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INSIDE

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Obstetrics Strategies to Increase Safety, Reduce Liability Risk

OB/GYN always is a challenge for improving patient safety and avoiding malpractice exposure, but there are strategies that work. As always, communication is a key factor, along with staffing the appropriate clinical professionals when needed.

Communication improves with daily safety briefings or huddles, says **Lynda Tyer-Viola**, PhD, RNC, FAAN, assistant vice president of OB/GYN and inpatient women's services at Texas Children's Pavilion for Women in Houston, which delivers 6,000 babies a year. She also is an assistant clinical professor in the Department of Obstetrics and Gynecology at Baylor College of Medicine in Houston. Teams at the Pavilion for Women huddle four times a day on the inpatient service and once a day as a system, looking at factors like staffing, any facility issues, patient numbers, high-risk patients, and what they call the "watchers list."

"This is the list where we include patients that might concern someone. The watchers list is those patients whom you believe, not clinically but from a gut feeling or your own personal experience and from knowing the patient's family, might need more attention from clinicians," she says. "They might need their care escalated, and we need to be ready."

> "OUR HOSPITALIST PROGRAM IS ABOUT QUALITY AND SAFETY, NOT ABOUT MAKING THE PHYSICIANS' LIVES EASIER BY DELIVERING BABIES SO THEY DON'T HAVE TO BE THERE AT 2 A.M."

The teams also talk about "safety scoops" in the huddles. A safety scoop is any deviation from what the clinicians expected to happen in a particular situation; not a clinical turn,

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but rather an irregularity in the expected process. An example would be a physician not arriving in a timely manner to care for a patient, requiring a change in plans or calling on another doctor.

Some facilities are finding that hospitalists can improve outcomes for babies and mothers by providing consistent care throughout a hospital stay, but Tyer-Viola says her hospital has found the most success with a nuanced approach. The hospitalist program is aimed at improving safety, she explains, and that does not mean turning over all inpatient care of a patient.

"Each and every one of our mothers has an OB/GYN that is intended to deliver her baby, and our hospitalists are not intended to deliver other doctors' babies unless there is an emergency and the doctor can't be there, or if the doctor is busy delivering another baby in another room," she says. "Our hospitalist program is about quality and safety, not about making the physicians' lives easier by delivering babies so they don't have to be there at 2 a.m."

Focus on Deadly Hemorrhage

The Pavilion for Women also focuses on obstetrical hemorrhage, an uncommon but extremely dangerous condition that can kill the mother during or after delivery. Although clinicians rarely see this threat, they must be ready to respond quickly and effectively when it happens, Tyer-Viola says. Ensuring readiness is a challenge, so the Pavilion for Women uses an evidence-based guideline and a cloud-based education program that must be completed by every provider, resident, midwife, and nurse.

That training is coupled with simulation, using the hospital's simulation center, an operating room, or on a nursing unit. Training in the different locations is important because the clinicians must see how their response times, and the ability to respond most effectively, can differ depending on whether all necessary team members and equipment are present.

All members of an interdisciplinary team are present for the simulations. A key component of the education is quantifying blood loss. This is more difficult in obstetrics than with many other patients, Tyer-Viola points out, for several reasons. The first reason is that obstetrical patients have more blood.

"They can lose a lot of blood, but not respond in the same way you would expect from another patient. They can lose an amount that would make other patients pass out, but the obstetrical patient keeps talking to you," she says. "If you wait for their vital signs to drop, they've lost

EXECUTIVE SUMMARY

Obstetrics poses one of the greatest liability risks in healthcare. There are strategies proven to work in improving patient safety and reducing exposure. Communication and simulation are among the most important issues.

- Physicians, nurses, and other team members should train together.
- Prepare for high-risk events such as obstetrical hemorrhage.
- Simulation drills should be learning opportunities, not tests.

more blood than you think and you have a very sick patient at that point. No matter how experienced and expert your clinician is, they can't accurately estimate how much blood has been lost."

That means the volume of blood lost must be carefully measured with OB patients and the amount frequently called out during delivery, she says.

The hospital also drills its rapid response team in different locations throughout the hospital, including the use of a massive transfusion protocol (MTP). The MTP is more commonly used in trauma, but the Pavilion for Women uses it to prevent women from losing so much blood that they can die. For an MTP call, the hospital can rapidly deploy six nurses, a respiratory therapist, a pharmacist, a house supervisor, an intensive care physician, and two anesthesiologists.

The Pavilion for Women's focus on obstetrical hemorrhage and MTP has made it a magnet for women with conditions such as placenta accreta that can lead to life-threatening bleeding.

"Most professionals see this once or twice in their careers. We did 36 last year," Tyer-Viola says. "Women come here from all over the country if they have this, because they want to be at a place where we do it all the time and have perfected our response."

Intensive Care Always Available

The hospital also can provide intensive care to both mother and child, which Tyer-Viola says is a significant contributor to patient safety. The Pavilion for Women is a freestanding facility dedicated to women and children and did not have ready access to intensive care, but research has shown that the best place for a high-risk mother to deliver is at a facility that can provide continuing care for the child.

The hospital is able to perform high-risk deliveries without any need to transfer the child or mother. A delivery suite was converted for intensive care, but still provides the birth experience that is important to most parents. An intensive care physician is present at the hospital 24/7.

> "I DO NOT BELIEVE THE DELAY OF TREATMENT FOR FETAL DISTRESS IS CAUSED BY SOMEONE NOT WANTING TO COME TO THE HOSPITAL. I BELIEVE IT BOILS DOWN TO A COMMUNICATION ISSUE."

"In their contract, it says they're actually not allowed to leave the building," she says. "They ask if they can go across the street to round at St. Luke's and they could be right back here in a few minutes. Our answer is no, you have to be present in this building for your entire shift."

The intensive care doctors are expensive for the hospital because they do not see many patients, typically billing for a total of about 200 patient days a year. But the Pavilion for Women considers their full-time presence important enough to absorb the cost, she says. The same goes for staffing with experienced, intensive care labor and delivery nurses.

"Having well-trained ICU labor and delivery nurses is very important. When one leaves, we have to replace them right away. We can't say we're not delivering that many babies this month, so we can wait," she says. "It is a special cadre of nurses that have to be trained in intensive care and also in all our systems. Just like with the intensive care physicians, we need these specially trained people in the hospital right now, all the time."

Communication among team members is a leading factor in obstetrical claims, says **Pamela Willis**, RN, JD, a regional patient safety risk manager at The Doctors Company, a Napa, CA-based professional liability insurer. She has 14 years of experience as a labor and delivery nurse, including serving as a travel nurse in five states.

The Doctors Company studied closed obstetrical claims and found that a top allegation was a delay in treatment of fetal distress, she notes, which is related to how clinicians in the hospital communicated with those outside. *(The closed claim study is available online at: http://bit.ly/2ACd0mW.)*

"I do not believe the delay of treatment for fetal distress is caused by someone not wanting to come to the hospital. I believe it boils down to a communication issue," Willis says. "That is about a nurse at the bedside being able to communicate effectively with a physician on the outside."

Willis advises hospitals to provide fetal monitor training for nurses and physicians together. That rarely happens, she says. Nurses are required to refresh their training periodically but do so only with other nurses, and physicians are similarly on their own.

"You have two sets of professionals learning something in their own

silos," she says. "But you're expecting them to communicate the most important and urgent information in the language they learned, which is not necessarily the language the other party learned. Everyone kind of knows what a category 1 strip means versus a category 2 strip, but there's still some gray area there."

Hashing out the small questions and understanding what each means with certain statements and questions can immensely improve communication, Willis says. This does not require any wholesale change in policy or procedures, but just getting people face to face so the nurse can explain, "Oh, I wouldn't call you for this level of concern. But if I call you for this, I'm very concerned about your patient."

