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JUNE 2022 Vol. 44, No. 6; p. 61-72

INSIDE

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Nurse's Criminal Conviction Could Chill Safety Investigations

A Virginia jury recently found former nurse RaDonda Vaught guilty of negligent homicide for mistakenly injecting a 75-year-old woman with the wrong medication and causing her death, along with a second charge of gross neglect of an impaired adult.

Prosecutors initially charged Vaught with criminally negligent homicide, but the jury chose the lesser charges. The trial was closely watched in the medical community — and now some healthcare professionals fear it will have a chilling effect on patient safety investigations.

> "THE CRIMINALIZATION OF MEDICAL ERRORS IS UNNERVING, AND THIS VERDICT SETS INTO MOTION A DANGEROUS PRECEDENT."

Investigations revealed Vaught injected the patient with the paralytic drug vecuronium instead of sedating drug Versed in December 2017. On May 13, Vaught was sentenced three years of probation.

Initially, the hospital did not disclose the patient's death was related to a medical error when it reported the death to the county medical examiner.[1] An anonymous whistleblower reported[2] the fatal error in 2018, prompting an investigation by CMS.[3]

After the CMS report, Vaught was indicted, arrested, and charged with criminal reckless homicide and impaired adult abuse. The hospital fired her, and the Tennessee Board of Nursing revoked her license after a hearing in which she testified she had been "complacent" and "distracted" during the incident.[4]

Prosecutors alleged Vaught made 10 separate errors, including overlooking multiple warning signs. Court records claim

Financial Disclosure: Consulting Editor **Arnold Mackles**, MD, MBA, LHRM, discloses that he is an author and advisory board member for The Sullivan Group and that he is owner, stockholder, presenter, author, and consultant for Innovative Healthcare Compliance Group. The relevant financial relationships listed have been mitigated. None of the remaining planners or authors for this educational activity have relevant financial relationships to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

HEALTHCARE RISK MANAGEMENT™

Healthcare Risk Management™, ISSN 1081-6534, including *Legal Review & Commentary*,™ is published monthly by Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468. Periodicals postage paid at Morrisville, NC, and additional mailing offices. POSTMASTER: Send address changes to Healthcare Risk Management, Relias LLC, 1010 Sync St., Ste. 100, Morrisville, NC 27560-5468.

GST Registration Number: R128870672

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that to use the medication, she would have had to look directly at a warning saying "Warning: Paralyzing agent."

After the verdict, the American Nurses Association (ANA) and Tennessee Nurses Association (TNA) released a joint statement critical of the result, noting "the criminalization of medical errors is unnerving, and this verdict sets into motion a dangerous precedent. ... We are deeply distressed by this verdict and the harmful ramifications of criminalizing the honest reporting of mistakes. This ruling will have a long-lasting negative impact on the profession."[5]

The Institute for Safe Medication Practices also criticized the verdict in a statement headlined *Criminalization of Human Error and a Guilty Verdict: A Travesty of Justice that Threatens Patient Safety*.[6]

Multiple Safety Measures Ignored

Prosecutors must have been motivated by the fact the nurse made a series of serious errors rather than one mistake that might be more easily understood, says **Carol Michel**, JD, partner with Weinberg Wheeler Hudgins Gunn & Dial in Atlanta.

"We don't want to make criminals out of medical providers who are human beings, too," she says. "They do make mistakes. Traditionally, that has been dealt with through the licensing boards and civil lawsuits. What sets this case apart is just the number of ways this nurse seemed to go around or defy the safeguards that were in place."

The criminal conviction does not necessarily signal a change in how prosecutors will view medical errors, Michel says. The legal system and juries tend to be sympathetic to healthcare professionals who commit errors when they are trying their best to provide good care. In this case, it appears the jury concluded Vaught was careless to a degree that was unusual and could not be excused.

The important lesson might be for hospitals to ensure proper dispensing safeguards and to properly train employees on critical safeguards and procedures that must not be overridden, or if overriding is necessary, the importance of exercising extreme caution.

According to the CMS report, Vaught could not find Versed on the list of medications in the dispensing cabinet, leading her to initiate an override setting so she could enter VE into a search field. She selected the first result, the neuromuscular blocker vecuronium, which normally would come with a red box warning on the screen noting the medication should be used only with a stat order. But because the override

EXECUTIVE SUMMARY

A former nurse was recently found guilty of negligent homicide related to a medication error. She admitted to overriding a safeguard before administering the wrong medication to a patient.

- Some healthcare leaders are critical of the verdict.
- The case may negatively affect safety investigations.
- Educate nurses about the extreme circumstances that led to the verdict.

function had been engaged, the red box warning did not appear.

Neuromuscular blockers were on the hospital's list of high-alert medications, according to CMS, but there were no specific precautions in place to prevent the nurse from obtaining it with an override.

Vaught noticed that the medication was a powder and not the liquid Versed she expected, CMS noted. She never looked at the front label, and instead turned the vial over to read the reconstitution directions.

"The culture of the institution must be one that ensures safety procedures are followed and [emphasizes] why they are important. Part of her defense was that she wasn't doing anything unusual with the override, that everybody does it," Michel says. "That may or may not be true, but if the perception is that everyone is overriding these safeguards just to get their jobs done, you have a culture that says it's OK to not follow the rules. That should worry a risk manager."

Overkill After Professional Discipline

The criminal charges were overkill after Vaught had experienced consequences professionally, says **Andrew J. Barovick**, JD, an attorney in White Plains, NY, who represents plaintiffs in medical malpractice suits but previously represented physicians and hospitals. Barovick recalls when he was an assistant district attorney in Queens, NY, years earlier, a fellow assistant district attorney convicted a local obstetrician of murder. That case was significantly different from the Vaught medical error, he says, because the doctor had been performing abortions in poor conditions at a storefront clinic. Two women died.

The criminal conviction made more sense in that case because the doctor's actions were particularly egregious, Barovick says. The state board had already revoked the obstetrician's license for gross incompetence and negligence involving five other patients, but the board allowed him to practice while he appealed.

However, Vaught did not have a history of endangering patients, Barovick notes. The hospital's safety protocols for medication dispensing seem to have contributed to the error.

It would be better to focus on how the hospital and other institutions can improve the safe delivery of medications. "I could have more of an understanding of the decision to prosecute [Vaught] if there was evidence that she was truly reckless and not caring, but that's not something I saw," Barovick says. "You have to look at her actions in the context of systemic errors in hospitals, but that's a harder question for people to talk about. You don't get any sense of justice against an individual when you start talking about why the system allowed her to make this serious error."

The healthcare system also has failed to address the related issues that led to Vaught's stress and distraction in performing this task. Nurses are routinely overworked and tasked with too many simultaneous duties without the ability to focus when necessary.

"I think what she did is, unfortunately, more routine that most people realize," Barovick says. "Our nurses are put in these untenable situations in which they are worked too long and too hard, yet they are expected to maintain a perfect, unwavering level of vigilance that is unreasonable in those circumstances. When they inevitably fail, we hold them accountable as if it is only their fault."

Fixing the systemic problems that affect patient safety is more important than seeking punishment for individuals who fail, even if they fail in obvious and tragic ways, Barovick says. Criminal prosecution is the easier path, but less effective in the long run.

"We have to do more than have criminal liability dangling over the heads of healthcare workers," Barovick says. "It seems a particularly tone-deaf time to threaten criminal liability after they've just been devoting themselves to saving everyone from the pandemic for the past two and a half years, and putting their own lives at risk."

