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INSIDE

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EHRs Still Not Improving Safety After Years of Promise

Recent research indicates electronic health records (EHRs) still are not improving patient safety, despite years of efforts to make them more effective in preventing errors and boosting adherence to best practices.

The researchers examined EHR data collected between 2009 and 2018 from more than 2,300 hospitals, assessing computerized physician order entry (CPOE) and clinical decision support data from The Leapfrog Group's annual survey. They found the overall mean total score for CPOE EHR systems, which assesses whether the EHR met basic safety standards, rose from 53.9% in 2009 to 65.6% in 2018.

Other scores also increased in that period. The mean score for basic clinical decision support rose from 69.8% in 2009 to 85.6% in 2018. The mean score for advanced clinical decision support rose from 29.6% in 2009 to 46.1% in 2018.

Drug-diagnosis contraindications — often heralded as the EHR feature that could most improve patient safety — actually was the lowest-performing category. The mean score increased from 20.4% in 2009 to 33.2% in 2018, meaning not quite one-third of EHRs met basic safety standards in this category. *(The full report is available online at: https://bit.ly/3dFZxgc.)*

> "THERE ARE REPORTS THAT WE'VE ACTUALLY INJURED PEOPLE WITH THE EHR. IF THE EHR'S ORIGINAL MAIN GOAL WAS TO IMPROVE PATIENT SAFETY, IT HASN'T WORKED OUT VERY WELL."

"These findings suggest that despite broad adoption and optimization of EHR systems in hospitals, wide variation in the safety

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performance of operational EHR systems remains across a large sample of hospitals and EHR vendors. Hospitals using some EHR vendors had significantly higher test scores. Overall, substantial safety risk persists in current hospital EHR systems," the study authors wrote.

The authors explained improvements in basic clinical decision support were greater than in advanced clinical decision support, which is consistent with other studies.

The researchers recommend three improvements: conduct CPOE safety assessments at least annually and after upgrades, share the results of safety assessments with EHR vendors to spur development of safer systems, and include CPOE safety assessment scores in publicly reported process quality measures.

The lead researcher in the study, **David C. Classen**, MD, MS, from the division of clinical epidemiology at the University of Utah School of Medicine, observes that one of the primary motivations for the wide adoption of EHRs was to improve safety. He notes as far back as 2012 there was evidence the industry was falling short of its goal.

"We've not used the EHR to measure safety effectively, which we can do, and we've not used the EHR to prevent safety problems," Classen says. "Indeed, there are reports that we've actually injured people with the EHR. If the EHR's original main goal was to improve patient safety, it hasn't worked out very well."

Classen's research is disappointing, he says, because it shows not much has changed in almost 10 years. "You would expect that if the focus on EHRs was to improve safety, we would see evidence of that in an objective, operational test like this one. This was not a test of software on the shelf; it was a test of operational software," Classen says. "This puts a big hole in the government's argument that if the software on the shelf improves safety, it should be true in operation, too. That's not true."

Other industries are much more vigilant about testing safety-critical software on an operational basis rather than trusting that it will achieve safety goals based on theoretical testing, Classen says.

Healthcare professionals have become more dependent on EHRs to backstop them on tasks that previously would have been performed manually, like checking for drug interactions, Classen says. Clinicians believe the hype that EHRs can improve safety automatically and let down their guard, he says.

Classen points out another problem that should trouble risk managers: The EHR may not be improving safety, but it

EXECUTIVE SUMMARY

Recent research indicates electronic health records (EHRs) are not improving patient safety in the way many users hoped. There are multiple explanations for the shortcoming.

- Physicians may be tuning out alerts that are not urgent or not configured properly.
- Some hospitals are customizing their EHR settings poorly.
- Incomplete data can hinder the effectiveness of EHRs.

is documenting every error and oversight.

"When your pharmacist doesn't do the drug interaction check because they're pushed on productivity and they've been told the EHR will take care of it, the EHR is creating a footprint of exactly what happened," Classen says. "There's a record of all that. When you get sued, you'll have to provide the EHR records, which may show that the EHR didn't do that drug check because the feature got turned off in an upgrade, and your pharmacist was relying on that."

Creating Potential Liability

The expectation that technology will solve all problems can be dangerous in healthcare and leads to liability risks, says **Roy Wyman**, JD, partner with Nelson Mullins Riley & Scarborough in Nashville, TN.

"The danger comes in the interplay between machines and humans. Machines will make certain types of mistakes, and humans will make other types of mistakes," Wyman says. "When you have human and technology input overlapping, that's sometimes when you have some of the biggest mistakes. At times, humans will tend to overrely on the technology and create issues, but they also can underrely on the technology and override things without understanding why they are there." *(See the story in this issue for another perspective on the latest research.)*

The research showed EHR vendor choice only explained approximately 10% of the variation in performance differences, says **Paul Dexter**, MD, research scientist with the Regenstrief Institute, and associate professor of clinical medicine at Indiana University School of Medicine. The combination of EHR vendor choice and observable hospital characteristics — such as an academic vs. rural setting — only explained approximately 15% of the performance differences.

"That is, what causes the majority of the variation in performance is left unexplained," Dexter says. "It seems likely that the bulk of performance differences found between hospitals relate to how the EHR systems were configured by the hospital. Dissecting the relationship between EHR configurations and Leapfrog scores might prove a useful follow-up study."

Dexter notes several study limitations related to the data available for analysis. Perhaps most importantly, he says, the existence of an alert usually does not lead to changes in clinician ordering practices. In the case of drug-drug interaction alerts, clinicians override more than 90%. Popping up an appropriate alert typically is only the first step in the process of avoiding adverse events and increasing patient safety, he says.

"This fact highlights the importance of monitoring the effects of particular alerts after they go live. How often are clinicians accepting or overriding the alert?" he asks. "When overridden, how often is the alert clinically appropriate vs. how often the clinician was correct to ignore it for a particular patient?"