Willis advises mutual reviews of fetal monitoring strips by physicians and nurses. When a doctor arrives for a delivery, the team can take five minutes afterward to review those strips and any other strips they had seen recently that were of interest.

"It's sort of an impromptu effort to communicate a little better. The nurses say they found this particular part interesting and the doctor might tell them something about that one and point out something else they could learn from," Willis says. "It goes a long way toward everyone being on the same page about what those strips mean and what kind of interventions they might signal, but it also is just one more way they improve their ability to talk to one another and get a clear message across."

Another top allegation in obstetrical claims is the improper performance of vaginal delivery, Willis notes. In the closed claims study, almost half of these claims involved shoulder dystocia — another high severity, low frequency event. The best way to address it to use more simulation drills, Willis says.

But clinicians often dislike simulation drills because they see drills as a test, she says. They see the drill not as an opportunity to learn or improve, but as something that could expose their weaknesses and harm them in the workplace.

"I'd like to see simulation drills move more toward what they're meant to be, an education tool. Not a test, but a way to choreograph that emergency," Willis says. "We need to be careful not to say at the end, 'How did everyone do? Did everyone pass the test?' We need to say, 'How did our team do? What could we do better? How could we position our supplies and medications better? What do we need access to?'"

The simulation must be repeated often, Willis notes, to ingrain the processes and highlight any shortcomings. It also is important for nurses and physicians to run the simulations together rather than each doing their own, she says.

"The best part of simulation comes when you can get the providers on the unit and finding the time to do the simulation with the nurses. The benefits are just incredible," she says. "It gives the providers a great benefit, rather than the doctor just being there to make it more realistic for the nurses. They learn how to communicate what they need and how to best work with these nurses who want to do their best for the patient, the same as the physician does."

The biggest challenge for these efforts is finding the time for simulations or other education efforts, Willis says. That is mostly because people think of them as big, formal events that require a lot of planning and coordination. They don't have to be, she says.

"You have to look for the opportunities to work these into your day-to-day operations, to make the best use of those few minutes you can find here and there. It doesn't have to be a big deal where you get out your million-dollar simulation baby," she says. "Throw a pillow in a bag, call it a baby, and take a few minutes to run through a shoulder dystocia drill and see what you might learn from it. Run through what you can do in those few minutes and do it often, so it all becomes second nature."

Documentation of shoulder dystocia should be a part of that simulation, Wills says. A shoulder dystocia documentation template can help nurses properly document the maneuvers performed by the doctor in real time, she says. Just as one person in a code blue always is the recorder, there should be a designated dystocia recorder.

"The form should be readily available in all labor and delivery rooms so that one person in the team can easily document in real time all the details of what maneuvers were performed, when exactly they were done, who was in the room, and what happened," she says. "This is not always documented well and the facts are difficult to reconstruct later when there is a malpractice case. This also requires good communication, with the doctor aware that someone is documenting and calling out the maneuvers clearly as they happen, so it should be part of the drill." ■

SOURCES

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Good Background Screening Crucial to Avoiding Liability

Proper background screening is critical for protecting patients and staff, as well as avoiding liability exposure that can come from allowing someone with a questionable history to work in your organization. Healthcare organizations can face special challenges with background screening, but there are ways to overcome them.

The issue of background screening always has been a difficulty for employers, says **William Hopkins**, JD, partner in the Shackelford law firm in Austin, TX. All employers know that they must perform the checks, but as most former employers are advised only to provide dates of employment and eligible-for-rehire status, there is a constant question of whether there is any value to the process.

There are ways to get to the answers, Hopkins says.

"Unfortunately, there is no perfect answer and the previous employer is always probably going to have more information than they will be willing to provide you, but by asking follow-up questions about the employee, you can sometimes get some cues that can help you make your decision," Hopkins says. "Given the potential stakes involved in hiring a healthcare employee, I think that healthcare providers need to go beyond just the surface in their questions."

The key to mitigating litigation risk is to ask questions that are factual and verifiable, Hopkins says. Usually, it is the prior employer's opinion comments that get them in trouble, but by asking questions that are factual, they are given more leeway to answer questions and perhaps provide some great information, he says.

"Also, by asking factual questions, you can sometimes gain insight by the subtle cues provided by the person that you are speaking to. Sometimes, it is what they do not say out loud that tells you what you need to know," he says. "Once someone is offered a job and is hired, it is incumbent on healthcare employers to ensure that all new employees are properly trained and oriented to their new job. That often may require some form of competency checklists, so that the employee's skills are verified and not just assumed. Also, going through this competency process will often expose other weaknesses in a new employee if there are any."

One of the biggest challenges to effective background screening is knowing what information can be relied on, says **Angela R. Matney**, JD, an attorney with Hirschler Fleischer in Fredericksburg, VA. Information from social media, for example, can be misleading and fail to present an accurate picture of the candidate. Criminal background checks also can yield results for people with the same or similar names.

Employers also must comply with screening laws. The federal Fair Credit Reporting Act (FCRA) sets out the minimum standards applicable to background checks conducted by third parties for employers. The FCRA applies to "consumer reports," which are generated by a third-party screening agency (a consumer reporting agency, or CRA). Credit bureaus are considered CRAs under the FCRA, Matney explains. *(See the story on page 140 for more on the FCRA requirements.)*

Peer Review May Hide Info

Some the challenges involve physician employees, says **Karen Owens**, JD, an attorney with the law firm of Coppersmith Brockelman in Phoenix. As hospitals employ physicians in ever-increasing numbers, some special issues arise in screening physicians for employment, she says. Physician quality and behavior issues typically are identified in the medical staff peer review process, which often is confidential under state law.

"Under some state provisions, human resource offices don't even learn of specific quality issues in their own employed physicians because

EXECUTIVE SUMMARY

Healthcare employers must screen potential employees and physicians carefully to avoid liability, but it is common to encounter roadblocks. Understand the pertinent laws and limitations.

- Sometimes, employers must read between the lines for an accurate idea of an applicant's past.
- Take care to comply with laws regarding the use of credit checks and other investigations.
- Always verify licenses and other credentials.

these matters are sequestered in medical staff committees. And even a healthcare administrator aware of specific quality issues may remove an employed physician using a no-cause termination agreement that may include negotiated reference language," Owens says. "Although some courts have made clear that healthcare employers who provide misleading references can be liable for fraudulent misrepresentation, employers of physicians generally can avoid that kind of liability by simply providing no substantive reference at all."

Because of these issues, hospitals seeking to employ physicians must get creative, she says. First, a hospital employer should work as closely as the laws allow with medical staffs in determining whether a physician should be appointed to the medical staff — and hired. Often, the medical staff will have access to information that is unavailable to human resources or the physician employment office, she says.

"For example, the medical staff obtains a report from the National Practitioner Data Bank, which contains mandatory submissions from prior hospitals and state medical boards about matters such as the surrender of clinical privileges under investigation; limitations on state licenses or medical staff privileges; and similar serious problems," Owens says. "Hospital employers also need to read between the lines with respect to physician quality."

She lists the following red flags:

- short stays at prior employers or as medical staff members at prior hospitals;
- frequent moves from state to state or community to community, especially when a move is close in time to a malpractice claim;
- difficulties obtaining references, especially when physician medical directors refuse to have conversations about the physician or seem uncomfortable or secretive during reference calls;
- numerous and/or high-dollar malpractice claims;
- lapses in employment or medical staff membership;
- any reports of problem clinical care or conduct that appear on professional board websites.

