation of connected medical devices being added to the network, new attack vectors are constantly emerging," Leatherman says. "In an urgent scenario, unsecured patient information can lead to harm or death, opening the hospital up to liability for not properly protecting the data. Implementing a zero-trust framework with microsegmentation and authenticated identity to restrict access to the entire network is something that should be implemented with urgency." ■

## CE QUESTIONS

1. **What should be the first consideration in a crisis event, according to Leslie M. Jurecko, MD, MBA?**

   a. The well-being of patients and family
   b. The reputation of the organization
   c. Informing the board of directors
   d. Cooperating with the media

2. **What does Stephen A. Timoni, JD, say regarding who should be the organization's spokesperson in a crisis?**

   a. It should never be the CEO.
   b. It should always be the CEO.
   c. It should be the most respected person in the organization.
   d. It should be someone who communicates well.

3. **How does Bette McNee, RN, NHA, recommend using technology in 2020?**

   a. To reduce the menial work burden of nurses so they can focus on skilled tasks
   b. To reduce the number of nurses and other staff in an organization
   c. To take on more skilled nursing care and improve profits
   d. To offer services that bring in more profitable patients

4. **Which data should be collected but usually are not, according to Scott Cormier?**

   a. Incidents of workplace violence
   b. Near-misses with workplace violence
   c. Training documentation in workplace violence
   d. Police reports regarding workplace violence

HEALTHCARE RISK MANAGEMENT™



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

# Court of Appeals: Plaintiffs Failed to Present Issue of Fact by Not Using Expert Testimony

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**News:** A court of appeals affirmed a trial court's decision that plaintiffs' medical malpractice claim against a hospital and two physicians lacked factual support, and that the claim required expert testimony to establish the applicable standard of care.

A patient's parents alleged that physicians negligently administered medication used to treat mental and mood disorders, causing the patient to suffer cardiac arrest and distress. They also alleged that the physicians failed to appropriately treat the patient's distress. During trial, the defendants moved to summary judgment, which was granted.

The court of appeals found that, although the plaintiffs identified an expert witness in their summary judgment affidavit, this alone was not sufficient to create an issue of material fact. Thus, the trial court did not err in granting summary judgment, nor did it abuse its discretion in failing to grant extensions for plaintiffs to produce an expert testimony.

**Background:** In 2012, a patient was admitted to a hospital to receive treatment for a mental health condition, where she received an antipsychotic medication. However, after the patient received two injections of the medication in a short time, the patient developed a pulmonary embolism and suffered from cardiac arrest and cardiac distress. In the litigation that followed, the plaintiffs alleged that the physicians did not adequately respond to the medical emergency and that the hospital was not equipped with trained personnel and appropriate equipment, which led the hospital to call a separate city emergency unit to administer emergency care to the patient. These emergency services were insufficient, and the patient died because of the cardiac arrest.

THE COURT OF APPEALS FOUND THAT, ALTHOUGH THE PLAINTIFFS IDENTIFIED AN EXPERT WITNESS IN THEIR SUMMARY JUDGMENT AFFIDAVIT, THIS ALONE WAS NOT SUFFICIENT TO CREATE AN ISSUE OF MATERIAL FACT.

A year later, the patient's estate and parents filed a malpractice complaint with the state under the state's medical malpractice act against two physicians and the hospital. The medical review panel unanimously found in favor of the defendant hospital and physicians, concluding that the evidence did not support a finding that any defendant failed to meet the applicable standard of care. The review panel found that the medication had been administered only once in accordance with the physician's instruction and pursuant to the "regular" course of treatment followed under these circumstances. Further, the panel found that the administration of the medication was in accordance with the standard practice, emergency services had been timely contacted to address the emergency, the patient had received the medication previously and had not experienced an adverse reaction, and no causal link had been found between the medication and the development of a pulmonary embolism.

Following the panel's decision, the plaintiffs sued in state court. Early in the litigation, the defendant hospital and physicians moved for summary judgment based on a lack of expert testimony. Between the filing of the motion for summary judgment, the plaintiffs presented an affidavit stating they had retained a physician who would testify as an expert, but the affidavit did not contain any of the substance of the physician's purported testimony. The court granted the motion for summary judgment because the plaintiffs' secured expert could not provide a written report; thus, there was no actual expert testimony on the necessary subjects for a medical malpractice action, including the applicable standard of care. The plaintiffs appealed the court's dismissal; the court of appeals affirmed the decision.

**What this means to you:** This case reveals lessons in substance and legal procedure, as the defendant hospital and physicians successfully defeated the medical malpractice claim in multiple forums and prior to the need for a jury. In the first forum, the medical review panel agreed that the hospital and physicians adhered to the applicable standard of care concerning the administration of the medication and the seeking of emergency services.

Procedures before medical review panels and trial courts are extremely important. Cases can be won far in advance of trial, saving substantial amounts of time, energy, and money, depending on the circumstances. Fortunately for the defendants in this matter, the legal procedures enabled a swift and decisive victory without a jury even hearing the allegations. When a patient alleges injury and brings litigation, the patient bears the initial burden of demonstrating multiple aspects of the claim, including that the physician or hospital failed to satisfy the applicable standard of care.