If a particular reminder pops up surprisingly frequently or is overridden in most cases, there could be an unanticipated problem in its logic, Dexter says. At worst, it can be a risk to patient safety.

"Given the realities of alert fatigue, those responsible for decision support in a health system need to prioritize alerts most likely to otherwise lead to adverse events, perhaps relegating less important alerts to non-interruptive status — alerts that are displayed for consideration, but don't interrupt clinician workflow with a pop-up," Dexter explains. "With respect to the different types of available alerts, despite large differences in adoption of these various types of alerts across hospitals, we don't know which categories are the most important from the standpoint of reducing adverse events. Are the most widely adopted types of alerts also the most important ones?"

Better Incorporation of Order Sets

In most cases, drug alerts do not indicate if the patient is receiving the optimal medication to treat the clinical problem, Dexter notes. Rather, only after the clinician has decided on a specific medication for a particular indication, will the alerts notify the clinician if there is an allergy, if there is a problem in the dose, or if there are renal dosing considerations. Increased incorporation of order sets into clinical workflow might increase the likelihood the optimal medication is selected, which Dexter says is arguably the first step in medication safety considerations.

"We don't know from this study what accounts for the bulk of hospital differences in Leapfrog scores. We do not know what available EHR functionality or alert logic went unutilized or was turned off to avoid clinician alert fatigue," Dexter says.

He notes the authors pointed out "the particular concern was that organizations purchase EHRs and medication safety tools from separate vendors and have great latitude in how they implement and maintain them, so substantial variation in safety performance could be present."

This "latitude" likely is at the heart of the wide hospital variation in Leapfrog performance differences, Dexter says.

Ways to Improve Safety

Dexter offers three recommendations for improving Leapfrog scores, and by extension, increasing medication safety:

• **Provide incentives or require hospitals to adopt minimum sets of the highest-priority alerts.** This might include the "top 100" drug-drug interaction alerts (lists that have been assembled by various groups). Renal or hepatic dosing alerts should be mandatory functionality given they are easily overlooked, he says.

• **More transparency in public reporting of hospitals' EHR systems, clinical decision support alerts, and adverse events.** Such transparency might help identify those alerts that prevent the most adverse events, providing the rationale for mandates of high-priority alerts. Trying to prioritize all alerts at the individual hospital level is inefficient and probably not feasible, Dexter says.

• **Leapfrog or similar testing could be a mandatory yearly exercise for all hospitals.** The authors of a recent study noted 1,812 hospitals took part in Leapfrog testing in 2018. Given there are currently 6,146 hospitals in the United States, this means only about one-third of hospitals participated in 2018. *(More information is available at: https://bit.ly/3dFZxgc.)*

A big component of medical errors is incorrect or incomplete information, notes **Daniel Cidon**, chief technology officer for NextGate, a company in Monrovia, CA, that provides technology services to the healthcare industry.

"Information contained in EHRs is predominantly inconsistent. This is because different systems capture patient demographic information in different ways. For instance, some EHRs will include hyphens, apostrophes, and suffixes in last names; others don't," Cidon explains. "This makes it extremely challenging to tie patient information from other facilities together."

As the use of EHRs and clinical applications exploded over the last decade, ensuring patients and individuals are accurately and consistently matched to their data became the focus, he says. But although roughly $35 billion of U.S. taxpayer dollars have been spent on digitizing health records, the programs remain disjointed, causing a flood of duplicate and disparate records.

"This means that individuals receiving care from more than a single provider in the network often have medical records in several other locations," he says. "Large-scale M&A [mergers and acquisitions] and consolidations exacerbate the issue, as acquired EHR systems often reside in silos."

The inability to match patients to their data can lead to dire consequences, including "inappropriate medications being dispensed, incorrect diagnoses, erroneous test results, and increased risk from redundant medical procedures," Cidon explains. "The *JAMA* study demonstrates that technology alone is not the solution to safety problems. Effective data governance policies are pivotal to ensure accurate data capture and make best use of the technology."

Patients will continue to suffer consequences if they are not consistently and correctly matched to their data, Cidon warns. EHR data-matching functionalities are not sufficiently compiled to unify information from various external systems.

EHRs that cannot communicate with one another can exacerbate inefficiencies, generating redundant information and duplicate, incomplete records. This can result in patient safety errors, skewed reporting and analytics, administrative burdens, and lost revenue, he adds.

Master patient indexes (MPI) within EHRs are limited in their ability to compare and link records from external sources, Cidon explains, especially those outside the network. A report from Pew Charitable Trust indicated EHR match rates within facilities are as low as 80%, meaning one out of five patients may not be completely matched to his or her record. *(The report is available at: https://bit.ly/2CrGYj0.)*

When exchanging records outside the organization, match rates can be as low as 50% — even when the providers are running the same vendor EHR, Cidon notes.

"Most data entry errors are preventable. But without a centralized data-matching system in place to automate record de-duplication and data integrity, hospitals are increasingly placing patients at risk and barring physicians from making informed, life-saving decisions," he says. "Hospitals and health systems that aren't running an efficient enterprise MPI are operating EHR systems fraught with duplicates and inaccurate patient information."

An enterprise MPI is one tool to help an organization with data governance, Cidon says, at least from the fundamental perspective of the identity of the patient on which all other information is based.

Healthcare organizations must pay attention to people, process, and technology. "It's not just

about the shiny widgets and fancy user interfaces. As healthcare consolidation continues to soar and organizations strive to create a more clinically integrated environment, patient identification across the continuum will become even more difficult and more critical," Cidon explains. "To keep pace, organizations must engage in a more comprehensive patient-matching approach. Leveraging the right technology, along with better processes, will be key."

A culture of mistrust over data-sharing can negatively affect EHRs and how data are handled, notes **Venky Ananth**, senior vice president and global head of healthcare at Infosys in Hartford, CT. To overcome this barrier, healthcare players should look to partner across ecosystems and with technology companies, he says.