Verify Licenses, Other Credentials

Many of these red flags also apply with respect to hiring patient care professionals other than physicians, such as nurses and physician assistants, says **Jill Chasson**, JD, also an attorney with Coppersmith Brockelman. Short stints of employment, gaps in employment, frequent moves, or difficulty in obtaining references can raise questions about whether there were issues with the quality of a candidate's work performance. Vague or less-than-credible explanations from the candidate about the circumstances of departure from prior jobs also can signal potential problems.

Chasson recommends that hospitals check the status of all professionals' licenses with the appropriate state licensing board and conduct a criminal background check on anyone who would be interacting with patients. In addition, she notes that the candidate should be asked in a written application and in an interview about the reasons for leaving previous employment, with appropriate follow-up questions as necessary to secure clarifications or additional information, such as whether the candidate has ever been terminated for performance reasons.

An application form also should include language stating that the candidate certifies the accuracy of the information he or she is providing, and that falsification or material omission of information is grounds for immediate termination of employment, Chasson says.

If a hospital employer finds clues about a candidate's possible problems at a prior hospital or other employer, the hiring hospital should insist on receiving more information from the prior hospital or employer and the candidate. In the absence of vindicating information, the hospital can decline to hire the candidate or, for a physician, consider placing the physician on probation or include significant protections for the hospital in the employment contract, she says.

Owens notes that probation or other protections can be difficult when the hospital badly needs a physician to serve the community, or is understaffed in other ways. But removing an employed physician who is on the medical staff, or terminating other kinds of professionals, can be even more difficult than refusing to hire candidates with red flags at the outset, she says.

Risk of Violence Ups the Ante

The threat of workplace violence is an added complication to the challenge of background screening, says **Molly R. Batsch**, JD, an officer with the law firm of Greensfelder, Hemker & Gale in St. Louis. The Bureau of Labor Statistics suggests that incidents of serious workplace violence are at least four times more common in the healthcare industry than in other industries, she notes.

At the same time, financial liability for the violent acts and other misconduct of employees is one of the most significant areas of exposure for healthcare providers. This exposure stems from the fact that hospitals and clinics may be held liable for injuries resulting from their failure to properly screen the employees they hire, she says.

While a comprehensive workplace violence prevention plan should be considered to fully address the risk of workplace violence, careful background screening should be conducted regardless of whether such a plan is implemented, Batsch says. In fact, most states require background checks to be conducted on certain healthcare workers, particularly those who have patient or child care responsibilities. She notes that Section 6201 of the Affordable Care Act likewise imposes background screening obligations on certain healthcare providers.

"Even if not required, conducting background checks on all employees working at a hospital, clinic, or other healthcare provider can be a very effective tool to reduce both workplace violence and potential liability stemming from workplace violence or other employee misconduct," she says. "However, when conducting non-mandatory screening, employers should be especially careful to review applicable background review restrictions and guidelines."

The Equal Employment Opportunity Commission issued guidance in 2012 that requires employers to conduct an individualized assessment of any criminal convictions discovered during a background check, Batsch notes. This assessment must consider the nature and gravity of the offense or conduct, the time that has passed since the offense, conduct and/or completion of the sentence, and the nature of the job held or sought.

Further complicating the background review process is the fact that most former employers now provide only very limited information about former employees to prevent potential litigation, she says. Many states regulate what information a former employer can and cannot disclose about a former employee.

"I ALWAYS ADVISE HEALTHCARE BUSINESSES TO SCRUTINIZE THEIR BACKGROUND-CHECKING PROVIDERS AS CAREFULLY AS THEY SCRUTINIZE THEIR EMPLOYEES."

"This new environment often leaves employers wondering why an employee left his or her last job and if they can rely upon the employee's self-serving explanation. However, there are a few limited options that may provide employers with additional information about an applicant's employment history," Batsch says. "For example, several states, including Missouri, require former employers to provide their employees with a service letter upon request, providing the true reason why their employment ended. While these letters must be requested by the employee rather than a prospective employer, and often must be requested within a limited time frame, a prospective employer may ask an employee to obtain a service letter in such states."

In addition, advising applicants that failing to be completely truthful during the hiring process will result in termination regardless of when the dishonesty is discovered may act to deter employees from misrepresenting information about prior discipline or terminations, Batsch says. This language should be included in the employer's background review policy, a copy of which all prospective employees should acknowledge during the application process.

Verify Background Check Providers

In addition to federal restrictions, many states and municipalities have screening laws regarding credit, criminal history, arrests, and other legal issues, notes **Charles A. Krugel**, JD, a human resources attorney and counselor on labor and employment law on behalf of business in Chicago.

Many of these laws prohibit the use of past arrests, certain criminal or civil convictions, and credit issues, he says.

"I always advise healthcare businesses to scrutinize their background-checking providers as carefully as they scrutinize their employees. Healthcare businesses should make sure that their screening providers are either licensed, bonded, or fully insured for errors or omissions in screening, and that those screeners will indemnify their customers for any errors or omissions," he says. "Alternatively, the healthcare company may want to consider insurance for these types of employment practices." ■

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FCRA Sets Strict Limits on Background Screens

The federal Fair Credit Reporting Act (FCRA) doesn't apply to background checks conducted in-house, but some state and local laws do, says **Angela R. Matney**, JD, an attorney with Hirschler Fleischer in Fredericksburg, VA. Employers must know what laws govern background checks in their particular state, Matney says. For example, California has some of the strictest background-check laws in the nation. Additionally, several jurisdictions have enacted "ban-the-box" laws that restrict what an employer can ask regarding an applicant's criminal history.

"It's important to be consistent and conduct the same types of background checks for similar positions across the board. Failing to do this can expose employers to claims of discrimination if their background checks are primarily focused on applicants and employees who are members of a particular protected class," Matney says. "Additionally, when doing criminal searches, it's a good idea to run as many local searches as possible, in addition to consulting national databases. This is because there is not one entity that has access to all criminal data."

Employers always should verify past education and employment by contacting schools and employers, Matney advises. Taking extra time to do this at the outset can prevent an employer from making a costly hiring mistake.

Watch for Excluded Individuals

Healthcare employers always should search for an applicant on the List of Excluded Individuals/Entities (LEIE) of the U.S. Department of Health and Human Services Office of Inspector General and the General Services Administration. An employer who hires an individual who has been sanctioned or excluded from participation in federal healthcare programs can expose itself to fines and penalties, she says.

"The biggest mistakes that employers make are failing to obtain proper consent before conducting a background check, and failing to notify employees when information from a consumer report is used in an employment decision," she says. "Under the FCRA, if an employer is going to obtain a consumer report about an applicant or employee, the individual must receive a document that contains a disclosure of this fact and nothing else. The authorization that the employee must sign can be included with the disclosure, but best practice is to have the disclosure and authorization on separate pages. The disclosure should not contain a release or any other extraneous information."

Matney cautions that obtaining consent to a background check electronically may be challenged in the courts. Some employers have faced class action lawsuits because they used an "I agree" box to obtain an applicant's consent to an online job application that included an authorization to obtain a consumer report buried in the application.

Also, be aware that "investigative reports" — reports based on personal interviews concerning a person's character, general reputation, personal characteristics, and lifestyle — bring additional obligations under the FCRA and other laws. These obligations include providing written notice that you may request or have requested an investigative consumer report, and giving a statement that the person has a right to request additional disclosures and a summary of the scope and substance of the report, Matney explains.

"Employers also can expose themselves to liability if they are not careful in how they use social media in screening applicants. Appearing to rely on demographic information

and conducting social media screens on some applicants but not others can lead to claims of discrimination," Matney says. "There are also a number of laws that restrict when employers can ask an employee to give an employer access to a personal social media profile. These vary by state, so it's crucial for employers to make sure they understand the law in each jurisdiction where they do business."

