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INSIDE

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Confirmation bias threatens patient safety, but can be overcome

Sometimes people see or hear what they expect, not real information

Is confirmation bias lurking in your hospital, waiting to cause havoc for even the most skilled, well-intentioned clinicians? This mental fault allows one to see or hear what is expected or desired, rather than what actually is. It has led to adverse events in many industries, and healthcare is exceptionally vulnerable.

Tufts Medical Center in Boston is dealing with the tragic results of confirmation bias, but the institution has implemented safeguards to keep the risk at bay, says **Lynn Worley**, RN, JD, CPHRM, senior risk manager and assistant general counsel at Tufts Medical Center. The family of a Tufts patient is suing the hospital after a surgeon injected the wrong dye into her spine, when the surgeon mistakenly assumed it was the correct dye he had asked for. The patient died the next day from the effects of the dye. The surgeon was baffled as to how he, the nurse who handed it to him, and others along the line failed to notice that the label clearly stated it was a different dye and included a warning not to use it in the spine. *(For more on the adverse event, see the article on p. 111.)*

The case is a good example of confirmation bias, says Tufts Chief Medical Officer **Saul Weingart**, MD, MPP, PhD. The surgeon and other clinicians "saw what they expected to see" even though the label clearly said otherwise, Weingart explains. Confirmation bias can take many forms,

Special Ebola coverage in December

Watch for the December issue of *Healthcare Risk Management,* with extensive coverage of the risk management concerns related to Ebola: patient safety, employee safety, liability, insurance, and staff training. Serious questions arose after the first infections hit hospital employees, and *HRM* will bring you answers. ■

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he says, from unconsciously giving more weight to data that support your political views to actually reading different numbers on a lab value or different words on a label. *(For more on confirmation bias, see the article on p. 112.)*

The dye error and an unrelated incident involving an embolism prompted Medicare to conduct a full-scale inquiry into Tuft's practices in February 2014. Medicare's findings and the Tufts' own investigation led to a series of hospital-wide improvements. As a result of the dye error and the subsequent root cause analysis, Tufts now require surgeons and operating room nurses to submit detailed written medication orders to pharmacists, in addition to other new checks in the system.

"All adverse events teach us something," Worley says. "We stopped and took a pretty hard look at all our systems. Among the things we looked at, one of the first was the process of orders from a physician to a circulating nurse to the pharmacy."

Written orders required

Worley investigated how other hospitals performed those tasks in the OR and found that some used "written verbal" orders — orders dictated to and written by a nurse when the doctor cannot write it, such as when a surgeon is scrubbed — and some just used verbal orders. Seeking the best practice to promote safety, Worley and her colleagues decided that a policy requiring written orders every time, for every step in the process, was the way to go. Tufts had always required written orders for all care outside the OR, but now surgery is included.

Written verbal is allowed as long as a specific process is followed.

"A nurse takes an order, writes the order down, and reads it back to the physician to make sure everyone is on the same page," Worley says. "We thought this was the right policy even for the OR, where things sometimes happen quickly and verbal orders are common. The fact that the OR is a highly critical situation and fast-moving made a compelling argument that the orders should be written."

The policy doesn't end there. For any medication, the written order must include the name of the drug, the route of administration, the patient's name, and any allergies.

"This was a team effort," Worley says. "Pharmacy staff were instructed that no written order means no medication, period. If a written order came without necessary information like allergies, the pharmacy refused to fill those. They understand that

EXECUTIVE SUMMARY

The phenomenon of confirmation bias can threaten patient safety if not addressed with policies and procedures. Cognitive bias was a central issue in a recent malpractice case.

- Confirmation bias leads people to see or hear what they expect to see or hear, regardless of the actual information.
- The problem can lead to misunderstood lab values, drug labels, and verbal reports.
- One hospital improved medication ordering procedures after a confirmation bias incident.

this is what we need to do to keep our patients safe, so if pharmacy staff do not receive a completely filled-out order, they simply do not give up the medication."

To keep the policy practical for the OR, Tufts worked with specialty leaders to develop order sets for each service to cover the most commonly used medications. Physicians can sign off on the order set or vary it as needed, before surgery begins.

Formulary changed

Prompted by the adverse event with the dye in a spinal procedure, Tufts assessed all use of contrast media in surgery. Worley found that the dyes are very infrequently used. The dye media are available in ionic and non-ionic types, and ionic contrasts in particular are used only for genito-urinary surgery at Tufts.