"Data-sharing improves EHRs, and in turn patient safety, by opening up the gates to innovation and opportunity, accelerating the process in identifying solutions and curing patient diseases. Given that healthcare is such a highly regulated industry, and data breaches are expensive, it is pertinent that patients play an involved role in managing their data," he says. "One example of this in practice is through wearable consumer technology, where patients themselves can input and monitor their health data." ■

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EHRs Are Still a Work in Progress

Recent research may not tell the whole story about electronic health records (EHRs) and patient safety, says **Rich Temple**, vice president and chief information officer at Deborah Heart and Lung Center in Browns Mills, NJ, and an Alliance Partner of the Cleveland Clinic Heart, Vascular & Thoracic Institute.

"To some extent, I question the premise that EHRs have not meaningfully contributed to patient safety. I believe they really have been transformative in supporting the drive toward safety catalyzed by the Institute of Medicine's *To Err is Human* report," he says. "While, clearly, EHRs are still a work in progress as they continue to evolve to address safety needs, I believe the biggest possible benefits accrue to those who are more mature users of EHR technology."

Hospitals must be vigilant in weighing the benefits of using clinical decision support (CDS) tools in EHRs against the potential downsides of overly tying doctors to their computers with an abundance of manual, perceived non-value-added tasks, Temple says.

Research indicates CDS testing over the course of 10 years, at an aggregate level, has contributed to an improvement in patient safety, Temple notes. "And, strikingly, it shows a dramatic improvement over the course of the last couple of years, as hospitals became more facile with EHRs and as additional tools for interoperability have been introduced and improved upon," he says. "When you dive into the analyses in more detail and evaluate the more detailed forms of CDS, some demonstrate dramatic improvements, and others, not nearly so much."

An important consideration is that CDS is not offered in a vacuum, Temple says. Workflow and configuration decisions loom large in facilitating an EHR's success in driving patient safety. Doctors often bypass alerts they deem to be "noise." If there are too many of these alerts, the CDS poses a risk of "alert fatigue," which can lead to bypassing important alerts, he says.

In this scenario, because there are so many alerts, they all just get tuned out. Going beyond merely CDS alerts, it is essential for provider institutions to strike the appropriate balance between rigorously displaying CDS alerts and not presenting an overly burdensome documentation regimen to the provider, which comes with the short-term risk of distracting from face-to-face care and the longer-term risk of physician burnout, he says.

"It also bears noting that the capture of the necessary building blocks for effective CDS — medications, allergies, and problems

— is a perennial challenge in healthcare institutions. For instance, who performs the initial data entry for these? Who verifies the data entered?" Temple asks. "While, typically, physicians are the first-line custodians of problems, medications and allergies are often entered by patient care technicians or medical assistants who don't have the depth of expertise on specific doses or routes of different medications and could be prone to erroneously entering vital medication or allergy information."

Even when they are pulling data in from external sources, such as Dr. First or Surescripts, there often is a "translation" from the nomenclature used by the external pharmacy data to that required by the EHR, Temple says. This is another opportunity for error.

"The maintenance of patient problem lists is a tribulation all unto itself. Problems come and go, and their relative importance directly correlates to what the patient's specific encounter is for, which can cause confusion and throw off the CDS algorithms baked into the EHR," he says. "A problem that should have been deactivated but wasn't can contribute to fallacious or even dangerous alerts; hence, the incredible importance of maintaining the problem list, which is cumbersome and time-consuming for providers already under stress from the day-to-day pressures of providing excellent patient care."

Another consequence and challenge of the movement to interoperate electronic data across provider care settings is that a glut of external information that may not be current or relevant can gum up the works of the CDS process, Temple says. The industry has come a long way in ability to paint a full picture of a patient's medical history across care setting. But Temple says the downside is that you can dilute the incremental value of the external information if you are loading too much into the record. You place an extra burden on physicians to take time to review data that may have no pertinence to the issue at hand.

Temple endorses the recommendation that providers share safety assessments with EHR vendors to help provide visibility into how CDS can be improved, noting regulations are pending that will open the door to facilitate this type of collaboration.

"The fact that there is significant variation on safety scores across different users of the same EHR speaks to how important process, culture, and workflow are in maximizing the safety potential of any EHR. The technology is generally there; the configuration of the technology and the people, process, and culture are the critical variables in success in utilizing an EHR platform to achieve clinical excellence," Temple says. "It can be done with the appropriate and unceasing commitment to doing it right." ■

SOURCE

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PowerPoint Is Not Enough: How to Improve Safety Education and Training

The days of calling employees into a meeting room and showing them a PowerPoint on the latest safety initiative are waning as risk managers find better ways to teach important lessons. Lecturing employees never worked well, and is increasingly disdained in favor of more creative and interactive teaching techniques.

A good education program will come with a top-down endorsement but a bottom-up empowerment, says **Herman Williams**, MD, MBA, MPH, managing director with the BDO Center for Healthcare Excellence & Innovation in Nashville, TN. Ideally, the CEO should endorse the program, he says. But everyone on the front lines should be empowered to "stop the line" if they recognize a threat to safety.

Training must be mandatory. Some organizations go wrong by launching a major safety initiative and only training clinicians, Williams says. In many cases, the safety message should be presented to other workers, including housekeeping, dietary services, and administrative staff.

"You can't just do a PowerPoint presentation accompanied by a speech," he says. "We've done a presentation, and then broke into small groups to role play scenarios in which this safety issue might come up. One person plays the patient and the other plays the doctor, then you switch so each person gets an opportunity to act on the safety measure."

Testing also is important, Williams says. Written or online post-tests are options, and you can conduct rounds to spot-check employees on their

retention and comprehension of the safety message, he adds.

Virtual Training an Option

Virtual training on an interactive online platform has many advantages over standard in-service lectures and PowerPoint presentations, such as providing universal access to an unlimited number of employees independent of work activities, says **Lois Wedlock**, director of clinical excellence for IntegriMedical, a company in Phoenix that provides needle-free drug delivery technology.