A Chilling Effect on Investigations

The worst outcome from the Vaught case could be a chilling effect on patient safety investigations, says **Kelli L. Sullivan**, JD, shareholder with Turner Padget in Columbia, SC. Vaught was remarkably open and honest about her actions when testifying to the nursing board and cooperating with the CMS investigation, but that information was used against her in the criminal prosecution.

"She did the right thing and fell on her sword, told the truth. The problem is those statements were admissible later in her trial," Sullivan says. "Now, we have to worry about these statements in investigations and licensure hearings being used against them. The whole purpose of these investigations is to make sure the truth comes out, but when someone risks jail time by telling the truth, a lot of lawyers would counsel their clients to take the Fifth."

Sullivan worries that such concerns by nurses and other clinicians could hamper a hospital's internal investigations of adverse events, with employees worried whatever they say could be used against them if criminal charges result. Whether such information could be used by prosecutors is subject to many factors, but just the fear of that outcome could make people hesitant to speak freely.

"That's going to hamper your investigation and the ability to fix systemic problems," Sullivan says. "There was evidence in this case that the hospital had been having problems with the dispensing cabinet and nurses were routinely overriding it to get the medications they needed. But if people are hesitant to talk about things like that for fear of criminal prosecution, the risk manager will never know what's really going on, and you can't fix a problem you don't know you have."

Patient care also could be affected in the opposite way, Sullivan notes. If a nurse needs to override a system to obtain medication but is too reluctant because of the Vaught case, the alternative might require calling or visiting the pharmacy, or contacting the physician for help. That could slow patient care in a dangerous way.

"From a nurse's and a hospital's perspective, you're darned if you do and darned if you don't," Sullivan says. "You don't want people overriding safeguards without a thought, but you also don't want them so paralyzed with fear that they won't override a caution when necessary and the patient ends up having an event because it took an hour to get the medication."

Risk managers should anticipate nurses and other clinicians knowing about the Vaught conviction and remaining wary of its implications, Sullivan says. It would be useful to educate them about the unique circumstances of the case, showing how Vaught's error was more than just overriding the system. Other critical steps, such as reading the name of the medication she removed from the cabinet, were missed.

"This is quite the extreme, a series of events that led to this tragedy. Some of them were in RaDonda Vaught's control and some weren't," she says.

Sullivan notes the hospital settled with the patient's family soon after the incident. The settlement agreement is sealed, meaning the family cannot speak about it publicly, which Sullivan says is unusual.

Unique Set of Factors

The underlying facts set forth seemingly unique events in this case, which likely influenced the prosecution and outcome, says **Elizabeth L.B. Greene**, JD, partner with Mirick O'Connell in Worcester, MA.

"To the extent that the same or substantially similar facts can be avoided in the future, this outcome hopefully will not be the dangerous precedent it is feared to be for holding a clinician criminally liable for a medical error," Greene says.

The most significant future risk of this case is the fear it creates in the medical community and the risk that review of the headlines alone will trigger a chilling effect on the reporting and appropriate investigation of medical errors. Risk managers should seek to understand the underlying facts in this case to determine the likelihood of a similar outcome in their state.

"The peer review process is critically important to patients and providers, as it improves quality and safety by enabling the frank analysis of care, which is necessary following some unexpected or adverse outcomes. However, as the protections of the peer review process vary by state, it is important for risk managers to stay abreast of the parameters of peer review protections in their state as well as any changes to federal law impacting peer review," Greene explains. "In states that have robust peer review protections, risk managers should consider reassuring providers now and emphasizing the importance of understanding and complying with the letter of the law on peer review and its value in evaluating and improving care."

Risk managers should not put their employees at risk of criminal punishment when investigating medical errors as long as they invoke peer review processes in jurisdictions that sufficiently protect those processes, Greene says. Consult with legal counsel as necessary to help maintain the privileged status of the peer review processes.

"However, caution must be exercised by all risk managers, particularly those who practice in jurisdictions where the peer review processes are not or may not be sufficiently protected," Greene says. "The variability in state laws on protection of peer review is significant, and the interpretation of this law may be changed by case law or legislative action. As such, hospital risk managers should consult with experienced legal counsel periodically to ensure there are no changes that should impact how the risk manager implements and guides on the peer review process."

Most medical errors that allegedly cause harm are addressed in the civil, not criminal, courts through litigation of medical malpractice

cases, where the providers and hospital systems are subject to financial risks, but not risks of criminal conviction.

"Only time may tell whether this case represents a dangerous precedent, as many critics contend, but a risk manager's best tools are to carefully follow the peer review laws, regulations, and their hospital's policies when investigating medical errors," Greene says. "Consult with legal counsel experienced in the peer review and quality assurance processes periodically and when you have questions or concerns." ■

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Engineering Students Help Hospital Address Safety Issues

Johns Hopkins Hospital is addressing patient safety issues in a unique way by collaborating with engineering students from Johns Hopkins University.

The students contribute as part of their work in the Strategies for Innovation and Growth class, led by **Pam Sheff**, PhD, director of the Center for Leadership Education and Master of Science in Engineering Management Program at Johns Hopkins Whiting School of Engineering.

At the end of a recent semester, 16 teams of engineering students presented their projects and recommendations to clinicians and administrators at the hospital. Recent projects included reducing the risk of cyberattacks on Johns Hopkins Hospital, reducing burn accidents for patients receiving home oxygen therapy, and improving OR efficiency.

EXECUTIVE SUMMARY

Johns Hopkins University's engineering program helps students find solutions to patient safety issues. The students developed several projects to improve safety at the hospital.

- Students work with hospital staff, physicians, and administrators.
- Many student recommendations have been adopted over seven years.
- Topics include reducing falls, infections, and burns.

The program began in 2015, and the hospital has adopted many of the recommendations from the engineering students. *(See the story in this issue for summaries of two projects.)*

For the engineering students, part of the project's value is in learning to incorporate more than technology when addressing a problem, Sheff says. The work helps them understand process improvement and human learning factors rather than depending on only a technological fix.

"It's been a completely amazing experience. We've worked out a system where we can accomplish a lot of good work that benefits our engineering students and the hospital," Sheff says.

Stacey J. Marks, MS, academic program manager with the Johns Hopkins Institute for Clinical and

Translational Research Training, Education, and Career Development Programs works with the engineering program and hospital administration to identify projects and match teams to the appropriate staff and physicians at the hospital.

The projects run for seven or eight weeks, with the first two weeks spent gathering data, Marks says. Then, the students create written recommendations and presentations for the hospital.

"It's all patient safety-related, but it could be about process improvement, cost savings, or other aspects of patient safety, depending on the particular project," Marks says. "Several projects have made direct improvements in patient safety by addressing things like reducing infection, proper training for surgical instruments, improved handwashing, fall prevention, and pressure injuries."

Sheff says one noteworthy project addressed a problem reported by OR personnel. Sterile wrap was arriving in the OR with perforations, which made it useless. At first, Sheff was skeptical of students addressing that problem because she thought it would be simple to find the cause and fix it.

"It was actually a very complex project that related to the way the sterile wraps were being stored and packed across the hospital," Sheff says. "It really was interesting, and they did figure out ways to get it to the operating rooms intact."

Another project involved preventing burn injuries to COPD patients when they are sent home with oxygen. Most burn injuries resulted from the patient smoking while using oxygen. The team developed a prototype for a smoke sensor inside the nasal cannula supplying oxygen so the flow could be stopped if it senses a danger of combustion. That team is working to patent the device.