With that limited use in mind, Tufts went to the pharmacy leaders and had the ionic contrast medium removed from the formulary so that it cannot be ordered, intentionally or accidentally, unless it is for genito-urinary surgery. The order must be accompanied by an attestation that it is to be used for that particular type of surgery.

Working with the radiology department, Worley and her colleagues also revised the formulary so that there is only one type of non-ionic contrast available, in three strengths. Those three options for non-ionic contrast medium satisfy the needs of all other types of surgery, Worley explains. Interventional radiology also specified the acceptable use of the three strengths of non-ionic contrast for specific procedures.

"The nurses are on high alert for these medication orders, particularly with contrast media," Worley says. "All orders for contrast go through the pharmacy, and the pharmacy knows the route before it is ever dispensed."

The improved medication ordering system is intended, in part, to reduce the chance of confirmation bias letting the wrong drug make its way to the bedside or the OR, Worley says. Confirmation bias can happen at many stages in the ordering system, so the written orders and specific requirements help minimize that risk. If those checks work properly, there is little likelihood that the surgeon will be susceptible to confirmation bias at the last step in the process.

Education strategies

Tufts used multiple modalities to first alert the staff and physicians about the risk of confusing contrast media and then to educate them about the new policies and procedures, Weingart says.

All clinical staff received an email immediately after the adverse event alerting them to the possible confusion, and then they attended multiple staff meetings to learn the new procedures. Nurses were required to complete learning modules by computer, and education also was required for surgeons and anesthesiologists. A weekly memo from Tufts leadership also reiterated the new policies and procedures, as did Tufts newsletters and other publications.

"Real time education also occurred when a person would have a medication order that did not meet the requirements," Weingart says. "The receiving person would explain the new process and require a proper order before providing medication."

Pharmacy also conducted its own education program to clarify what pharmacy staff members should require before fulfilling an order. Tufts also audits the medication ordering system periodically, and the most recent check found 100% compliance.

Worley says that after learning from their adverse event, she recommends highly that all ORs require written verbal orders. "It's a hard lesson to learn," she says. "If you've never had a problem before, don't wait for it. Get a handle on this before it becomes a problem." ■

Surgeon looks at dye label, 'sees' what he expects

Caroline Carcerano underwent spinal surgery at Tufts Medical Center in Boston in hopes that the procedure would resolve pain from a back injury. During the procedure, her neurosurgeon requested a special dye to test the location of tubing threaded into her spine.

The pharmacy did not have the dye requested by the neurosurgeon, so it sent a different one, hospital leaders confirmed in statements released since the incident in November 2013. When an operating room nurse handed him the dye, the neurosurgeon checked the label but did not see that the label was for a different dye and that the label specifically said "not for intrathecal use," warning against using it in the spine, according to Medicare investigators.

That warning was unheeded because the surgeon "saw" what he anticipated the label would say: the name of the correct dye, says Tufts Chief Medical Officer **Saul Weingart**, MD, MPP, PhD. The OR scene was dynamic, and all team members were busy because the procedure was

technically challenging, he says. "He asked for the contrast, looked at it, and he doesn't exactly recall what he saw, but it seemed to be what he thought it was. And off he went," Weingart says.

The patient died the next day from the effects of the spinal injection. Carcerano's sons filed a malpractice lawsuit against in June 2014 against Tufts and 12 pharmacists, nurses, and surgeons. ■

Confirmation bias is pitfall for all clinicians

Confirmation bias has been known in healthcare for years, but clinicians still are learning how to avoid this pitfall. Emergency physicians are particularly susceptible, according to the study that most often is cited in explaining the problem.

The severity and volume of emergency care means many emergency physicians often must rely on heuristics, such as rule-out protocols, as a guide to diagnosing and treating patients, the author notes. The use of heuristics or protocols can be potentially misleading if the initial diagnostic impression is incorrect, notes author **Jesse M. Pines**, MD, MBA, an emergency physician at the Department of Emergency Medicine (ED) at the University of Pennsylvania in Philadelphia.[1]

"Confirmation bias occurs when people selectively focus upon evidence that supports their beliefs or what they want to believe to be true, while ignoring evidence that serves to disconfirm these ideas," Pines explains.