"In contrast, training that interrupts normal work activity or is done as an add-on to normal workflow is generally less effective," Wedlock says. "Additionally, virtual training enables employees to complete coursework at their own pace, giving them more control over their time and enabling them to engage with the training content over multiple sessions."

Training events must be convenient and meaningful to participants while demonstrating to employers that training was completed with documentation of new learned material, she says.

To create value, trainers should begin lessons with a knowledge base that explains the "what" and "why" behind the training, and then continues to the "how-to," she says. Above all, trainers should respect staff members' time, which is normally spent taking care of patients. Time is the most valuable asset healthcare workers have, so trainers must be careful to make the most of it.

> "TRAINING THAT INTERRUPTS NORMAL WORK ACTIVITY OR IS DONE AS AN ADD-ON TO NORMAL WORKFLOW IS GENERALLY LESS EFFECTIVE."

"One common mistake is when trainers don't provide another training opportunity for staff who miss sessions as a result of getting called away to perform patient care duties. Additionally, it is wise to avoid scheduling training in the middle of a shift when staff members' minds are on patient care rather than training," she says "To help ensure that training is not perceived as redundant or irrelevant, make sure that trainees understand what they will learn will help them carry out their missions."

Use technology and empower employees to be efficient with options such as virtual training programs that are easily accessible from any electronic device, Wedlock says. A virtual option enables trainees to revisit training sections that may be complex without the pressure of asking for help and drawing attention to themselves because they do not know the answers. Technology also allows efficiency in time for staff to learn at their own pace, while administrators can generate a report of who has completed the required training, she says.

"The era of having designated training days where staff gather to attend an in-service, with most being distracted and only required to sign an attendance sheet without measuring their base of knowledge, is over," she says.

Measure Knowledge Before and After

Training should include testing to measure participants' knowledge before and after the training session, Wedlock says. Employees should be required to pass a certification test to complete the class.

After the class is completed, stay in touch with trainees via newsletter, updates, and surveys to determine the effectiveness of the training. Importantly, none of these follow-up activities should interfere with staff members' patient care activities, Wedlock says.

Digital training tools empower people to learn at their own pace and style by giving them access to a combination of pictures, videos, and voice modules, says **David Yanez**, CEO of Andonix, a company in Detroit that provides a platform to educate frontline workers on safety.

These features cater to different learning styles because they are

EXECUTIVE SUMMARY

Safety education requires more than a dull presentation and a few slides. Risk managers should seek effective methods.

- Training should be mandatory and wide-reaching.
- Virtual training options may be effective.
- Follow with assessments of comprehension.

powered by artificial intelligence, he says.

"Therefore, leaders can make safety training more situational, circumstantial, and recurrent," he says. "There are tangible metrics like risk-based measurements and rate of injury, which show that digital training for safety improves in every applicable industry including healthcare."

"Safety is a bottom-line issue that can have a massively positive impact on an organization and its employees," Yanez continues. "When safety becomes everyone's priority, the leadership focus shifts away from enforcement and toward empowerment and enablement. Culture is how people behave when nobody is watching. If safety is about habits, and habits forge culture, then building a culture around workplace safety is the right strategy."

Yanez suggests watching for these common mistakes in training:

- not assessing team members to identify their proficiency and training level;
- not creating a comprehensive program that captures foundational training;
- assuming all team members have the same learning styles and speed;
- not linking training to performance, and performance to desired safety behavior;
- not promoting people based on their safety record and leadership;
- not evolving and continuously improving the learning system with lessons learned and best practices. ■

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Avoid Common Mistakes in Handling Medical Malpractice Claims

Although a medical malpractice claim can drag on for months or years, the ultimate outcome of the case may be determined by what happens in the first hours or days. Some mistakes and oversights can put you at a disadvantage when defending against the claim.

Engaging legal counsel to assist in investigating claims and to represent defendants is prudent at the outset of a claim or litigation, says **Elizabeth L.B. Greene**, JD, partner with Mirick O'Connell in Worcester, MA.

"Understanding the parties involved, including each defendant's specialty, alleged involvement in the care at issue, employment status, and insurance coverages and limitations, are important at the outset of a claim or litigation," Greene says. "Similarly important at the outset of a claim is securing medical records, and when appropriate, imaging studies, pathology, instrumentation, and metadata." *(See the story in this issue on the do's and don'ts of handling claims.)*

Putting the appropriate insurance carriers on timely notice of the claim is vitally important, Greene says. If appropriate to the facts and issues in a matter, exploring the potential for presuit resolution is good practice, she says.

"Where a matter cannot or should not be resolved presuit, then during litigation the risk manager can help ensure the best outcome by periodically reviewing the established facts and assessing the strengths and weaknesses of the claims and defenses, including the discovery from all parties to the litigation and the expert witness opinions," she says. "Keeping the insurers and appropriate individuals within the hospital system apprised of any changes in the assessment of the case is important. A best practice is to diary appropriate intervals for case assessment and reporting."

EXECUTIVE SUMMARY

The outcome of a medical malpractice claim can be determined by how it is handled from the outset. Avoid some of the most common mistakes.

- Involve legal counsel as soon as possible.
- Secure relevant documentation and other material immediately.
- Notify insurance carriers promptly.

Support Providers

Risk managers can help ensure the best outcome for the case and the hospital system by supporting

the providers within the system, and understanding when it is appropriate to assign legal counsel for nonparty witnesses employed by the hospital, Greene says.

At times, during a case and/or at the conclusion of a matter, it may be important for the risk manager to assist in properly addressing the media in a manner that is coordinated with the appropriate constituencies in the hospital and litigation counsel, she adds.

Greene notes some key points to keep in mind include understanding the role of each party, the nature of the claims, the defenses raised, and the scope of available coverage. Track significant changes or developments as the claim progresses from inception to the final resolution of the matter. Appropriately communicate the status of the claim and significant developments within the hospital system and with insurers.