A recent project involved reducing falls in the psychiatric ward through better assessment of a patient's medication use. Another addressed the same issue for geriatric patients.

"My engineering students respond so well to this project opportunity. They find the idea of using their engineering knowledge and skills to help improve safety to be very compelling, something they are excited about," Sheff says. ■

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Engineering Students Offer Patient Safety Improvements

The following are examples of recent patient safety improvements suggested by engineering students at Johns Hopkins University.

Example 1: Improving compliance of surgical hand scrub.

Students participated in the Patient Safety Collaboration Program (PSCP) to help Johns Hopkins Hospital mitigate the risk of surgical site infections (SSI), which account for almost 20% of all hospital-acquired infections. The students created "a three-prong approach to analyzing the problem that included interviews, observations, and surveys, and identified one of the most impactful causes: the low compliance of surgical hand scrub usage."

Some units reported a hand-scrubbing compliance rate of only 7%. Over seven weeks, the students identified unclear training as the main reason for low compliance. The student proposed these tactics:

• Long-term: Regularly train all surgical staff to inform them of updated sanitation requirements.

• Short-term: Hang a poster near the scrub sinks to describe the scrubbing process. One person should be designated to monitor and collect data for surgical hand scrub.

The students also created a sample metric for responding to substandard hand scrub compliance:

• Verbal warning;

• Week one and two: Written warning;

• One month of substandard performance: Strict action warning.

"Combining knowledge from different disciplines, the PSCP not only helped solve a real-world issue but also initiated the possibility of bridging engineering and the healthcare industry," the students wrote.

Example 2: Epic user interface and notification problem.

Johns Hopkins Hospital uses the Epic electronic medical record system. However, staff reported the OR's workflow management board was cluttered, inefficient, and difficult to interpret.

The students spent eight weeks interviewing staff and surveying potential solutions, finding Epic's layout was represented in a vertical orientation that clinicians needed to spend extra time "deciphering the information on the board instead of capturing the information at first glance."

The students made these recommendations:

- Create a horizontal layout to be read left to right;
- Divide the interface into time-scaled horizontal frames using white dotted lines in the background. The horizontal frame will update every hour, creating new space for upcoming information.
- Reconfigure the interface to show precise information, including the patient name, doctor name, and patient identification, for procedures. ■

Improve Patient Safety with Employee Rewards, Celebrations

The most important way hospitals can achieve patient safety goals is to build a culture of safety that includes patients, providers, and staff, says **Julie Walker**, executive vice president and managing director at symplr, a company in Nashville, TN, that provides risk, patient safety, and compliance consulting for healthcare organizations.

Recent news stories about clinicians facing criminal charges for medical errors and patient safety concerns have many providers feeling anxious about what will happen to them if they report an incident or near-miss, Walker says. A safety-first culture rewires this mindset, encouraging employees to report unsafe conditions to protect patients.

Walker suggests an effective safety culture can be created and encouraged using these five policies and behaviors:

- **Reward employees.** Organizations are most successful when they reward caregivers and employees, either with praise or money, for reporting never events, near misses, and unsafe conditions. The emphasis should always be on collaborating to ensure an incident is never repeated rather than punishing an individual for making a mistake.

"By praising those who report issues and making a cultural change, healthcare organizations build team camaraderie around improving patient outcomes," Walker says.

- **Close the loop.** Employees need to know incidents will be investigated and changes will be made. Action validates the importance of incident reporting and helps employees know their time was well spent.

"Communication with staff before, during, and after the actions were taken — apprising them of what exactly was done — is essential," Walker says. "A hospital I worked with in Pennsylvania saw a huge increase in reporting after adopting this 'close the loop' practice."

- **Celebrate results.** This is another way to praise employees for reporting and to close the loop. Sharing the incident or near-miss stories can inspire employees to be vigilant and adopt a safety culture. Keeping strict records of improved patient safety outcomes and sharing results helps employees feel ownership and pride in their patient and staff safety work.
- **Invite the broader community to participate in the initiative.** The culture of patient safety does not stop with the healthcare organization's employees. It should be extended to patients, family members, and friends.

"Through facility signage and verbal invitations, everyone should be empowered and know how to report their concerns," Walker explains. "If they see something, they should be able to say something."

Cultural change starts from the top, Walker says. Leaders must be outspoken advocates for patient safety. Praise employees for reporting

EXECUTIVE SUMMARY

Active engagement with employees can help improve patient safety. Build a culture of safety by showing employees how much their contributions matter.

- Reward employees for good safety behavior.
- Celebrate achievements that signify a good safety culture.
- Keep employees informed about incidents and results.

dangerous situations. Celebrate positive changes. Make this a standard part of both formal meetings and casual conversations.

Another step hospitals can take to effectively meet and exceed patient safety goals is to make reporting easy and incorporate it into the regular clinical workflow.

"For example, I've worked with hospitals that switched from cumbersome paper forms to mobile reporting apps. Hospital staff were easily able to take a picture, fill out a few prompts about what happened, and then continue with their busy schedules," Walker says. "Making incident reporting electronic resulted in a significant increase in reports, which is always the goal. I've also seen hospitals find success by making event reporting accessible from within their electronic health record to avoid disrupting clinicians' workflows."

Walker notes healthcare historically has been hierarchical and paternalistic, but that should not continue, especially when it comes to patient and staff safety. It is important to empower everyone in the healthcare ecosystem to be mindful and vocal about their safety concerns. Providing different avenues for reporting, including anonymity in certain circumstances, will encourage incident reporting.

"COVID-19 presented new challenges by creating an incredibly stressful healthcare environment. Recent reports show that safety incidents and medical errors increased during the pandemic," Walker says. "Experts are still investigating the root causes for the rise, although burnout, understaffing, and medical supply shortages are absolutely factors. Addressing those issues will make a difference." ■

SOURCE

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Hospitals Underreport to NPDB, Creating Doubt

The Department of Justice (DOJ) recently announced a large healthcare system in the Northwest agreed to pay more than $22 million to settle allegations that two former spine surgeons falsified or exaggerated patient diagnoses and performed unnecessary surgeries.[1] In addition to the noteworthy size of the settlement, the case is the latest to show how problematic physicians often are not reported to the National Practitioner Data Bank (NPDB).

Hospital staff reported concerns to administrators. The hospital conducted independent analyses of the surgeons' practices, with both investigations lasting longer than 30 days. Hospitals are required by law to report to the NPDB any professional reviews that last over 30 days as well as any restrictions of clinical privileges, and when a clinician surrenders privileges while under or to avoid investigation.

The health system "admitted that, while it eventually placed both Dr. B and Dr. A on administrative leave in February 2017 and May 2018, respectively, it allowed both doctors to resign while on leave, and did not take any action to report Dr. A or Dr. B to the National Practitioner Data Bank" or the state department of health, the DOJ reported. Both surgeons eventually resigned.

NPDB Sometimes Misunderstood

Reporting requirements for the NPDB often are misunderstood, says **Rebecca M. Lindstrom**, JD, shareholder with Polsinelli in Chicago. One common misconception is that only physicians must be reported in certain circumstances.

"In fact, nurses are the profession most commonly reported to the data bank," Lindstrom notes. "The reporting requirements actually apply to a wide range of healthcare practitioners, not just physicians."