In this case, the issue revolved around whether the plaintiffs presented an issue of fact pertaining to the standard of care and whether it was satisfied. The plaintiffs initiated the proceeding with the medical review panel, which was comprised of three qualified physicians. The decision stated that no evidence existed in support of a claim that the defendant physicians and the hospital had failed in administering care in compliance with the applicable standard. The report was admissible in the summary judgment proceedings, and the court explained that the findings of a medical review panel are admissible as evidence in a subsequent action brought by an injured patient. In particular, the report served to demonstrate that the plaintiffs' claim failed to present an issue of fact. The plaintiffs then should have introduced evidence in support of their negligence claim to prevent summary judgment.

In fact, based on the panel's findings, the medication was administered to the patient in accordance with proper medical standards. Furthermore, the patient had been administered the same medication before and had not experienced adverse reactions. The dosage and frequency of administration also were in compliance with the accepted standard of care. Lastly, although the patient suffered from a pulmonary embolism, there was no indication in medical literature that a link existed between the administered medication and the development of pulmonary embolism. The report of the medical panel, which was introduced into evidence by the defendants, effectively exonerated the hospital and physicians from a negligence claim because the plaintiffs could not produce evidence of factual or expert support for essential elements of their claim.

Because of the inherently complex nature of a medical malpractice case — which typically is beyond the scope of a layperson's knowledge — the plaintiffs were required to introduce expert testimony to support the allegations, particularly those related to the applicable standard of care. There are rare medical malpractice cases in which the negligent actions are self-evident and can be easily understood by a layperson, such as if a physician amputates the incorrect limb. But absent those exceptional and rare circumstances, expert testimony is required. If a patient fails to retain and present sufficient expert testimony, it is almost inevitable that the care providers will be successful in defending against the action.

Defendants in such circumstances can defeat a malpractice claim in advance of trial by bringing a motion for summary judgment, as the defendants did here. A motion for summary judgment is a legal mechanism that enables a court to resolve claims as a matter of law — without the need for a jury's findings — based on undisputed facts. In this case, the defendants' position was that even assuming everything the plaintiff alleged is true, the plaintiff did not and could not satisfy its burden because the plaintiff did not show evidence that the defendants deviated from the applicable standard of care.

The defendants also presented the panel's report, which similarly found that there was no evidence that the defendants failed to satisfy the standard of care, and the report further found that the medication was properly administered. Although the plaintiffs presented an affidavit identifying an expert witness, the court explained that merely naming a witness and promising that he or

she will testify in the future does not create a question of fact.

This case demonstrates the importance of securing proper expert testimony and how successful claimants must ensure that each element of a negligence claim is addressed and supported by evidence. Furthermore, the case demonstrates how trial procedures and adequate preparation may be used to defeat a claim at an early stage of the litigation. Here, the plaintiffs requested and were granted several extensions; nevertheless, the plaintiffs failed to present appropriate evidence to overcome the motion for summary judgment. As a result, the defendant hospital and physicians saved a substantial amount of time and money through the early dismissal of the action prior to trial. Typically, maximizing the effectiveness of these types of legal procedures is the realm of attorneys. However, physicians and care providers should keep these in mind and work closely with counsel when defending malpractice actions to evaluate the potential for seeking summary judgment and dismissal of an action as early as possible to reduce the burden on innocent physicians and care providers. ■

## REFERENCE

Decided on July 24, 2019, in the Court of Appeals of Louisiana, Fourth Circuit, Case Number 2019-CA-39.

# Appellate Court Finds Expert's Affidavit Sufficient Evidence of Triable Issue of Fact

**News:** An appellate division of a state court reversed an order granting summary judgment to defendants and held that the plaintiffs' introduction of an affidavit by a physician was sufficient to raise a triable issue of fact. The action involved an allegation of medical malpractice and lack of informed consent, brought by a mother, individually and on behalf of her son, who alleged that the infant suffered the loss of his right testicle due to the hospital's and the physician's delay in diagnosing and treating testicular torsion.

The appellate court's decision analyzed the qualifications of the plaintiffs' expert witness and concluded that he possessed the necessary expertise to opine in such a case. Furthermore, the appellate court confirmed that the opinions contained in the affidavit successfully raised an issue of fact that precluded summary judgment.

**Background:** In March 2011, an infant was suffering from lower right abdominal pain. Physicians ruled out appendicitis, but failed to perform a genital or urinary examination. Additionally, the hospital failed to call for a surgery or urology consult and to perform further tests, such as a testicular ultrasound. The source of the infant's pain was not further investigated once appendicitis was ruled out. The following day, while the infant continued to suffer from pain, the physician and hospital failed to order a stat sonogram or attempt a manual detorsion of the infant's testicle.

The infant's mother, individually and on behalf of her son, filed a complaint alleging medical malpractice and lack of informed consent against the urologist who treated her son, the hospital, the hospital association, and two other medical practitioners. The complaint alleged that the physician's failure to timely diagnose and treat the infant's testicular torsion led to the patient losing his right testicle.