Matney says another area where it's possible to run afoul of the law is when the employer decides to act on information obtained from the background check. The FCRA and other screening laws contain strict requirements to notify individuals in advance of making an adverse employment decision. Notifying applicants in advance and providing them with a copy of the report on which the decision is based allows them to tell the employer if any information is incorrect.

The FCRA doesn't state how far in advance notice must be given, but five days has been found to be reasonable, Matney says. Employers also must notify individuals after an adverse decision has been implemented. The FCRA has strict requirements for what this notice must contain, so employers should make sure the notice complies and deliver it in writing to have a record of their compliance, she says.

"Another potential error is failing to properly dispose of consumer reports. When the employer has finished using a consumer report, it must securely dispose of the report and any information gathered from it," Matney says. "That can include burning, pulverizing, or shredding paper documents and disposing of electronic information so that it can't be read or reconstructed."

The liability for not doing all this correctly is significant. Damages available to individuals are capped at $1,000 for each FCRA violation, but courts can require employers to pay attorneys' fees, court costs, and punitive damages, Matney says. Employers also face civil penalties for FCRA violations in actions brought by the consumer Financial Protection Bureau, which are set at $3,500 per violation.

"Criminal penalties can be imposed in extreme cases," Matney says. "And if an employer has committed violations with respect to one applicant or employee, it's likely that the employer has committed many similar violations with other employees."

Matney notes that several employers, including UPS, Home Depot, and Marriott, have been hit with class action suits for failing to comply with the FCRA either due to lack of an effective consent, or for failure to notify individuals in advance of making adverse employment decisions.

In April 2017, an applicant sued Cathedral Health Care Centers, claiming that she was denied a job as a nurse because of a criminal background check that incorrectly contained multiple felony convictions. The complaint alleges that IDE Management failed to provide the applicant with a copy of the consumer report that was the basis for denying her application and refused to identify the screening agency that provided the report. Each of these actions is a violation of the FCRA, Matney notes. ■

Opioids Lead List of Drug-related Malpractice Claims

Opioids were the leading drug associated with medication-related malpractice claims, according to recent research from Boston-based medical liability insurer Coverys. The second most common claim was anticoagulants. Coverys calls this the "dangerous duo" for medication errors and liability.

A recent report from Coverys analyzed more than 10,000 closed medical professional liability claims from 2012 to 2016 to determine the causes of medication error and how to prevent it. *(The full report is available online at: http://bit.ly/2gkcMrT.)*

Key findings include the following:

- Opioids are involved in more medication-related claims than any other drug, followed by anticoagulants. Twenty-four percent of medication-related claims involved opioids, while 16% concerned anticoagulation drugs;
- 42% of medication errors occur in an office or clinic setting;
- 31% of medication errors are related to inadequate monitoring of a patient's medication regimen;
- 38% of medication error cases ultimately involve a patient death.

Claims about alleged issues with administration of medications represent 31% of all medication-related claims and are the third highest process issue for providers, notes

Robert Hanscom, JD, vice president of business analytics with Coverys.

The report notes that "When verifying instructions, preparing or measuring a dose, or physically administering a dose of medication to a patient (or when patients take the medications themselves), much can go wrong. Our data show a slight rise in the incidence of these issues — 28% of such cases resulted in indemnity paid."

Hanscom says the continuing prevalence of medication errors and medication-related claims is surprising.

"We actually thought we would have made more progress with medication-related malpractice cases from 10 or 15 years ago with the promise of what electronic medical records would do for us," Hanscom says. "We hoped that the process-based components of that technology would almost cure these kinds of errors, but they are still with us. We've made a lot of process in some of the process-based vulnerabilities out there, like the dispensing and administration of drugs."

There still are issues related to ordering medications, which includes evaluating the patient and providing the right drug treatment, Hanscom says. That is where the opioid epidemic ties into the ongoing number of medication-related malpractice cases, he says.

"Opioids are special medications and there is never the intent for the patient to stay on them for long periods of time, but that's what we're seeing with so many patients. And there is the question of whether some patients should ever have been on opioids in the first place," Hanscom says. "Those are the elements we're seeing at play in some of these very bad malpractice cases."

Coverys advises managing the "Five Rights" during medication administration: right patient, right drug, right dose, right route, and right time.

"According to our data, monitoring and managing a patient's medications is the second riskiest step in the medication episode of care, resulting in more than 31% of medication-related claims," according to the report. "Evidence indicates that a lack of vigilance in medication reconciliation can contribute to an adverse event. While technologies have significantly improved the selection, dispensing, and administration of medications, the work of medication reconciliation is an ongoing challenge."

Medication monitoring and reconciliation — ensuring that the full collection of various medications any given patient is taking are still safe, necessary, and appropriately dosed — requires "impeccable processes and clear communication as patients move across the continuum of care and ongoing medication adjustments are made," the report says.

Anticoagulants are a common problem, Hanscom notes. Patients on blood thinners must discontinue them before elective surgery, but may not resume the regimen properly, he notes.

"Things get lost in the system and confusion is created about what medication the patient should resume after, and when they should resume. They may not even be put back on the medication and no one notices until there is a bad outcome," Hanscom says. "This can happen when you have many providers involved and many medications, and no one is clear on who is in charge. This is a problem that has been worrisome for us and has not really gotten any better over a period of time."

Coverys notes that the healthcare industry has focused more on medication reconciliation, but with many patients seeing many doctors in different systems and with multiple medications, it can be hard to keep up.

"Sometimes patients are not well aware of all the medications that have been prescribed to them and go on new ones at each physician visit. At the monitoring and management stage, communication is key. It's important to discuss how a medication is working, whether the patient is having any side effects or adverse reactions, and — over the long term — to reassess whether the medication is still the right choice, taking into consideration other medications the patient is taking and/or new symptoms or conditions," the report says. "We suggest the slightest mention of a side effect be documented in the patient's medical record and that providers find reliable ways to get patients to comply with medication reconciliation processes. There are dozens of mobile apps patients can use to keep track of their medications, or they can use paper 'medication cards' that are regularly updated." ■

EXECUTIVE SUMMARY

Recent research indicates that opioid-related claims are among the most common malpractice claims. Many medication errors occur in a clinic or physician office.

- Anticoagulants were involved in 16% of medication error cases.
- Inadequate monitoring also was cited frequently.
- More than one-third of medication error cases involve a patient death.

SOURCE

- **Robert Hanscom**, JD, Vice President, Business Analytics, Coverys, Boston. Phone: (800) 224-6168.

EHR-related Claims Involve Design Issues, Entry Errors, Alert Fatigue

Two reports on the risks related to electronic health records (EHRs) reveals the broad range of alleged and actual user and system mistakes in recent EHR-related malpractice claims. The pace of these cases has grown rapidly over the last 10 years, the research indicates.

In a study of closed claims by The Doctors Company, a medical liability insurer in Napa, CA, the data indicate that the EHR typically is a contributing factor in a medical malpractice claim rather than its primary cause. Of all claims closed by The Doctors Company from January 2007 through June 2014, 0.9% (97 claims) had EHR-related contributing factors. In the follow-up study of all claims closed from July 2014 through December 2016, 1.6% (66 claims) had EHR-related contributing factors. *(The study is available online at: http://bit.ly/2kYwe2q.)*

The following are key findings from The Doctors Company report:

• System factors, such as technology and design issues, lack of integration of hospital EHR systems, and failure or lack of alerts and alarms contributed to 50% of claims.

• User factors, such as copy-and-paste errors, data entry errors, and alert fatigue, contributed to 58% of claims.

• More EHR-related claim events are occurring in patient rooms and fewer are occurring in hospital clinics/doctors' offices.

• Obstetrics/gynecology remain the top specialty in which these claim events occur.