Querying the database also can be misunderstood. Many healthcare entities are eligible to query, but hospitals are the only entities mandated to query. Federal law requires hospitals to query the database when physicians, dentists, and other practitioners apply for medical staff appointment or clinical privileges, and then every two years thereafter.

Another common misconception is that querying the database is enough to satisfy due diligence. "A lot of times, administrators feel like once they query the database and get the results, they've done their job, everything they're supposed to do. [It] was never the intent for the NPDB to be your sole source of information," Lindstrom says. "It's a flagging system, but people can rely on it too much. It only works if people use it properly. We can't use it as the single way we're going to catch everything."

The NPDB's usefulness depends on reliable input by those who are supposed to report, Lindstrom says.

A healthcare entity's failure to report required information breaks the system. The value of any query is diminished if users cannot rely on everyone reporting properly.

"If everyone reported everything they're supposed to report, every time, the system would be more valuable, but it still wouldn't be perfect," Lindstrom says. "It can be dangerous to depend on the NPDB query to catch every bad person out there, because it doesn't."

Hospitals are required to report medical malpractice payouts, but some scenarios might be confusing, Lindstrom says. Hospitals must report a medical malpractice payment resulting from a written complaint or a written claim demanding monetary payment for damages.

The NPDB states it interprets this requirement to include "any form of writing, including pre-litigation written communications. The NPDB, not any other entity, determines whether a written claim has occurred for purposes of filing a report."

The data bank also noted a medical malpractice payment report (MMPR) is submitted on a particular healthcare practitioner, not an organization. "For an MMPR to be submitted to the NPDB on a particular healthcare practitioner, the practitioner must be named, identified, or otherwise described in both the written complaint or claim demanding monetary payment for damages and the settlement release or final adjudication, if any," the NPDB stated.[2]

Risk managers might encounter physicians who insist a malpractice settlement is not reportable if the terms of the settlement are confidential. "That's not true. You still have to report it," Lindstrom says. "A confidential settlement does not excuse the reporting requirements."

The size of the settlement or award also does not matter, she says. Even small amounts trigger the reporting requirement. That can be a deterrent for a physician who otherwise would be willing to settle a complaint with a token payment.

Exactly where the funds originate can affect whether a payment must be reported, Lindstrom says. Before 1993, the NPDB required the reporting of all medical malpractice payments made on behalf of a practitioner, even if the payment was made with personal funds. A court determined that was not legal, so individuals are not required to report to the NPDB payments they make for their own benefit.

But a corporation or other entity that makes a payment for the benefit of a named practitioner must report that payment to the NPDB.

"When it comes to reporting malpractice payments, and also when you need to report adverse actions against clinicians, it is important to study the NPDB guide because there are a lot of nuances that might apply to your particular situation," Lindstrom explains. "The NPDB provides a lot of useful guidance and explanations in their online guidebook, so it's worth consulting that information before you assume what you have to report or don't have to report." ■

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Improve Handoffs with Patient Care Partners

Quality patient handoffs are crucial to patient safety. They can be improved by expanding the scope of a handoff to include discharge, says **Karen Curtiss**, BCPA, founder and executive director of The Care Partner Project in Chicago. Ideally, this handoff will be from hospital staff to the patient's personal support staff.

Hospitals can proactively ensure every patient is discharged with someone who is prepared to help the patient recover at home, or prepared to find others who can and will.

"Expand the scope of what is considered the care team to include patients and their personal 'care partners,' usually family and friends," Curtiss advises. "They usually are referred to as advocates, but that's a loaded term. We use the more accurate term to encompass all the many ways patients need help."

Meaningfully include the patient and their care partner in handoffs, Curtiss suggests. Most mnemonics for handoff communications, such as SBAR and I-PASS, do not focus enough on the patient voice so patient goals, concerns, and questions are inadequately addressed.

"Physician goals are front and center. They are important, but what about the patient's goals?" Curtiss asks. "Not only would their inclusion be an opportunity to increase HCAHPS [Hospital Consumer Assessment of Healthcare Providers and Systems] scores by supporting good communication and preventing missed expectations, but patients hold a wealth of information that may not be included on their medical records that could impact care."

Encourage patient care partners to participate in every handoff conversation, Curtiss says. When necessary, they can stand in to express the patient's voice and relay the physicians' handoff information to patients.

"This extra layer of communication is exactly what's needed for the Swiss cheese of care," she says. "Modifying the mnemonic or creating new [terms] would institutionalize this norm, but it's ultimate success rests on the ability or willingness of medical professionals to speak in lay terms."

Not every family member or friend a patient may choose is equipped to be a care partner, Curtiss notes. TheCarePartnerProject.org provides training that can help. ■

SOURCE

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Many ED Malpractice Claims Are Rooted in Poor Communication

By Stacey Kusterbeck

Most ED patients are, at some point, handed off to other providers — admitting physicians, the ICU team, on-call consultants, or primary care physicians. Good communication is crucial in the ED, "more so than in most settings," according to **Chris Landrigan**, MD, MPH, chief of general pediatrics at Boston Children's Hospital. "The ED doctor takes an initial sense of what's going on and, in every case, has to convey that to someone else. It's just so core to what they do that thinking about miscommunication for ED docs is particularly important."

Landrigan and colleagues set out to learn the proportion of malpractice claims that involved a communication failure and the nature of those claims.[1] "We wanted to better understand how frequently, and in what way, communication impacts medical malpractice," says **Kate E. Humphrey**, MD, MPH, CPPS, a pediatric hospitalist at Boston Children's Hospital and associate medical director of patient safety and quality.

Researchers analyzed 498 malpractice claims that were filed from 2001-2011 in the CRICO Strategies Comparative Benchmarking System. They searched for claims that involved a communication failure and failure type. About 10% of the claims involved the ED. "We knew that in studies looking at adverse events in hospitals in general, miscommunications are responsible for something like 50% to 80% of the most serious medical errors that happen in hospitals," Landrigan says. "Typically, cases are multifactorial. But communication is this thing that kind of goes awry in almost all serious cases reported."

However, in the malpractice literature, it was unclear what role communication was playing because claims usually are analyzed based on setting and clinical subtype of errors, rather than root causes. "We wanted to see if in the malpractice world, the same things held true that we were seeing in the patient safety world generally," Landrigan explains.

Miscommunication was responsible for 49% of malpractice cases. "This is largely in line with the broader literature in patient safety, but it hadn't emerged from the malpractice literature. It was great to harmonize that, and to harmonize ways of looking at malpractice," Landrigan says.

Contingency plans, diagnosis, and illness severity were the information types miscommunicated most often. If there was a communication error, researchers examined who it involved. In ED claims, "a lot of times, the communication error was between the providers and the families, as opposed to the medical team itself," says **Melissa Sundberg**, MD, MPH,

another study author and a pediatric emergency physician (EP) at Boston Children's Hospital.

Of claims with communication failures, failed handoffs were involved 40% of the time. For ED claims with handoff errors, the problem was providers did not know the next step if the patient's condition declined. "Contingency plans are not always communicated well," Sundberg notes.

As a hospitalist, Landrigan has observed poor communication when ED patients are handed off. In some cases, the EP obtained a neurology consult for a patient with a ventricular peritoneal shunt. The neurologist indicated it probably was OK for the patient to go to general service because the problem did not seem like a shunt failure. Those cases did not always go as expected. "If things start to deteriorate, you need to get neurosurgery involved very quickly," Landrigan says.