"The provider defendant has the most impact on the outcome of the claim. A provider who is well prepared and understands the litigation process will best be positioned to demonstrate their clinical knowledge and expertise in a nonthreatening manner, so as to connect with the jury," she says. "Ultimately, a provider who instills a level of confidence in jurors such that they would choose that provider to care for their loved ones will have the most impact on the outcome of the case."

Identify the key participants in the case so you can talk to them while memories are still fresh, notes **Carol Michel**, JD, partner with Weinberg Wheeler Hudgins Gunn & Dial in Atlanta.

"So many times when the lawsuit comes two years after the occurrence, memories have faded by that time and it is hard for these people to remember exactly what was done or said," Michel says. "It also is important to support and prepare those people for depositions."

Michel has seen problems in which risk managers engaged in direct communication with plaintiff's counsel. She says that is almost always a bad idea.

"Representations may be made, or things may be said that later come back to be an issue in the case — things that did not need to be an issue in the case and just complicate the matter," she says.

Policies and procedures often will become a central point in a medical malpractice case. It is necessary to review them and assess how uniformly they are followed, says **Savera Sandhu**, JD, partner with Newmeyer Dillion in Las Vegas.

"We need to know how often they update them, how often they speak to the medical staff about them, and how often the staff is trained if there is a revision in the policies" Sandhu says. "Hospitals often fail to talk to all the staff involved to determine uniformity of the applicable policies and procedures for that patient. I highly recommend that once you receive notice of the suit, the hospital and counsel should get everyone involved in the event together to go over the chronology of treatment and the order of who treated the patient."

That meeting can create a uniform story and understanding of events. "Once you're in deposition, all the nurses and staff have the same uniform discussion about the chart and their scope of work. The doctors have a clear chronology of who was involved and in what order, and you have a clear picture of the uniformity of how policies and procedures were followed."

An important aspect of the document preservation is not just gathering all the pertinent material, but showing no relevant documents were left out, says **Jeff Kerr**, JD, a former litigator and the CEO of fact management company CaseFleet in Atlanta.

"A critical thing in litigation today is ensuring that you have all the relevant documents but also that you can demonstrate you have all of them and you haven't left out certain kinds of documents or allowed them to be overwritten, or made them more difficult to access," Kerr says. "You don't want to look like you're concealing anything or giving the other side any reason to think you're being less than transparent about the evidence." ■

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Expert Tips for Handling Malpractice Claims

It is important to approach every potential lawsuit with the right mindset from early on, even before you receive notice of a claim, says **Keith Felty**, JD, managing partner at Sullivan, Ward, Patton, Gleeson & Felty in Southfield, MI.

Felty highlights some of the biggest pitfalls in handling malpractice claims:

• **Failing to approach every claim as an eventual trial upon first notice of a possible claim.** The prospect of going to trial should guide everything as soon as something goes wrong. Do not wait until an attorney mails an initial notice. Answering what jurors would want if they were in the patient's position is the way to win cases and settle claims for less, Felty says.

"Empathetic response from doctors and nurses when the event occurs is crucial from the first moment," Felty says. "Showing that medical folks care is the No. 1 loss prevention advice. In other words, the standard of care evaluation starts before there ever is a claim."

• **No communication among doctors.** Time and again, jurors and other objective observers state that doctors not contacting each other or engaging each other for the patient's best interests causes adverse verdicts and bigger settlements, Felty says.

• **Not hiring counsel who actually try lawsuits.** Whether a trial is really desired or whether you want to settle for less money, the threat of counsel who will actually try the case is the most important factor for getting the best result, Felty says.

• **Focusing on the quantity of documentation of events rather than the quality.** Lawsuits may be avoided with good records that document discussions with the patient, Felty says. Also document the discussions among doctors. Both are highly important in defending claims, he explains.

Chanel A. Mosley, JD, shareholder at Marshall Dennehey Warner Coleman & Goggin in Orlando, offers this list of reminders for handling a medical malpractice claim:

• **Do not delay.** Timing is key. Some states, like Florida, mandate presuit screening requirements that must be followed before a lawsuit can be filed. Upon receiving a notice of potential medical negligence, it is imperative to involve defense counsel immediately. Doing so ensures presuit discovery requests, investigation deadlines, and early evaluation of the claim can be conducted in a timely manner.

"Delays in complying with these statutory requirements can result in sanctions such as an award of attorney's fees and costs against the party engaging in dilatory behavior, as well as the striking of pleadings and defenses. I recently resolved a claim that was transferred to me after the prior defense counsel delayed participation in the presuit investigation process," Mosley explains. "As a result of the delays, the defendant physician was facing sanctions in the form of striking his defenses, essentially forcing him to admit liability in an otherwise defensible claim. The physician was forced to settle the case for a much larger amount than preferred in order to avoid the possibility of sanctions."

• **Do not sacrifice early expert assessment of the claim to conserve litigation spend.** Medical negligence cases often come down to a battle of the experts. Knowing the strengths and weaknesses of your case early on can save money in the long run. Once you know the critical issues in your case, retain the proper experts to evaluate your liability exposure. Know where your exposure lies and work closely with your experts to formulate your defense strategy early on.

"While expert retention can be costly, it is important to have a thorough understanding of the medical issues impacting your case. This knowledge can be invaluable during the initial stages of discovery and in depositions. A well-planned deposition can ultimately result in a more favorable settlement for the medical provider," she says. "Since most cases settle at mediation or during negotiations prior to trial, it is important to ensure that you have a strong, organized defense theory going into those settlement discussions. This allows you to position yourself for a better settlement."

• **Do not wait to meet with your witnesses.** The statute of limitations often allows for a claimant to bring a medical negligence lawsuit several years after the alleged negligence occurred. The litigation process itself can be lengthy, spanning several more years. Turnover in the healthcare setting can be frequent, and individual memories can fade quickly.

"As soon as you receive notice of a claim, work with defense counsel to reach out to your witnesses and meet with them. Interview them about their recollection of the events and preserve as much information as possible," Mosley says. "Waiting too long can result in the loss of invaluable information and the loss of a key witness who could make or break your case."