The findings are "modestly reassuring," says **Robert Wachter**, MD, chair of the Department of Medicine at the University of California in San Francisco.

"The number is not as high as I might have expected, but the problem is still real," Wachter says. "The report demonstrates that even though one of the promised benefits of the electronic health record was to improve safety, and I believe they have, there are hazards in these systems. They're demonstrable and measurable, and we can take steps to reduce EHR-related harm."

Wachter draws attention to the data related to hybrid systems, those in which paper systems and electronic systems, or two electronic systems, try to mesh.

"There can be a transitional period where you have one part of your system on an EHR and another part is still on paper, and we've seen that that is a situation where a lot of things can go wrong with information not making it into the system or being distorted once it enters the electronic record," he says. "Similar issues occur when you move to a new EHR but you do so in phases, with some parts of your operation still working with the older system. These are scenarios that conspire to threaten patient safety and require the utmost vigilance once you know you are in that risky situation."

Another report by CNA, which provides risk management services for healthcare organizations and professionals, concludes that an "optimized" EHR may reduce diagnosis-related professional liability claims in the ED.

Healthcare organizations often complain about the challenges that accompany the advantages of EHR use, says **Chris Heckman**, vice president of underwriting with CNA Healthcare.

"Unfortunately, these electronic health record systems have not always been designed with patient safety and risk management considerations as their paramount objectives," he says. "As a result, the limitations of this technology, and the negative habits it can engender among users, must be acknowledged as potentially affecting both quality of care and legal defensibility in the event of a claim or lawsuit."

The CNA report examines major EHR-related issues and presents strategies designed to help protect patients, ensure quality of care, and minimize liability exposures. *(The report is available online at: http://bit.ly/2zwnuX6.)* The overuse and abuse of the copy-and-paste function is a big concern.

The following are the top EHR-related risk management strategies recommended by CAN:

• establish policies and procedures delineating appropriate use of the copy-and-paste function;

• require ongoing education regarding proper use of the copy-and-paste function;

• consider adopting a voice-activated dictation system for the EHR;

• investigate the option of using software technology;

• audit EHRs on an ongoing basis;

• respond to EHR reviews or audits that reveal potential chronic misuse of copy-and-paste;

• consider EHR-based simulation training of residents and the medical staff to improve the efficient access to critically needed patient care information. ■

SOURCE

- **Robert Wachter**, MD, Chair, Department of Medicine, University of California, San Francisco. Phone: (415) 476-0909. Email: robert.wachter@ucsf.edu.

HEALTHCARE RISK MANAGEMENT™

CME/CE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:
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CME/CE QUESTIONS

1. **How does Texas Children's Pavilion for Women in Houston use hospitalists for childbirth?**

   a. Hospitalists are not intended to deliver other doctors' babies unless there is some reason the doctor can't be there.
   b. Hospitalists are intended to deliver most babies at the hospital, but the mother's obstetrician can elect to deliver the baby.
   c. Hospitalists are prohibited from delivering any babies at the hospital.
   d. The hospital requires that a hospitalist deliver all babies, with no exceptions.

2. **The intensive care physicians always present at the Texas Children's Pavilion for Women in Houston bill for a total of about how many patient days per year?**

   a. 50
   b. 200
   c. 600
   d. 1,000

3. **Why does the federal Fair Credit Reporting Act contain strict requirements to notify individuals in advance of making an adverse employment decision?**

   a. Notifying applicants in advance and providing them with a copy of the report on which the decision is based allows them to tell the employer if any information is incorrect.
   b. The notification allows sufficient time to contact a lawyer if the applicant decides to sue.
   c. Applicants must be allowed to withdraw an application if adverse information is discovered.
   d. Applicants can be allowed to contact prior employers to learn what information was reported.

4. **According to recent research from medical liability insurer Coverys in Boston, what drugs are the "dangerous duo" that feature most prominently in medication-related lawsuits?**

   a. Diuretics and stimulants
   b. Diuretics and opioids
   c. Opioids and anticoagulants
   d. Stimulants and anticoagulants

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

Post-childbirth Sepsis Yields Largest Wrongful Death Verdict in Minnesota History

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News: A wrongful death case involving a new mother resulted in Minnesota's largest wrongful death verdict. The patient suffered a severe vaginal tear during childbirth. After the patient was discharged, she returned to the hospital and underwent several tests, which revealed sepsis related to the childbirth. Notwithstanding these test results, the treating nurse practitioner diagnosed the patient with a urinary tract infection and discharged her. That same day, the patient's symptoms worsened until she passed out and returned to the ED of the same hospital.

Efforts to stabilize the patient were unsuccessful, and she died eight days after the birth. The patient's husband filed suit against the nurse practitioner and others, claiming that their negligence in misdiagnosing the patient caused her wrongful death. The case eventually proceeded to trial and, after a lengthy deliberation, the eight-person jury returned a verdict in favor of the estate for more than $20 million.

Background: In mid-August 2013, a 30-year-old pregnant physician assistant presented to a hospital in Minnesota with her husband — also a physician assistant — to give birth to her first child. She suffered a severe vaginal tear, but the birth was otherwise uneventful, and she was eventually discharged. The patient soon returned to the hospital with symptoms of chills, fever, worsening vaginal pain, and nausea. The patient was seen by a nurse practitioner, who worked as an agent of a consulting company contracted by the hospital.

DESPITE THE TEST RESULTS INDICATING SEPSIS, THE NURSE PRACTITIONER DIAGNOSED THE PATIENT WITH A URINARY TRACT INFECTION AND MADE THE DECISION TO DISCHARGE THE PATIENT.

The nurse practitioner tested the patient's urine, which returned a bacteria-free result. However, the nurse practitioner also ordered lab tests, including a complete blood count test, which showed that the patient had an elevated white blood cell count and an abnormally low platelet count of 50,000 — less than one-third the minimum normal count. Further, the patient exhibited a left shift along with bandemia, or an increase in immature white blood cells. Despite the test results indicating sepsis, the nurse practitioner diagnosed the patient with a urinary tract infection and made the decision to discharge the patient with amoxicillin and Tylenol.

Over the course of the same day, the patient's sepsis worsened until she eventually lost consciousness. The patient was then admitted to the ED of the same hospital, where, despite the best efforts of physicians, she died from her undiagnosed and untreated infection. The patient's husband sued on behalf of the patient against the nurse practitioner, her employing consulting company, and the hospital, alleging the nurse

practitioner's negligence in failing to diagnose and treat the patient's sepsis caused her wrongful death. The other defendants were sued on a vicarious liability basis.

The patient's estate argued that proper and full antibiotic treatment at the time when she originally presented to the hospital ED likely would have resulted in her full recovery. It further claimed that the surgeon who performed the patient's hysterectomy — conducted immediately prior to her death in an attempt to save her life — denied any visual evidence of flesh-eating bacteria.

Rather than contesting the nurse practitioner's negligence, counsel for the defendants argued that the patient's fast-moving infection likely would have caused the patient's death even with a more timely, full antibiotic treatment. Additionally, the defendants' expert contended that the patient's infection likely included flesh-eating bacteria.

After deliberating for six hours, seven of the eight jurors found that the nurse practitioner's negligence was a direct cause of the patient's death. The plaintiff estate was awarded $20.6 million, almost 75% of which was awarded for future loss of counsel, guidance, aid, comfort, assistance, companionship, and protection.

What this means to you: A salient lesson to be learned from this case is the importance of critically evaluating test results. At least in the context of this case, a critical evaluation demanded cross-referencing the results of tests with a patient's symptoms as established by self-reporting and physician-directed questioning to develop a running list of potential diagnoses. Further, where ambiguities arise from test results and when tests and symptoms are inconsistent, additional testing and questioning may be warranted. Successful medical professionals also will consider the patient's medical history when developing a diagnosis. These data will allow the medical professional to refine his or her list of diagnosis hypotheses and arrive at a final diagnosis.