It is critical the team on the floor is attuned to the EP's thought process on what to do if things do not go as planned. "In digging through the claims on the types of communication failures that contributed to malpractice claims most often, it was exactly that type of thing," Landrigan observes.

In some cases, providers were quite worried about a patient, but that did not come across to whoever treated the patient next. "In those cases, there may be a delay in escalating care or taking action because the team up on the floor or ICU is not adequately keyed up on just how sick this patient is and what our worries are," Landrigan says.

Securing buy-in from hospital administrators to make investments to improve patient safety, including handoff communication in the ED, can be challenging. Compelling anecdotes about cases when things went terribly wrong can grab leaders' attention. "But you also need hard data to make a financial business case," Humphrey argues. "Having numbers behind us to show the financial burden of medical malpractice can help us speak to different leaders in the organization to further that work."

Malpractice claims that included communication failures were less likely to be dropped, denied, or dismissed than claims that did not involve communication failures (54% vs. 67%) and were more expensive to defend. Mean total costs for cases involving communication failures were higher ($237,000 vs. $154,000).

Investigators studied how many malpractice claims could have been mitigated with a properly used handoff tool. "We found that a structured handoff tool can be very helpful to make sure the appropriate information is transferred," Humphrey reports.

In looking at the subgroup of handoff-related claims, researchers found 77% of those cases could have been averted if clinicians had used a handoff tool. "We found there is a lot of potential there," Landrigan says.

As co-founder of the I-PASS Patient Safety Institute, Landrigan's work has focused on how to hand off in an evidence-based way. One problem is handoffs have been handled inconsistently and haphazardly in EDs. "It was really idiosyncratic and based on individual physicians. A lot of times, handoffs weren't happening at all," Landrigan says.

During his own training, Landrigan often heard providers making comments such as, "You don't have to tell me anything. If something goes wrong, I'll figure it out."

"There is a growing recognition of the notion of the importance of making people attuned to the things you're worried about," Landrigan notes.

Although small communication problems arise all the time with ED handoffs, major adverse outcomes that result in litigation rarely happen. Thus, individual EPs do not take it as seriously as they should. "We need to shift that thinking," Landrigan asserts.

Many EPs view handoffs as a task they have to handle without the appropriate sense of urgency. "There's a failure to recognize that doing a handoff in those few minutes at the end of a shift is probably the most dangerous thing you're going to do all day," Landrigan says. "Getting it right is really critically important."

For EDs, the implementation of handoff tools can lower the likelihood of errors. "It's not a huge leap to say that if you are decreasing injurious errors, you are probably avoiding malpractice claims," Landrigan says. "Connecting the dots is not terribly difficult." ■

REFERENCE

1. Humphrey KE, Sundberg M, Milliren CE, et al. Frequency and nature of communication and handoff failures in medical malpractice claims. *J Patient Saf* 2022;18:130-137.

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1. **After mistakenly injecting a 75-year-old woman with the wrong medication and causing her death, former nurse RaDonda Vaught was convicted of:**

   a. negligent homicide and gross neglect of an impaired adult.
   b. negligent homicide only.
   c. gross neglect of an impaired adult only.
   d. criminally negligent homicide.

2. **How did Vaught obtain the medication that was injected into the patient?**

   a. From a nursing cart
   b. From the patient's bedside
   c. From an automated dispensing cabinet
   d. From a pharmacy technician

3. **What does Julie Walker say is one effective way to increase safety incident reporting?**

   a. Switch from paper reports to electronic reporting.
   b. Offer monetary rewards for reports.
   c. Make all reports public.
   d. Require a minimum number of reports from each employee.

4. **According to Rebecca M. Lindstrom, JD, what group of healthcare professionals is most often reported to the National Practitioner Data Bank?**

   a. Physicians
   b. Nurses
   c. Radiology technicians
   d. Dentists

CE OBJECTIVES

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

- Describe the legal, clinical, financial, and managerial issues pertinent to risk management.
- Explain the impact of risk management issues on patients, physicians, nurses, legal counsel, and management.
- Identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

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

Allegations of Failure to Diagnose Resulting in Toddler's Death Sufficient for Malpractice

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Former Director of Risk Management Services (2004-2013)
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News: Parents of a toddler with cystic fibrosis and chronic pseudomonas sought treatment for the child's complaints of abdominal pain. An emergency physician ordered X-rays and prescribed anti-nausea medication. The following morning, the child was found not breathing due to air escaping from her bowels and into her heart, causing obstruction.

The parents filed a malpractice suit, alleging the physician and hospital failed to diagnose their daughter. A court granted summary judgment in favor of the hospital. On appeal, the court ruled the parents sufficiently raised a question of fact to support the litigation.

Background: In May 2015, a 2-year-old girl who suffered from cystic fibrosis and chronic pseudomonas complained of moderate abdominal pain. An emergency physician ordered X-rays of the child's abdomen. The physician personally reviewed the films and diagnosed the child with constipation, prescribed a laxative, and sent the child home.

Approximately one week later, the child's parents brought her to the same hospital. By this point, the child's complaints had increased to more severe abdominal pain, abdominal distension, abdominal cramping, vomiting, and diarrhea. A different ED physician conducted a physical examination and ordered an X-ray. The physician determined the child's bowels were dilated and filled with stool and gas, similar to the previous X-ray. This subsequent physician diagnosed the patient with acute vomiting, likely a viral syndrome, and prescribed an anti-nausea medication. The physician discussed the findings with the parents and discharged the child at approximately 1:30 a.m.

Around 2:30 a.m., the child fell asleep on her mother's chest. When the mother awoke at 6:00 a.m., the child was no longer breathing and was unresponsive.

Later that morning, while the hospital and physicians were unaware the child had already passed away, a radiologist reviewed the child's X-rays and described a "rather notable obstipation," bowel distension, and a small amount of bowel dilation — similar to the previous physician's interpretation.

An autopsy revealed the child's cause of death as severe malabsorption syndrome secondary to cystic fibrosis and acute cardiac pump failure secondary to right heart air embolism. The pathologist indicated the child suffered torsion of the omentum, leading to avascular necrosis of the small bowel, which was grossly dilated. Because of the child's severe bowel condition, air escaped from her bowels and reached her heart, causing an air embolism.

Following the child's death, the parents filed a lawsuit against the hospital and the second ED physician. The initial physician and radiologist were not named. The parents resolved their claims against the individual physician, and the hospital filed a motion for summary judgment, claiming there was no violation of the standard of care. The parents and hospital presented conflicting expert witness testimony concerning the alleged violation.

The hospital presented an expert physician who was a professor of surgery at a university, the surgeon-in-chief at a children's hospital, a board-certified medical examiner, surgeon, pediatric surgeon, and advanced trauma life support provider. The hospital's expert testified there was nothing the hospital could have done during the second visit to prevent the child's death due to her extensive health complications and the extent of the bowel damage.

The plaintiffs presented two expert physicians: a board-certified radiologist specializing in neuroradiology and a board-certified internal medicine and emergency medicine physician who also was a professor of medicine at a university. The radiologist claimed the films revealed serious bowel complications, suggesting the need for emergent medical or surgical attention. The emergency physician testified the hospital breached the standard of care when the X-rays were reviewed only by the attending physician, rather than by a radiologist, before discharge. This expert claimed the child would have survived if she had been timely diagnosed and treated.

The trial court granted the hospital's motion for summary judgment, ruling the parents had not raised a genuine issue of fact that the hospital's alleged negligence caused the child's death. The plaintiffs appealed, and the justices ruled the plaintiffs' emergency medicine physician's testimony was sufficient.