• **Do not underestimate the importance of witness preparation.** Healthcare providers possess an innate

sense of compassion, and by nature aim to please others. While this is an excellent quality in healthcare, it can be disastrous in litigation, Mosley says. A deposition or trial is an unnatural environment for most healthcare providers, and can be overwhelming and intimidating.

"For example, some healthcare providers have a tendency to be more passive or deferential at times, particularly when dealing with a difficult patient or family member. However, those qualities are less than desirable in a litigation setting," Mosley says. "Don't just rehearse important questions and answers. Work closely with your witnesses to ease any anxiety or nervousness about testifying and prepare them for what to expect during the deposition or trial. Offer tips on how to manage difficult questions and educate them on how best to approach certain topics with confidence and competence."

If the opposing attorney is known to be particularly difficult, prepare them in advance to avoid your witness crumbling in the middle of the deposition, Mosley advises. A firm, confident healthcare provider is far more likely to present as a credible witness than a passive, deferential, timid one, she says.

• Communicate often with counsel. A collaborative approach between risk management and defense counsel is imperative and ensures a cohesive, well-planned defense strategy.

• Implement a litigation hold and follow through. "I cannot stress enough the importance of ensuring key evidence is preserved and properly maintained from the moment there is the prospect of a claim, and at the very least, when notice of the claim is received," Mosley says. "A thorough search for all medical records, emails, text messages, and any other evidence involving the individuals and events which form the basis for the claim should be conducted immediately. All information uncovered should be preserved for the duration of the litigation."

Involve your defense counsel in this process, too, Mosley says. Counsel can provide guidance and assistance on obtaining and collecting key pieces of evidence and information from important witnesses before the information is misplaced — or worse, lost or destroyed. Additionally, attorney/client and work product privileges may attach, which can help preserve the confidentiality of the investigation. Failure to preserve and maintain evidence can expose one to spoliation of evidence claims or sanctions down the road.

• Know the opposition and conduct research. In the world of social media and fast-paced online technology, research your claimant. Conduct social media sweeps, obtain surveillance, look for an online presence, and investigate background information. These data sources can be a gold mine of information that can drastically reduce the value of a case if something untoward or contradictory is discovered about the claimant, Mosley says.

"Research your opposition's experts and utilize negative or contradictory information for impeachment. A successful cross examination of the plaintiff's experts has the ability to obliterate their entire case," she says. "Research your jury pool, your judge, and your opposing counsel. An extensive, thorough evaluation of your opposition and venue can have a significant impact on the manner in which you litigate the claim, and the level of success you achieve in resolving it." ■

SOURCES

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HEALTHCARE RISK MANAGEMENT™

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CME/CE QUESTIONS

1. **What did researchers conclude in a recent study of the electronic health record (EHR) safety?**

   a. Wide variation in the safety performance of operational EHR systems remains across a large sample of hospitals and EHR vendors.
   b. There is consistency in the safety performance of operational EHR systems across a large sample of hospitals and EHR vendors.
   c. Hospitals have failed to implement EHRs widely enough to obtain a true measure of their effect on safety.
   d. The effect on safety is greater with an operational EHR than the shelf version of the software.

2. **Paul Dexter, MD, notes the combination of EHR vendor choice and observable hospital characteristics — such as an academic vs. rural setting — accounts for which percentage of performance differences?**

   a. 5%
   b. 15%
   c. 35%
   d. 55%

3. **What does Keith Felty, JD, say is one mistake to avoid when managing a malpractice claim?**

   a. Not hiring a lawyer who actually tries lawsuits
   b. Not hiring a lawyer familiar with your healthcare organization
   c. Not hiring a lawyer from a large law firm
   d. Not hiring a lawyer specializing in the particular area of medicine in the case

4. **What does Carol Michel, JD, cite as a potential mistake in handling a malpractice claim?**

   a. The risk manager communicating directly with the family of the patient
   b. The risk manager communicating directly with the plaintiff's counsel
   c. The risk manager refusing to communicate directly with the plaintiff's counsel.
   d. The risk manager communicating with the hospital's counsel without first consulting hospital leadership

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

$3.1 Million Awarded to Veteran for Permanent Damages from Negligent Abscess Drainage

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***Elena N Sandell**, JD*
UCLA School of Law, 2018

News: A patient underwent a procedure to drain an abscess. During the procedure, the physician became confused about the location of the trocar (a sharp instrument) and pushed it too far, puncturing the patient's lung, liver, and heart. As a result, the patient suffered severe, permanent, and debilitating injuries.

Liability was previously resolved. The patient was awarded the maximum permitted for noneconomic damages, but economic damages were unresolved. During this phase of the trial, the judge resolved the dispute and awarded $3.1 million in medical expenses.

Background: In October 2015, a patient, a military veteran, underwent a cholecystectomy, the surgical removal of the gallbladder, at a federally funded hospital. After the surgery, the patient developed a peritoneal abscess, which required draining. The abscess was discovered in May 2016. A physician drained the abscess using ultrasound and a CT-guided technique.

During the procedure, the physician became confused about the location of the trocar, a sharp medical instrument used to access a patient's body cavity. The physician impacted and punctured the patient's hepatic diaphragm and pericardium. The patient's blood pressure dropped severely, requiring emergency surgery. Furthermore, blood was discovered in the patient's pericardium, as well as a large clot surrounding the heart. The surgery also revealed the physician misplaced the drain tact, causing additional injury.

DURING THE PROCEDURE, THE PHYSICIAN BECAME CONFUSED ABOUT THE LOCATION OF THE TROCAR AND PUSHED IT TOO FAR, PUNCTURING THE PATIENT'S LUNG, LIVER, AND HEART.

The patient remained hospitalized for nearly two weeks after the surgery, after which he was transferred to a different hospital. Additional procedures were performed at the second hospital, including drawing fluid from the patient's lungs and treating a collapsed lung. All the injuries were related to the initial botched procedure. In addition, the patient required speech, occupational, and physical therapy. Because of the piercing of the pericardium and diaphragm, the patient continued to suffer from injuries, including blood clots in his legs and lungs, which required additional and ongoing medical treatment.