It also is important that medical practitioners bear in mind that absolute certainty in diagnosis is impossible, and the goal is to reduce uncertainty to an acceptable range. Many medical malpractice claims arise out of a failure to diagnose or misdiagnosis. Hospitals would do well to ensure proper diagnosis procedures are instituted and followed loyally by practitioners. The focus should lay on ensuring sufficient time is spent on arriving at a diagnosis, and on delaying treatment until the practitioner is reasonably certain of his or her diagnosis. Potential consideration when creating such procedures include the level of certainty with respect to the diagnosis, the potential harm of delaying treatment to gather further information, and the potential harms or benefits of pursuing a particular treatment option.

Sepsis often is viewed by physicians as a three-stage process, including sepsis, severe sepsis, and septic shock. As with many other diseases, early diagnosis and treatment can render a life-threatening disease easily treatable. However, detecting sepsis may be difficult since its symptoms often can be caused by other disorders as well. Physicians should test the patient's blood for infection, clotting issues, abnormal liver or kidney function, impaired availability to oxygen, and electrolyte imbalances. Based on the results of those tests and the patient's symptoms, physicians may decide to test the patient's urine or wound secretions for infection. If a physician is unable to determine the location of the sepsis, imaging scans such as X-rays, CT, MRIs, and ultrasound may be used. Finally, the patient's medical history may offer further clues to illuminate the infection site; for example, the patient's vaginal tear in this case. The treatment of sepsis depends on the degree of severity and location, and may include inpatient care, antipyretics, antibiotics, fluid and oxygen replacement, vasopressors, surgery, and dialysis.

A test used in this case that was helpful in determining the proper diagnosis was a complete blood count test. These generally are used to review a patient's health, but also can be particularly helpful in diagnosing sepsis when coupled with other potential detection methods. The test also may be useful in evaluating the efficacy of a particular treatment and to validate the diagnosis given by a medical professional. Tests such as the complete blood count are widely used and are one of many available detection methods where sepsis is a possibility.

All of the above information is essential if accurately presented to the practitioner, and if the practitioner double-checks to assure that the tests and reports received are for the correct patient. From the fact pattern, one wonders whether this occurred here. One possible explanation of events is that specimens were mislabeled in the ED and the nurse practitioner based the diagnoses on lab tests belonging to another patient. Unfortunately, this is not a rare occurrence. The test results for the patient showed obvious sepsis and no evidence of a urinary tract infection. There is no plausible reason for a highly trained nurse practitioner whose educational background goes

well beyond what is required for a registered nurse to make such an error in judgment unless he or she was viewing results from a different patient. When evaluating results of any test, if the symptoms don't match the results, one must always consider and validate the patient source of the test and repeat tests if any doubt exists. ■

REFERENCE

Decided on Aug. 28, 2017, in the District Court of Minnesota, Fourth Judicial District, Hennepin County; case No. 27-CV-2016-001269.

Exclusion of Expert Witness Results in Successful Defense of Infection Case

News: In the summer of 2012, a minor child was taken to an ED in Texas for severe pain in his legs. The child was diagnosed with contusions on his legs and was quickly discharged with instructions to take Tylenol with codeine and to follow up with a pediatrician. The child was soon thereafter admitted to another hospital for a lengthy period following a diagnosis of a bacterial infection. As a result of the infection, the child suffered bone damage, among other injuries, and required multiple surgeries.

The parents filed suit, claiming that a delay in treatment constituted medical malpractice. After a series of motions for summary judgment (a motion asking the court to rule in a party's favor based on undisputed evidence obtained in discovery, prior to a full presentation to a jury to resolve disputed questions of fact) as well as an appeal involving a dismissed defendant, the court ultimately ruled in favor of the physician and hospital, granting their summary judgment motion. The exclusion of the plaintiffs' expert witness under the critical *Daubert* case governing expert witnesses was the primary basis on which the summary judgment motion was granted.

Background: On June 29, 2012, two parents took their minor child to the ED at a Texas hospital because he was complaining of leg pain. The physician who examined the child diagnosed him with contusions on both hips. Shortly thereafter, the physician discharged the child and instructed the parents to give their son Tylenol with codeine for pain, and follow up with a pediatrician in a few days. Unfortunately, the child's symptoms worsened overnight, prompting the parents to take him to the ED at a pediatric hospital the next day.

Medical professionals at the hospital conducted tests that suggested the child suffered from a bacterial infection. Thus, the hospital admitted him and administered antibiotics. The child was hospitalized for more than a month, during which time he underwent multiple surgeries and was treated for a methicillin-resistant *Staphylococcus aureus* infection.

Because of the infection, the child suffered permanent bone damage and is at risk for future injuries and infection. The parents, individually and as next friend for their minor son, asserted claims of medical malpractice in March 2014 against the hospital, the physician, and the physician's employing consulting company. The parents contended their child would have experienced a better outcome if he had received antibiotics and been transferred to a pediatric medical center sooner.

The parents asserted claims against the hospital for medical malpractice and for violations of the Emergency Medical Treatment and Labor Act (EMTALA). The medical care entity then moved for summary judgment on all of plaintiffs' claims and causes of action against the hospital, and plaintiffs filed a cross-motion for partial summary judgment on their EMTALA claim. Particularly important to the dispositive motion that terminated this case, defendants also filed separate motions to strike the opinion of plaintiffs' physician expert witness.

On Aug. 7, 2015, the court held a hearing on the parties' motions for summary judgment and motions to exclude the opinions of the plaintiffs' expert witness. The court granted the hospital's motion for summary judgment and denied plaintiffs' cross-motion. The court also determined the expert testimony was "not the product of reliable principles and methods and he did not reasonably apply the principles and methods, had those been reliable, to the facts of the case." Thus, the court ruled that the expert testimony was inadmissible under Federal Rule of Evidence 702.

Following a denied appeal, the physician's and consulting company's

pending summary judgment motion was heard. The crux of that summary judgment motion was that the plaintiffs could not prevail on any of their remaining claims because, as a result of the prior exclusion of expert testimony, the plaintiffs proffered no competent medical expert testimony that any alleged negligence by the physician caused the plaintiff's injuries. Rather than developing new evidence and writing new briefs, the plaintiffs adopted the briefs and appendices they previously filed in opposition to the hospital's summary judgment motion and the separate motions to exclude their expert's causation opinions as their response to the pending summary judgment motion. Plaintiffs did not submit any additional argument or evidence.

The court ultimately granted the latter defendants' summary judgment motion because the court found that plaintiffs failed to present any evidence of causation by an expert witness, as is required where the standard of care is not well known to laypeople.

What this means to you: When the child was brought to the hospital, his treatment was subject to EMTALA, a federal law that requires anyone coming to an ED to be stabilized and treated, regardless of their insurance status or ability to pay. A potential claim under the EMTALA, which the plaintiffs brought here, is a failure to provide an adequate medical screening examination. To comply with EMTALA, it is important hospitals ensure that all patients whose care falls under the act receive the same treatment, regardless of their ability to pay, and that adequate medical screening procedures are in place.

An issue arose in the case over what comprises an "appropriate medical screening examination," since the phrase is not defined in the act. The court determined that the main inquiry in determining whether a screening is adequate is differences between the screening examination that the plaintiff received and examinations that other patients with similar symptoms received at the same hospital; whether the hospital followed its own standard screening procedures; and whether the hospital provided such a cursory screening that it amounted to no screening at all.