What this means to you: This case reveals a common theme in medical malpractice actions: the critical importance of expert witnesses and testimony. As often is the case, both sides presented testimony from expert witnesses — qualified physicians who would support the actions taken by the respective side in the prosecution or defense of the litigation. In this matter, the parents retained two expert physicians while the care providers presented one such expert physician. Since juries are composed of laypersons, expert testimony almost always is necessary in medical malpractice cases, except when it is so abundantly obvious even to the untrained eye or mind that negligence occurred.

But for most cases, choosing the right expert can make or break a defense. First, expert witnesses must be appropriate and qualified. An important lesson here is the defendant care providers challenged one of the parents' experts based on his qualifications, claiming he lacked sufficient expertise to testify as to the standard of care for ED administration and lacked qualification to estimate the child's chances of survival because he did not specialize in pediatric medicine or surgery. Initially, this challenge was successful.

While this was overturned on appeal, the lesson remains: A care provider should carefully examine the background, training, qualifications, specialization, and every aspect possible of an opposing expert to determine whether it is a fruitful avenue to challenge the so-called expert's ability to offer an opinion. A successful challenge to an opposing expert can disqualify that individual's testimony and greatly damage an opposing party's case. Similarly, choosing the right expert to support the physician or care provider's defense is equally critical, as it is inevitable the same scrutiny will occur from a plaintiff's side.

Tying into these procedural issues is another lesson from this matter: Appeals present the opportunity to rectify erroneous decisions — and those decisions can flow both ways. In this case, the trial court erred by giving an inordinate amount of weight to one side's expert while discounting the other side's expert. That also could have been prejudicial to the defendants, and examining avenues for relief from erroneous decisions is necessary in medical malpractice actions.

There are several methods for limiting exposure in advance of litigation. However, once litigation has occurred, mitigating risk becomes more challenging. In this case, the first physician avoided these disputes and appellate gymnastics because he was not named in the suit. While the terms of the settlement are unclear, reaching an agreement places the outcome in the hands of the parties rather than a jury, mitigating risk and reducing exposure. Runaway juries who award millions of dollars in damages can be prevented — and cases such as this present circumstances ripe for an emotional jury to award a significant verdict.

Beyond a complete settlement, there are other potential methods for mitigating risk while continuing to challenge damages, such as a "high-low" agreement. In a high-low agreement, the parties agree to a minimum and a maximum recovery, thereby guaranteeing an injured party will recover some amount while limiting the maximum exposure for the care provider. For example, the parties may agree to a $1 million minimum and $2 million maximum. If a jury awards $50 million, the care provider will be protected and only have to pay the $2 million maximum. In cases where an injury is undisputed, it may be useful to agree to pay some amount while reducing exposure. It is important for care providers to critically evaluate the evidence and litigation positions throughout the case to determine whether such mitigation methods are appropriate, or whether the injured patient's case is subject to defeat altogether through a more efficient method, such as a motion for summary judgment.

Finally, note here an expert witness was needed in litigation because the physicians did not initially call an expert to review the child's studies during the multiple ED visits. When patients keep returning with similar or worsening complaints about an ailment in the same location, physicians must look past the obvious diagnoses that are not responding to their interventions, and if they cannot think beyond those diagnoses, find someone who can. In this situation, perhaps the patient's diagnosis was

not survivable, but patients must be provided the best and most thorough care possible. Choosing the path of least resistance is often the direct way to get to the litigation highway. ■

REFERENCE

- Decided April 21, 2022, in the Court of Appeals of the State of Washington, Case Number 38054-8-III.

Failure to Perform Sterilization Leads to Unwanted Pregnancy, Litigation

News: In 2014, a pregnant patient received obstetric services for her third child. The patient claimed she requested and paid for a tubal ligation; however, the ligation was never performed, and the patient was not informed. The patient became pregnant again and alleged the care providers' failure to perform the procedure constituted negligence and caused the unwanted pregnancy. The defendants denied liability.

A trial court ruled in favor of the defendants, but the appellate court determined the patient presented sufficient evidence to demonstrate the defendants' duty, breach, and the existence of damages.

Background: From April 2014 until July 2014, a pregnant patient received obstetric services from an individual physician and a medical center. The patient did not meet or speak with the physician until she was admitted to the hospital for a scheduled cesarean delivery — the patient's third. The patient did not tell the physician she wanted him to perform a tubal ligation, and the physician did not inform the patient he would perform the procedure. The physician testified he does not perform such procedures by default, and that patients must request the procedure.

The patient received federally funded health insurance that does not cover the cost of surgical sterilization. The patient knew she had to pay $400 before the physician would perform a tubal ligation. Before the scheduled cesarean delivery, the patient paid the $400 and received a receipt, although it did not indicate the reason for the charge.

According to the patient, when she arrived at the hospital the next day, she told staff she was going to have her tubes tied. However, the patient did not receive any counseling from the physician about tubal ligation, and the records did not reveal any informed consent signed by the patient granting permission for the procedure. The physician did not discuss the procedure.

The medical center requires patients seeking a tubal ligation to sign a "Requirements for Sterilization" form that advises the patient about the risks of the procedure, including the risk of death, and informs patients even if a portion of the tube is removed, an unplanned and undesired pregnancy still may occur. This patient did not sign this form.

The patient underwent the cesarean delivery but not tubal ligation. During a postnatal visit, the medical practice's records indicated the patient was requesting tubal ligation as a contraceptive method.

Approximately one year later, the patient became pregnant with her fourth child and returned to the same practice, which confirmed the physician did not perform the tubal ligation. The practice refunded the patient the $400. The patient gave birth to her fourth child. Although the physician who delivered that child recommended a tubal ligation, the patient did not request and did not undergo the procedure.

One or two months following the patient's delivery of her fourth child, she again became pregnant, but that child did not survive to term. The patient did not discuss tubal ligation with the physician who provided services during the patient's most recent pregnancy.

The patient filed a lawsuit against the physician and practice, claiming her fourth pregnancy resulted from malpractice and a failure of the healthcare providers to inform her the tubal ligation was not performed. The defendants denied liability and filed a motion for summary judgment. The trial court granted the defendants' motion, but the appellate court reversed, finding the patient presented some evidence of a duty by the healthcare providers and a breach of that duty. The appellate court also found sufficient damages for mental anguish if medical negligence was proven.

What this means to you: This case presents lessons about consent, notice, and records issues as well as interesting aspects of damages for this rather unique malpractice action. A more typical medical malpractice action is focused on informed consent: whether a care provider fully informed a patient about the nature, benefits, and risks of the procedure, and allowed the patient an opportunity to ask questions. Failure to provide this information and to secure a patient's knowing,

informed consent is a common form of malpractice.

By contrast, this case is a twist on consent and notice whereby the patient wanted a procedure, requested it, paid for it, and believed she received it. The lack of information did not occur before the procedure — it occurred after, whereby the patient was never informed that she did not undergo the procedure. This patient claimed these circumstances constituted malpractice because the physician and practice actually took her money but did not perform the procedure — and, more importantly, did not fully inform her.

Transparency in healthcare is fundamental and critical. Patients must be informed at all reasonable times of their medical treatment options, risks and benefits, and what actually happens. Of course, there are certain circumstances in which it is impossible to fully inform and receive a patient's consent before providing emergency care. But in the absence of that, securing a patient's full informed consent before and fully informing a patient after are standard duties for care providers. Here, the appellate court agreed the patient sufficiently presented evidence indicating the physician breached the duty of care. The court found the care providers knew or should have known the patient requested the procedure but did not receive it.