The patient filed a lawsuit against the United States, since he received services from the federally funded hospital that employed the physician who performed the surgery. The patient alleged the physician breached his duty by failing to provide care within the applicable standard, specifically by piercing the patient's internal organs during surgery. In his request for damages, the patient claimed that as a direct result of the physician's negligence, he suffered permanent and severe damage to his diaphragm, cardiovascular system, and respiratory system; incurred additional medical expenses; and underwent significant pain and suffering from the protracted hospitalizations and remedial procedures.

After a bench trial in November 2019, a judge agreed the defendant physician's negligence was the proximate cause of the patient's injuries. The judge awarded the maximum allowed amount for noneconomic damages — $500,000 — but economic damages, including the patient's recovery of medical fees, was unresolved due to a dispute over reductions.

On May 13, 2020, the court resolved the dispute and awarded the plaintiff $3.1 million in economic damages. The court ruled the patient would remain permanently debilitated, susceptible to infection, and would require more medical care for the remainder of his life. The amount awarded sought to compensate the patient and his spouse for the injuries suffered, for pain and suffering, for his extensive medical expenses, and for his lost wages. The court noted the plaintiff already sustained more than $2 million in medical expenses alone.

What this means to you: This case, and the significant monetary award, reveals some important lessons about liability and damages, including how statutory maximums can affect medical malpractice actions. The $3.1 million award reflected the severe injuries the patient suffered in a case where the physician's negligence was well documented and beyond question. In its opinion, the court found the permanent and catastrophic injuries were due to multiple breaches of the applicable standard of care. More specifically, the physician's multiple perforations during a standard procedure, the drainage of an abscess, were indisputably below what a reasonable physician would have done in the same or similar circumstances.

These initial perforations were the direct and proximate cause of the patient's subsequent complications and injuries. On top of negligence, subsequent failures to discover and promptly treat the resulting injuries compounded the situation. At the time of the initial negligence and injury, the physician and the hospital staff should have consulted with another appropriately qualified physician to evaluate the patient and to determine the proper course of treatment. This course of action would have enabled the care providers to mitigate damages caused by the initial injury and reduce the likelihood of further injuries. According to the plaintiff's expert, if the patient's condition had been appropriately monitored and treated, several injuries he suffered months after the drainage surgery never would have occurred, including a collapsed lung and several blood clots.

Beyond the actions that constituted malpractice, this case also provides insight into an injured patient's recovery of damages in terms of the substantive amount of recovery and some procedures concerning recovery. Damages are comprised of two parts: noneconomic damages (for pain and suffering, physical impairment, disfigurement, and other subjective, nonquantifiable categories) and economic damages (for medical expenses, lost income, out-of-pocket expenses, and other specifically quantifiable categories). In this case, the noneconomic damages initially were awarded with the finding of liability: $500,000. This concrete amount is a result of a statutory maximum for medical malpractice actions for the state in which the injury occurred. Many other states have enacted similar laws, limiting the maximum noneconomic damages an injured patient may recover, even if the pain and suffering otherwise would be more compensable.

For care providers, these statutory maximums serve important functions, including facilitating the reduction of insurance premiums, and are important when evaluating a prospective or actual medical malpractice claim. For example, if a patient claims to have suffered severe emotional distress, but has not paid much out-of-pocket costs through lost income or actual medical bills, the patient's recovery may be almost exclusively noneconomic — and limited, based on the applicable state's maximum. While each case is unique, settlement may be a more sensible option if the patient's recovery is based on this maximum amount, as a runaway jury could not award an eight- or nine-figure sum based solely on the patient's pain and suffering. Care providers should consult closely with counsel to determine any applicable statutory maximums and how such maximums affect case analysis and resolution.

In this case, the evidence presented indisputably showed the physician's negligence caused the patient irreparable harm. The court recognized the significant pain and suffering the patient endured, and confirmed the highest award available by law for noneconomic damages. Furthermore, the litigation sought to recover costs for the three years of continued assistance and care the patient's wife was required to provide. The court recognized the care was necessary, but while the plaintiff alleged his wife's assistance was required for 16 hours a day, the court reduced this amount to eight hours a day. Accordingly, the court awarded $113,120 for past attendant care. Regarding future medical expenses, the court calculated the 70-year-old plaintiff had a realistic life expectancy of 9.5 years. The court considered conflicting expert opinions proffered by both the plaintiff and care provider,

which respectively predicted 14- and six-year life expectancies.

Due to the nature and severity of the injuries and the plaintiff's age, he argued he could not effectively manage his day-to-day activities independently, and would require constant care and assistance. Although the defendant argued to the contrary, the court agreed and found the patient would require at least some degree of assistance for the remainder of his life, but this did not justify the expense of a permanent attendant. The court's reduction of future anticipated necessary care to eight hours per day reveals how judges and juries evaluate the specific facts and circumstances of a medical malpractice action and craft resolutions to fit each case. Here, the court did not merely accept the plaintiff's argument that he would need permanent care for the rest of his life; instead, the court considered expert opinions and tailored the damages to fit what the court believed would be necessary to provide for the plaintiff's medical care. It is appropriate for defendant physicians and care providers, when faced with liability, to analyze the extent of the patient's injuries, and to retain experts who are appropriately qualified to determine life care planning needs to supply judges and juries with this analysis. ■

REFERENCE

Decided on May 13, 2020, in the United States District Court for the Southern District of Mississippi, Case Number 3:17-cv-00551.

Appellate Court Vacates $109 Million Verdict for Botched Surgery Case

News: A patient developed an abdominal infection following a laparoscopic abdominal surgery. The patient's recovery was prolonged, and a subsequent exploratory surgery revealed a perforation in the patient's intestines, as well as abdominal tissue damage. The patient filed a malpractice lawsuit against the initial physician.