The court concluded that the screening procedure followed by the hospital in this case was appropriate under EMTALA. Despite the ruling, it is important that compliance officers also focus on the equality of treatment among patients, rather than setting a particular procedure. However, setting procedures for medical screening examinations can be very valuable when compliance comes into question.

Another claim made by plaintiffs under EMTALA was a failure to stabilize the child prior to discharge. EMTALA focuses on any permanent effects of failing to administer medical care to patients in emergency medical situations. However, considering the degree of uncertainty with diagnosing patients, the act has been interpreted to take the physician's diagnosis as it stands — here, a pair of contusions, which naturally did not give rise to an emergency. This gives physicians power to stand by their diagnoses under the act and prevents second-guessing in emergencies. The only other issue that might be considered was the extent and detail of the history given by the parents and the child. Although this is hindsight in motion, was any trauma to the hips in which there was a wound included in the history? Infection in bone usually seeds from an external source, such as direct trauma to the site or a tooth, gum, ear, or other infection, especially anaerobic, even if resolved. However, if all bloodwork results, physical examination, and history including the above questions did not indicate infection, it was likely within the standard of care to not consider infection as the source of the child's pain.

Another argument made by the plaintiffs in this case was that the physician was negligent because of a failure to place the child on a broad-spectrum antibiotic. However, given the symptoms exhibited by the patient, and especially considering the diagnosis given by the physician, such a use of antibiotics was not appropriate. Unwarranted antibiotic prescriptions contribute to drug resistance and can cause health complications in young children. The physician's acts were a good model for other medical professionals.

Finally, this case again illustrates the continuing power of *Daubert v. Merrill Dow Pharmaceuticals*, 509 US 579 (1993), which established the standards for admissible expert testimony. It is important for defendant physicians to retain quality experts early in the case and for their counsel to properly attack retained experts on the other side and/or move for summary judgment if the plaintiff has an unqualified expert or no expert on an issue requiring expert testimony because it is too complicated for the average layperson to understand on his or her own. ■

REFERENCE

Decided on Aug. 7, 2017, in the United States District Court, N.D. Texas, Dallas Division; case No. 3:14-cv-0898-M.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

HHS May Be Taking Different Tack With HIPAA Enforcement

HHS and the Office for Civil Rights (OCR) may be adopting a different approach to HIPAA compliance under the Trump administration, as evidenced by a notable reduction in enforcement actions in the past year. But don't let down your guard just yet. HIPAA still has teeth.

The last year of the Obama administration saw a significant increase in HIPAA enforcement, with record-setting penalties and new compliance audits targeting both covered entities and business associates. There were 13 resolution agreements totaling almost $25 million in 2016.

That aggressive approach seemed to continue in the first half of 2017, with nine resolution agreements totaling $18 million in penalties. But then the enforcement actions dramatically slowed, explains **David P. Saunders**, JD, an attorney with the law firm of Jenner & Block in Chicago.

HHS went from commanding headlines with its HIPAA compliance resolutions to no one hearing from them at all for months, Saunders says. Does this signal a new attitude at OCR, one that would remove some heat from healthcare organizations' efforts to comply with HIPAA?

Not necessarily, Saunders says. "It's a little too soon to tell if this is the new normal or not, especially with a new secretary to be named," he says. "That new secretary will have his or her own priorities in terms of how to go about HIPAA enforcement. We don't know yet what HHS is going to look like under this administration."

Looking back at the past year does suggest that HHS has been much less active with HIPAA enforcement than in the prior year, and the continuation of aggressive enforcement in the first half of 2017 may have been only a continuation of Obama-era policies until the new administration had time to influence the department, Saunders says.

"It could be because everyone's attention was taken up with Obamacare reform, or it could be a purposeful new direction, but the objectively true fact is that they are concluding a lot fewer enforcement actions," he says. "They seem to be more reactionary to breaches than proactive, aggressively so, in the prior year."

> IT IS POSSIBLE THAT THIS IS ONLY A LULL UNTIL THE NEW ADMINISTRATION EXPRESSES A CLEAR INTENT TO CONTINUE ACTIVE ENFORCEMENT, PARTICULARLY SINCE THE AGENCY IS WAITING FOR A NEW DIRECTOR.

But Saunders cautions that this is not necessarily what the healthcare industry will see from OCR in the next three years. It is possible that this is only a lull until the new administration expresses a clear intent to continue aggressive enforcement, particularly since the agency is waiting for a new director. OCR leaders may be waiting to get the go ahead for continuing enforcement actions at the same level as 2016, he suggests, because the Trump administration has a pro-business stance and has criticized what it calls excessive regulations.

The amount of money at stake may be a factor in deciding to continue the previous level of enforcement, Saunders says.

"Until May of this year HIPAA had been an area of tremendous growth for enforcement actions, going from low-level, million-dollar fines to double-digit, million-dollar fines, and billions in the aggregate," he says. "They were doing it against not just ordinary run-of-the-mill hospitals, but they were also coming after business associates and not-for-profit hospitals. If you were violating HIPAA, you stood at some risk."

Those large settlements are major achievements and career boosts for OCR leaders, so it will be hard for them to stop pursuing such trophies, Saunders says. The enforcement strategy could change, but OCR is unlikely to become a pushover in the next three years.

OCR has begun Phase 2 of the HIPAA Audit Program, reviewing the policies and procedures of covered entities and their business associates, and that is likely to yield some significant violations, Saunders says.

The enforcement actions that come out of the Phase 2 audit could bring more clarity to how the Trump administration's OCR will pursue HIPAA compliance, he says.

Aggressive enforcement and huge settlements could mean a continuation of 2016's OCR strategy, or smaller settlements could signal a more relaxed approach.

At whatever level, OCR will continue to focus on business associate agreements, Saunders says. OCR has demonstrated that the agreements are a primary concern in audits and enforcement actions, with regulators wanting to see that covered entities have agreements with associates and also that they are monitoring the compliance of contractors and subcontractors.

"It's great to have the piece of paper, but if you're not doing anything to confirm that the subcontractor is complying, that exposes you to some risk. HHS has made it clear that you can't just point to a piece of paper and they'll assume everything is fine," Saunders says. "One organization got fined last year because they had the paperwork but weren't doing anything with it."

Saunders cautions that the current drop-off in HIPAA enforcement actions is no reason to let up on compliance. Even if OCR does pursue enforcement as much as it did in 2016, covered entities and business associates still have plenty of reasons to comply, he says.

"Don't be led astray because of the small sample size of what's going on late in 2017," he says. "This is still a significant risk factor for any company that handles protected health information. The risk of HIPAA enforcement action is great, and you don't want to be the next Equifax with not only the financial penalties and losses but also the damage to your reputation." ■

SOURCE

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HIPAA Hampering Patient Engagement, But Solutions Exist

Risk managers and compliance officers have heard the same complaint from so many clinicians: Complying with HIPAA gets in the way of interacting well with patients. And they're right.

There is evidence to back up their complaints, but it doesn't have to be that way, says **Ameet Sarpatwari**, JD, PhD, instructor in medicine at Harvard Medical School and assistant director of the Program on Regulation, Therapeutics, and Law in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital in Boston. Misinterpreting HIPAA as inflexible is a key problem, he says.

HIPAA often prevents providers from properly engaging patients, according to a recent report in *The New England Journal of Medicine* by Sarpatwari et al. (*An abstract of the study is available online at http://bit.ly/2m0ZF4B.*)

Covered entities and business associates are so afraid of HIPAA noncompliance penalties that they have "understandably interpreted HIPAA conservatively," the report says.

Conservative interpretations often mean saying no when someone requests information, which can stifle communication and hamper patient engagement, Sarpatwari says.

"It is easy to establish blanket policies from an administrative perspective because it requires fewer resources to comply and monitor compliance," Sarpatwari says. "But that fails to capitalize on approaches that could foster patient engagement but also be HIPAA-compliant."