Notably, an increasing number of cases are emerging where larger healthcare facilities, clinics, and hospital systems servicing multiple areas have failed to create systems that allow open communication between departments, sub-departments, and staff. Here, when the patient first requested the procedure, the individual receiving the request should have informed the surgeon so the procedure could be added to the informed consent. The admitting department, where the money was paid, did not send the authorization with the patient as part of her medical record. This form must be reviewed and signed by the patient in the presence of the surgeon before anything can happen. If this surgeon does not perform sterilizations, the staff should have communicated this to the admitting department so the patient would be notified when the request for the form was generated. That way, she could have chosen a different practitioner or a different hospital to receive the care she wanted. Finally, before she was taken into the operating room, a nurse and an anesthesiologist should have asked the patient what procedure they are undergoing and match the answers to the various consent forms. Had this occurred, the surgery might have been postponed. If not feasible, at the very least, the patient would have known she was not going to receive the tubal ligation during her cesarean delivery. While this may seem like a complex maze to navigate, these steps are essential to assure a complete understanding by all involved of what is about to take place.

Related to these issues of consent and notice, an important lesson of preparing, reviewing, and keeping records emerges. Medical malpractice actions take many years, particularly when appeals are involved. Memories fade, but medical records are eternal. Demonstrating a patient was actually fully informed of the risks and benefits of a certain course of treatment without accurate medical records is an uphill, if not impossible, battle. Care providers must ensure proper policies and procedures are in place, and all staff prepare thorough records, review those records for accuracy, and maintain those records for later use, whether for the underlying healthcare of the patient or in defending against malpractice actions. Here, the records accurately indicated the patient did not receive the ligation, yet it was unexplained how the care provider accepted and kept records of the patient's payment toward the procedure. Oversight and review of such records could have revealed this discrepancy and allowed the care provider to shed light on it before unwanted consequences occurred.

Finally, there are interesting takeaways concerning damages. The court found the parents of a healthy child born after an unsuccessful (or unperformed) sterilization may not recover monetary damages for the care, education, maintenance, and support of that healthy child. The parents may recover actual medical expenses incurred because of the procedure — which, in this case, was the mere $400 out-of-pocket expense. The care provider had reimbursed the patient this amount, thus undermining the damages. At the same time, the court recognized mental anguish damages tied to the unwanted pregnancy and birth were a prospective measure of damages if the patient could adequately prove the care providers' negligence. That enables actual, significant damages in the event of liability. When the appellate court determined triable issues existed, the court opened up these damages, and the patient may be able to recover far more than $400. Thus, it is important for defendant care providers to challenge not only liability, but the proper measure of damages to mitigate risk. For example, a patient who suffers only nominal harm will be entitled to far less recovery than a patient who suffered an unwanted pregnancy and gave birth to an unhealthy or disabled child, necessitating significant costs for care. Reviewing and challenging the alleged damages or harm is critically important for defendants. ■

REFERENCE

- Decided April 8, 2022, in the Court of Appeals, Eighth District of Texas, Case Number 08-19-00287-CV.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

Breach Report Reveals 61% Increase in Breaches Affecting 500+

The Office for Civil Rights (OCR) recently submitted a report to Congress setting forth the HIPAA breaches and complaints reported in 2020 as well as the enforcement actions taken by OCR.[1]

The Health Information Technology for Economic and Clinical Health (HITECH) Act requires OCR to issue annual reports to Congress detailing HIPAA breaches and complaints. For 2020, OCR reported 656 notifications of breaches affecting 500 or more individuals, 66,509 notifications of breaches affecting fewer than 500 individuals, and 27,182 complaints alleging violations of HIPAA and the HITECH Act.

Overall, breach reports decreased 4%, but the number of breaches involving more than 500 affected individuals increased by nearly 61% over 2019. Those 656 breaches affected more than 37 million individuals.

> OVERALL, BREACH REPORTS DECREASED 4%, BUT THE NUMBER OF BREACHES INVOLVING MORE THAN 500 AFFECTED INDIVIDUALS INCREASED BY NEARLY 61% OVER 2019.

The increase in reported breaches affecting 500 or more patients is concerning but not surprising, says **Richard Sheinis**, JD, partner with Hall Booth Smith in Charlotte, NC.

"Most of those affecting more than 500 people involve compromised servers related to hacking incidents, which supports what we all know experientially — that the hacking groups are driving up these numbers in the large data breaches," Sheinis says. "The big takeaway here is confirmation that these bad actors are going after your servers. That is the real threat, not the inadvertent breach of a file here and there."

Sheinis advises focusing on the vulnerabilities that most frequently lead to these data breaches and the preventive measures that can be taken, such as multifactor authentication for remote access.

"Surprisingly, I'm still seeing a fair number of practices and medical providers that do not have multifactor authentication, and it's so easy to put in place. We're still seeing so much phishing in which the threat actor gets login credentials to use from their remote location, but if multifactor authentication is in place, that would cut off that threat actor," Sheinis explains. "I haven't seen a case yet in which the threat actor stole the mobile phone of the person whose credentials they stole through phishing, so they would not get the multifactor code."

The report also underscores the need for IT professionals who focus specifically on security. Many healthcare entities employ IT professionals whose priority is to keep the computer system running smoothly so employees can access it when needed, and they work on the security component as an additional task. The time when that was feasible is quickly passing.

"When you need to work on the security of your network, get the expertise of a security specialist, not an IT generalist," Sheinis advises. "I think that is lacking a lot in the medical community."

Training also is becoming specialized, Sheinis says. People in any healthcare organization come from varied backgrounds and comfort levels with technical issues, and

older employees are more likely to be compliant with security requirements than younger employees. That diversity means the training for one group of employees might not be the best for another group.

Patient Access Request vs. Disclosure Request

OCR's recent reports to Congress are a reminder for healthcare providers to respond to patient access requests in a timely manner, says **Scott Bennett**, JD, an attorney with Coppersmith Brockelman in Phoenix. Part of that involves providing education to the personnel who handle medical records requests so they understand the difference between an access request and a disclosure request under HIPAA.

"It is quite common for healthcare personnel to confuse the two types of requests. Healthcare providers need to educate their personnel on the two types of requests and the different requirements for each type," Bennett says. "It is also helpful to provide personnel with concrete, actionable guidance documents, like checklists or flowcharts, that they can use to determine whether a request is an access request or a disclosure request."

It is critical for healthcare providers to put in place to ensure every access request receives a response within 30 days as required by HIPAA, Bennett says. OCR has brought enforcement actions against many providers for failing to respond to access requests in a timely manner.

Every access request needs to be logged, and processes must be in place to ensure a response is sent within 30 days. When an access request does not receive a timely response, the healthcare provider should perform a root-cause analysis to discover the reason or reasons for the failure and take steps to prevent it.

"Another striking point from the OCR's reports to Congress is the importance of covered entities and business associates performing a security risk assessment that is enterprisewide. The OCR's resolution agreements underscore the importance of making sure that risk assessment extends to all electronic PHI that the organization creates, processes, stores, or transmits," Bennett says. "That includes every piece of hardware and software that touches electronic PHI."