The complaint alleged that the urologist deviated from the accepted standard of care by failing to promptly respond to the emergency and by causing further delay in the treatment of the condition. The plaintiffs claimed that the urologist also failed to attempt a manual detorsion of the patient's testicle. The plaintiff alleged that this delay in care resulted in the infant losing his right testicle during an emergency operation.

During trial, each of the defendants moved for summary judgment and presented expert witness testimony that argued no deviation from the standard of care occurred, and no triable issue of fact existed. The plaintiff opposed the motions for summary judgment by introducing an affidavit from a board-certified pediatrician specializing in emergency medicine, who stated that the physicians had failed in the timely diagnosis and treatment of the infant's testicular torsion and that such delay had been the proximate and actual cause of the patient losing his right testicle.

The trial court granted the defendants' motions and stated that the plaintiff had failed to introduce sufficient evidence to establish a triable issue of fact. Because the plaintiff's expert was not a board-certified urologist, the expert was not qualified to testify as an expert witness in this matter. The plaintiff appealed the adverse decision, and the court of appeals reversed the trial court's order, finding that the plaintiff's expert was sufficiently qualified to opine on the

delays and deviations. The plaintiff's expert affidavit was sufficient to raise a triable issue of fact, and the matter was improper for summary judgment.

**What this means to you:** In contrast to the previous case, which was properly dismissed on summary judgment, such a motion was inappropriate here because of the expert's substantive affidavit. This expert provided more than a simple declaration stating that the expert was retained and would eventually opine; this expert, who was appropriately qualified, offered a specific opinion on issues of the standard of care, delays in diagnosing and treatment, and deviations of the standard of care. On appeal, the court addressed these two questions: if the expert was sufficiently qualified and if the introduction of the affidavit sufficed as evidence of a triable issue of fact.

In its analysis, the court reiterated how the introduction of expert testimony on behalf of a plaintiff is crucial to the success of the case and to the plaintiff's success in defeating motions for summary judgment. While it is well established that an expert must be qualified to opine on a specific case, the court focused on whether the proper foundation supporting the expert's qualification had been laid by the plaintiffs. The defendants argued that the plaintiff's expert did not practice urology but was an emergency pediatrician, and that the expert was certified in a different state. However, the appellate court disagreed and noted how the expert had presented a strong case in support of his qualification. In particular, the physician worked in pediatrics and dealt specifically with emergency situations.

The court found that this case, which involved an infant who was treated in an ED, was a situation with which the plaintiff's expert was certainly familiar. In addition, the court explained that an expert need not be from the exact geographic location of where the case is tried; in other words, the practice of medicine in one state is sufficiently similar to the practice of medicine in another state. Thus, the court's reasoning leads to the inference that in medical malpractice claims it is especially important to ensure not only that an expert holds the proper qualifications to present testimony, but also to clearly explain the reasons why those qualifications provide the expert with the necessary expertise to opine on a specific matter.

The court found that the expert's affidavit adequately explained each element of the claim. Specifically, the expert analyzed the events that had led up to the infant's emergency surgery and identified specific breaches in the standard of care. First, the delay in ordering additional testing when the infant's pain did not subside and appendicitis had been ruled out led to a worsening of his condition. Pain is a symptom of a medical problem that requires investigation. It is the body's way of letting us know that something needs attention. An adult might be able to understand what is wrong and how to fix it. But pain in an infant or child, usually manifested by continued crying, requires investigative diligence and persistence from care providers until the source of the pain is identified and treated. To discharge an infant from an ED because a common problem, such as appendicitis, has been eliminated can constitute negligence. Second, the urologist's failure to attempt manual detorsion and his delay in reaching the ED also led to the emergency surgery, which caused the infant to lose his testicle. In the expert's opinion, any one of these breaches could be the proximate cause of the infant's injuries. With this opinion, the plaintiff met the burden and raised questions of fact, which precluded summary judgment for the defendants.

Given how critical an expert's opinion is, it is important for care providers to analyze and dissect opinions from opposing experts, whether those opinions are written in affidavits or presented through an expert's deposition. In these two cases, written affidavits offered vastly different substance: One merely stated an expert's intention to opine on substance while the other offered a substantive opinion by the expert.

A physician or care provider's motion for summary judgment is far more likely to succeed when only opposed by the former type of affidavit; a substantive affidavit by an expert physician, who testifies about his or her appropriate qualifications and the applicable disputed facts, such as the standard of care and deviations from the standard, is more difficult to overcome. However, it is important to note that in this case, even though the defendant physicians and hospitals were unsuccessful on summary judgment, the case remains active — and the defendants will have an opportunity to challenge the expert's sufficiency during trial. Summary judgment is not always an option, and when a defendant attempts but is unsuccessful, that is not a complete defeat. Moving for summary judgment may reveal strengths or weaknesses in the plaintiff's case and give valuable insight into where to focus subsequent efforts to defend against the malpractice action. ■

## REFERENCE

Decided on Aug. 21, 2019, in the Supreme Court for the State of New York, Appellate Division, Second Department, Case Number 2016-13016.