The use of encryption, while highly touted for improved security, can be detrimental to patient engagement. When a patient receives an encrypted message on a patient portal, the content of the message may be mundane but may require more effort and time than the patient is willing to take, he says.

"It might just be a notification that a prescription is ready, or it could be something more significant, but the steps necessary to read that message are often a bit of a hassle," he explains. "That can discourage engagement in the health system, but that encryption is an addressable issue. There is discretion as to whether it is necessary, but there is a misnomer that HIPAA is inflexible. It's actually quite flexible."

Healthcare providers are not capitalizing on that flexibility, he says.

There are ways to improve patient engagement without violating HIPAA, he notes, including the more strategic use of patient portals, Bluetooth-enabled biometric devices, smartphone applications, and text messages, which all can help improve patient engagement.

In addition, clinicians should be given some leeway to use common sense with individual patients, Sarpatwari says. The clinician can ask the patient if anyone else has access to the email address on file, and if the answer is no, there may be no need for encryption, he says.

"You can craft a more tailored policy that is still HIPAA-compliant but encourages more patient engagement," he says. "The trouble comes when you try to impose one blanket policy that takes the most conservative approach so that you can be assured every single encounter is HIPAA-compliant even if it means you're inconveniencing people and discouraging the patient engagement that is so important to providing good care."

Another possible solution is for providers to let patients opt into a system that allows sharing of protected health information, Sarpatwari says. That could require amending current HIPAA laws, but would it improve patient engagement for many people, he asks.

"There can be a greater discussion in the industry about steps that could be taken to make sure patients are aware of the risks and can give informed consent to have their information shared without encryption and without some of the other impediments to patient engagement," he says. "Those are the areas where you can craft more tailored policies that don't come in a one-size-fits-all approach." ■

SOURCE

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HHS Clarifies HIPAA as It Applies to Opioid Crisis

The HHS Office for Civil Rights (OCR) has clarified how it expects healthcare providers to comply with HIPAA when they need to share patient information on opioid overdoses: Providers can share protected health information (PHI) in limited ways during overdoses.

There has been some confusion about how to comply with HIPAA during emergencies, such as drug overdoses and natural disasters, OCR notes. Healthcare providers have been confused about whether the law allows them to disclose necessary information to family members or caregivers when the patient is experiencing an opioid emergency.

OCR makes clear in recent guidance that providers can use common sense in these situations because HIPAA was never intended to interfere with proper medical care. In some situations PHI can be shared without the patient's permission if that is in the patient's best interest, the guidance explains. (*The OCR guidance is available online at http://bit.ly/2ieZopg.*)

OCR includes the caveat that the sharing must be limited to what is necessary related to the immediate emergency. It is not OK to open the door completely and share other PHI.

OCR cites two examples in which healthcare providers can share limited PHI without the patient's permission during a drug overdose.

PHI may be shared with family and close friends who are involved in care of the patient if the provider determines that doing so is in the best interests of an incapacitated or unconscious patient and the information shared is directly related to the family or friend's involvement in the patient's healthcare or payment of care. "For example, a provider may use professional judgment to talk to the parents of someone incapacitated by an opioid overdose about the overdose and related medical information, but generally could not share medical information unrelated to the overdose without permission."

The healthcare provider may inform persons in a position to prevent or lessen a serious and imminent threat to a patient's health or safety. "For example, a doctor whose patient has overdosed on opioids is presumed to have complied with HIPAA if the doctor informs family, friends, or caregivers of the opioid abuse after determining, based on the facts and circumstances, that the patient poses a serious and imminent threat to his or her health through continued opioid abuse upon discharge."

However, the OCR guidance notes that patients with decision-making capacity must be given the opportunity to agree or object to sharing health information with family, friends, and others involved in the individual's care or payment for care. The provider must respect a patient's decision not to share PHI unless there is a serious and imminent threat to safety.

OCR also points out that a patient's decision-making capacity may change during the course of treatment, and the provider must adjust accordingly. ■

Most Clinicians Admit to Sharing EMR Passwords

A majority of medical staff surveyed recently said they have accessed an electronic medical record (EMR) system using a password improperly supplied by a fellow medical staffer, and explained that strict confidentiality rules can make it difficult to get the data needed to do their jobs properly.

The survey results are part of the first study to examine EMR access among medical providers. In the study, researchers gathered survey responses from 299 medical professionals, including residents, medical students, interns, and nurses. The research team included researchers from Ben-Gurion University of the Negev, Harvard Medical School, Duke University, Hadassah-Hebrew University Medical Center, and the Interdisciplinary Center in Herzliya, Israel. (*The survey results are available online at http://bit.ly/2x2tdiw.*)

Nearly three-quarters (73%) of the 299 participants claimed to have used another medical staff member's password to access an EMR at work, and more than 57% of participants (171 out of 299) estimated they have used someone else's password an average of 4.75 times.

All medical residents said they had obtained another medical staff member's password with consent. Within the student and intern groups, 77% and 83%, respectively, used someone else's access credentials because they said they "were not given a user account."

In addition, 56% of students and almost 70% of interns cited that their user access had inadequate permissions "to fulfill my duties," forcing them to ask for someone else's access credentials. Only half of the nurses surveyed (57.5%) reported using someone else's password. The researchers offer these recommendations:

• Attaining access credentials needs to be less difficult and time-consuming.

• "Understaffed hospitals, especially during on-call hours, may need to delegate administrative tasks and extend EMR system access to paramedical, junior staff, interns, and students," they wrote. "Nurses, who generally carry out more precisely defined duties, are more likely to have the EMR privileges they need."

• "Healthcare organizations should add an option for each EMR role that grants maximum privileges for one-time use only. When this option is invoked, the senior physician and a protected health information security officer would be informed," the researchers wrote. "This would allow junior staff to make urgent, lifesaving decisions under formal retrospective supervision without having to sneak onto the EMR." ■

IT Workers Can Fall for Online Scams

Healthcare IT staff often assume they know what they're doing when it comes to data security, and all the other employees are likely to create a data breach by falling for an online phishing scam or other hacking attempt. But a recent report suggests IT staff can make big mistakes, too.

One-quarter of IT workers admitted to falling for a phishing scam, compared to 21% of office workers and 34% of business owners and high-execs, according to a recent survey by Intermedia, a company providing data protection. Intermedia surveyed more than 1,000 full-time workers and asked questions about data security and the behaviors that can lead to data breaches, malware, and ransomware attacks. (*The report is available online at http://bit.ly/2zlyGWS.*)

Another disconcerting finding was that 14% of office workers either lacked confidence in their ability to detect phishing attacks, or were not aware what phishing is.

Confidence in the ability to detect phishing scams generally was high among office workers, with 86% believing they could identify phishing emails, although knowledge of ransomware was found to be lacking, especially among female workers. Forty percent of female workers did not know what ransomware was, compared to 28% of male workers. Thirty-one percent of respondents said they did not know what ransomware was prior to taking part in staff training sessions. The report includes these other findings:

• Thirty percent of office workers said they did not receive regular training on how to deal with cyber threats. Only 70% of companies provide regular training and threat information to employees, and 11% of companies offered no security training whatsoever.

• Many employees are so embarrassed and concerned about installing ransomware that they pay the ransom demand out of their own pocket. Out of the office workers who had experienced a ransomware attack, 59% personally paid the ransom and the average ransom payment was $1,400. The ransom typically was paid quickly in the hope that data could be restored before anyone else found out about the attack. Only 37% said the ransom was paid by their employer.

• Even when the ransom is paid, businesses still experience considerable downtime. One in five ransom payments will not see viable decryption keys provided by the attackers. ■