After two mistrials, a third jury awarded the patient $109 million for her injuries, including loss of her hands and feet. However, the physician's employer appealed, arguing it was improperly denied the ability to attribute fault to a third party, a critical care team. A three-judge appellate panel unanimously agreed, and ordered a new trial.

Background: A patient underwent a laparoscopic abdominal surgery to remove an ovarian cyst, performed by a gynecologist who specialized in minimally invasive surgery. The physician worked for a university hospital. After the surgery, the patient's recovery did not progress normally. Due to the delayed recovery, the patient was admitted to a hospital for observation, and her condition worsened. She was transferred to the intensive care unit (ICU). Throughout her stay in the ICU, the physician and a critical care provider team followed the case jointly. They suspected the patient had developed an abdominal infection. The patient was put on antibiotics, and an exploratory surgery was performed to determine the source of the infection.

During the second surgery, physicians discovered a perforation in the patient's small intestine. They also found the patient lost a significant amount of abdominal tissue to necrotizing fasciitis. After five months in the hospital, the patient was discharged to a rehabilitation facility. The patient filed a medical malpractice action against the physician, the hospital, and the university. However, the critical care team was not part of the litigation because the patient reached a separate settlement with them.

The patient alleged the physician perforated her small bowel during the original surgery and her injuries were caused by the perforation. Additionally, the patient argued the failure to timely diagnose her infection delayed the antibiotic treatment which, if administered earlier, would have prevented her injuries. The defendants denied liability, arguing the physician had not departed from the standard of care. They also argued the plaintiff's injuries were a direct result of negligence of the critical care team that failed to timely administer the antibiotic treatment.

After hearing the evidence, the court dismissed the hospital and asked the jury to determine only the university's liability. The university attempted to attribute liability to the critical care team, including on the verdict form. The plaintiff opposed this motion, and the court found in favor of the plaintiff. Two juries could not reach a verdict, resulting in mistrials. The third jury reached a verdict against the university, and awarded the plaintiff $109 million in damages.

The defendant university appealed, arguing the trial court incorrectly

excluded expert witness testimony and incorrectly excluded the request to attribute liability to the critical care team. These two errors were related, as the proffered expert witness testimony attributed the patient's injuries to negligence by the critical care team, rather than the university. The appellate court agreed, set aside the verdict, and ordered yet another trial.

What this means to you: This case reveals a possible method for defending against medical malpractice actions, as well as the importance of appealing erroneous decisions by the court. Although the patient's injuries were clearly due to medical malpractice, the defendant's main contention on appeal was the critical care team should have been included in the verdict, particularly considering assertions from the plaintiff's expert witness. The defendant university alleged the physician did not deviate from the standard of care, and any alleged negligence of his did not cause the patient's injuries. Instead, the defendant university argued the critical care providers failed to detect the infection and promptly start the antibiotic treatment, causing the necrotizing fasciitis and loss of abdominal tissue.

This is called the "empty chair" defense, whereby a named defendant seeks to attribute liability to a third party who is not included in the medical malpractice action. Here, the critical care providers had reached a settlement with the patient; thus, they were not active participants in the litigation. However, for the remaining defendants, this presents an opportunity to place fault on a party with no need to defend itself. Of course, such a theory must be based on the facts and circumstances of the case. Juries may be suspicious of defendants who have injured a patient but then try to divert blame to the empty chair. Nevertheless, it may actually be the case that the third party does bear liability, in whole or in part. Such arguments are appropriate to raise to the jury.

In this case, the defendants were prevented from presenting testimony of the plaintiff's expert, who opined the failure to start antibiotic treatment in a timely manner caused the patient's injuries. The timeline and procedure of this case is muddled, as there were two initial trials that ended with hung juries. Ultimately, the court refused to permit the plaintiff's expert's testimony. The defendants raised this issue on appeal, arguing it deprived them of a reasonable and valid defense concerning causation.

The care provider defendants additionally challenged the trial finding the physician acted negligently and injured the patient on two grounds. The first basis was this same argument: The plaintiff's own expert witness testified the failure to administer antibiotics promptly caused the plaintiff's injuries, not the physician's actions. Second, by finding the physician was the original wrongdoer, the court inappropriately usurped the role of the jury by making a determination on a finding of fact (which should have been decided by the jury).

In fact, the defendant hospital argued that although a perforation in the patient's small bowel was found, it had not yet been determined whether the perforation occurred during the laparoscopic abdominal surgery, during the second surgery, or at a different time. In other words, the court determined the physician had negligently perforated the patient's intestines, thus precluding the jury to make this determination in light of the evidence.

The appellate court agreed with the defendant hospital and ordered a new trial. In support of this finding, the appellate court cited the position of another plaintiff expert, who testified that the perforation itself did not fall below the standard of care. Rather, the fact the injury went unnoticed and caused infection and necrosis breached the physician's duty of care. Because the patient was in the care of a physician team after the surgery, including the critical care unit, the failure to notice the infection could be attributed to the negligence of all care providers who were involved in the patient's postoperative care.

Perforation of abdominal organs during laparoscopic abdominal surgery is one of the possible risks of this type of surgery, as is infection. When perforated, the intestines release unsterile, bacteria-laden intestinal contents into the abdominal cavity, causing contamination and infection. Providing prophylactic antibiotic coverage is standard when perforations occur, are suspected, or any time a patient presents with postoperative symptoms that cannot be definitively attributed to another cause.

While this case remains unresolved, the defendant care providers will now have an opportunity to present evidence and testimony to support their arguments. Courts, judges, and juries are not infallible, which is why courts of appeal exist. In this case, the trial court made erroneous determinations, and the care providers were correct in pursuing a timely appeal to correct those errors. Appellate review can be a critical part of medical malpractice litigation, and care providers should carefully consider whether to proceed with that review process. ■

REFERENCE

Decided on May 22, 2020, in the District Court of Appeal for the State of Florida, Second District, Case Number 2D18-1219.