Decrease in Overall Reports Misleading

The OCR report is misleading when it focuses on a 4% overall decrease in reports received over 2019, says **Mac McMillan**, CEO of CynergisTek, a healthcare information security company based in Austin. There was a 61% increase in the number of reports involving more than 500 records.

"While there may have been fewer reports, slightly, the year was certainly worse in terms of total records potentially exposed," McMillan says. "Secondly, they don't emphasize enough that the biggest contributor to the number of breaches reported, as well as the increase in size of the breaches, was hacking. Healthcare is no longer defined by insider threat. Clearly, the threat is external, which everyone seems to get except OCR." Seventy-three percent of those hacks involved email or a network server, he says.

OCR recommends better compliance with the HIPAA Security Rule, but McMillan says that is another problem.

"Again, this demonstrates that they do not get it. First, the HIPAA Security Rule is not adequate to secure the modern healthcare IT environment. Second, a focus on compliance as it relates to cybersecurity demonstrates a lack of understanding," McMillan explains. "Third, the report fails to address the fact that the rule needs to be updated, that elements of security are not even addressed by the rule that are critical today."

Of the violations involving fewer than 500 records, the report references 93% involved unauthorized access or disclosure, meaning predominantly an insider threat.

"OCR knows full well that you cannot effectively monitor for insider abuse with some form of automated monitoring, yet it does not measure this or discuss it," McMillan says. "The bottom line is these reports emphasize as an industry we are still focused on compliance at the expense of good security. We have modern technology, an interoperability initiative, a 21st Century Cures Act, and antiquated standard for cybersecurity."

Driving Compliance Reviews

The reports indicated data breach reporting is the biggest driver of OCR compliance reviews, which serves as a warning to HIPAA-subject entities to stay off the HIPAA "wall of shame," says **Alaap B. Shah**, JD, an attorney with Epstein Becker Green in Washington, DC. Overall, about 86% of compliance reviews resulted in some sort of corrective action plan and/or monetary penalty.

The report also showed OCR shifted focus toward HIPAA Right of Access enforcement in 2020, which has continued into 2022.

"Nevertheless, despite this shift in enforcement priorities, the largest penalties levied by OCR in 2020 remained tied to breaches arising from hacking incidents and where the OCR review evidenced lack of conducting adequate risk analysis and risk management activities," Shah says. "Hacking was a dominant driver for breaches in terms of volume of events, percentage and location of ePHI systems impacted, and number of affected individuals per breach and across all breaches in 2020. This trend is continuing into 2022."

The reports also sent a clear signal providers as a covered entity class were at greatest data breach risk associated with hacking in 2020, and concomitantly at greatest risk for findings of noncompliance by OCR, Shah says. This is not a new trend, either, as providers have historically lagged in terms of HIPAA Security Rule compliance for many reasons.

The reports also indicated all types of covered entities and their business associates struggle with Security Rule compliance and, in particular, conducting security risk analysis and management activities.

To reduce risk related to data breaches and findings of noncompliance, Shah recommends entities continue to focus efforts on these key activities:

- Improving authentication controls, including implementing multifactor authentication;
- Improving risk analysis and management processes, leveraging OCR's Security Risk Assessment tool and the National Institutes of Standards and Technology guidance;
- Increasing audit logging and monitoring, and improving security awareness and training to reduce risks related to phishing and other social engineering attacks.

The increase in some breaches could be a sign that covered entities are taking HIPAA more seriously and better recognizing when a breach must be reported, says **William P. Dillon**, JD, shareholder with Gunster in Tallahassee, FL.

"They are becoming aware of things and reporting incidents that they may not have reported in the past," Dillon says. "It's my sneaking suspicion that we've had those high breach numbers for a while but now everyone knows they have to report these incidents. I don't know that even five years ago that was the case." ■

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1. Office for Civil Rights. Annual report to Congress on HIPAA Privacy, Security, and Breach Notification Rule compliance for calendar year 2020. 2022. https://bit.ly/3vWAQbK

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OCR Researching How Covered Entities Implement Security Practices

OCR recently released a request for information (RFI) soliciting public comment on how regulated entities are voluntarily implementing security practices under the HITECH Act. It also is seeking public input on sharing funds collected through enforcement with individuals who are harmed via HIPAA violations.

Because of the Jan. 5, 2021, amendment to the HITECH Act, HHS is required to consider certain recognized security practices of covered entities and business associates when determining whether to impose penalties for violation of HIPAA, says **Layna Cook Rush**, CIPP/US, CIPP/C, shareholder with Baker Donelson in Baton Rouge, LA.

While covered entities and business associates are not required to implement recognized security practices, demonstrating such practices were in place for 12 months before an incident will be considered as a mitigating factor in the analysis of a HIPAA violation penalty.

"The recent RFI is an opportunity for covered entities to have a voice in how recognized security practices are determined and reviewed by OCR in the wake of a HIPAA breach," Rush says. "HHS specifically stated that it is seeking input on additional information or clarifications regulated entities need from OCR regarding

implementation of the HITECH amendment."

OCR is requesting information on two issues. First, it appears OCR is seeking to better understand how covered entities are determining and implementing recognized security practices, Rush says. Since the HITECH amendment, when conducting a HIPAA breach investigation, OCR routinely inquires whether the regulated entity uses recognized security practices. Information shared by covered entities on the recognized security practices may be used to help OCR assess whether entity under investigation uses reasonable security practices, Rush says.

Second, the amendments to HITECH require HHS to establish a methodology under which individuals harmed by a potential HIPAA violation can receive a percentage of any civil monetary penalty or monetary settlement collected for the offense.

"OCR is seeking input from all stakeholders to assist it in developing regulations or guidance that will dictate when a portion of a penalty or settlement amount will be shared with victims, and the methodology for determining the amounts distributed," Rush says.

After the comment period, HHS also may issue regulations or guidance on implementing and documenting recognized security practices that are a mitigating factor when a covered entity has experienced a breach.

Upon the issuance of any new regulations or guidance, covered entities should be prepared to re-evaluate their security practices and determine whether any adjustments are necessary.

"Recognized security practices outlined in any potential guidance resulting from this RFI may not be required, but in the event of a HIPAA breach investigation, covered entities could certainly benefit from being able to show they have adhered to these practices," Rush says.

Recognizing Good Work

OCR's request for comment on the HITECH Act's provision regarding "recognized security practices" represents a welcome effort to recognize the good work many covered entities are performing to bolster their cybersecurity through adoption of best practices and adherence to the National Institute of Standards and Technology and other industry standards, says **Adam N. Hirsch**, JD, an attorney with Roetzel & Andress in Chicago. However, it remains to be seen how much OCR actually takes recognized security practices into account to reduce penalties or forgo enforcement actions.

"The RFI is a bit of a double-edged sword. The focus on recognized security practices suggests a more even-handed, covered entity-friendly approach to HIPAA enforcement," Hirsch says. "On the other hand, the focus on civil monetary penalties and settlement-sharing and the creation of a HIPAA whistleblower mechanism could lead to a spike in HIPAA enforcement activity."

One issue to watch is how harm to the individual is defined under the HIPAA whistleblower process because that will form the basis for allocating settlement amounts.

"A broad interpretation of harm that goes beyond actual financial damages suffered would be likely to lead to a wave of HIPAA whistleblower complaints," Hirsch says. ■

REFERENCE

1. Office for Civil Rights. Considerations for implementing the Health Information Technology for Economic and Clinical Health (HITECH) Act as amended. Federal Register. April 6, 2022. https://bit.ly/3N3SO1W

SOURCES

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