The author notes that ED physicians are particularly susceptible to cognitive errors of all kinds because they are required to integrate their knowledge base with new situations to create a diagnostic and management plan. Combining that situation with the fact that diagnosis errors are the foremost cause of malpractice claims makes the effects of confirmation bias even worse.

"Because of the rapidity with which EPs [emergency physicians] must work and the importance of an accurate diagnosis, it is important that EPs be cognizant of the possibility that diagnoses may be compromised by confirmation bias," Pines writes. "Put simply, this means that one may have an initial or a preconceived idea about something and interpret subsequent information or data so as to confirm that idea," which can mean incorrectly confirming a diagnosis.

Confirmation bias is closely related to "anchoring bias," in which an incorrect initial impression or diagnosis determines the course of action even contradictory information presents. Pines cites an example in which a patient who has been treated frequently for headaches actually has a subarachnoid hemorrhage on the next ED visit but the headache diagnosis prevails.

Noting that is no single solution to avoiding confirmation bias, Pines suggests that healthcare institutions should teach clinicians about the phenomenon and to be aware of its insidious nature.

"When the initial clinical impression is not corroborated by objective data, EPs must be open to revisiting the possibility of an inaccurate diagnosis and may have to start again at diagnostic time zero or, alternatively, defer to an appropriate inpatient or outpatient workup," the author concludes.

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Better handoffs improve safety at children's hospitals

Eliminating distractions and standardizing the process for patient handoffs has helped a group of children's hospitals reduce handoff errors by 69%.

Patient handoffs are increasingly recognized as potential threats to patient safety, and critically ill children might be even more at risk than other patients, says pediatric critical care doctor **Michael Bigham**, MD, at Akron (OH) Children's Hospital. Responsibility for critically ill children is frequently transferred from one clinician or unit to another, he notes. Because of their ages, pediatric patients might be affected more by errors that occur with the handoff.

Bigham has studied how to improve patient handoffs for six years. He led the team that recently published a yearlong study, "Decreasing handoff-related care failures in children's hospitals," which involved 23 children's hospitals across the country. The researchers examined 7,864 patient handoffs and the effect of implementing standardized procedures to reduce

miscommunication and care failures during the handoff process. The study did not directly measure patient harm, but rather a predicate marker of harm. *(See the story on p. 114 for more on the study.)*

A major safety concern

Patient handoffs have been identified as a major patient safety concern by major healthcare organizations, including The Joint Commission (TJC), the World Health Organization (WHO), and the Institute of Medicine (IOM). In 2006, The Joint Commission required accredited hospitals to implement a standardized handoff process, and in 2007, the WHO highlighted the role standardized processes had in reducing handoff-related errors. In 2008, the IOM recommended focusing on handoff processes to improve patient safety.

"The Joint Commission has looked at a decades' worth of sentinel events between 1995 and 2005, and breakdown in communication was the leading root cause of sentinel events in that period of time," Bigham says. "The IOM also has stated that inadequate handoffs are where the safety process fails first. Handoff failures are a huge risk to patient safety."

With years of emphasis on improving patient handoffs, Bigham and his colleagues realized that among children's hospitals, handoffs were the poorest performing safety domain. Early in the study research, Bigham and others investigated the baseline rate of handoff failure at the hospitals. Selecting patient handoffs at random, they interviewed the receiving patient care team about whether they had encountered any care failures as a result of inaccurate or missing information at the handoff.

Patient safety leaders from the hospitals studied their data on patient handoffs and also developed a "change package" that explains the components necessary to improve the process. The researchers developed these four key steps:

- Define the handoff intent.
- Define the handoff content.
- Define the handoff process.
- Combine all of those in a way that maximizes teamwork.

"THE IOM ALSO HAS STATED THAT INADEQUATE HANDOFFS ARE WHERE THE SAFETY PROCESS FAILS FIRST."

The hospital leaders recognized early on that there would be no single way to roadmap the handoff procedure that would work for every hospital. Instead, each hospital identified the pertinent handoff scenarios in their facilities, applied those steps to their own facilities, and developed their own improvements. As a result of process improvements flowing from the research, the participating hospitals decreased handoff-related failures by 69% during the study.

"The solutions developed at the different hospitals were shared with the other participants, so people could pick and choose the parts they liked and apply them to their own settings," Bigham says. "At the end of a one-year cycle, all 23 hospitals had either moderate-scale or large-scale implementation of improvements involving one or more different types of handoffs."

When the research team compared the handoff failure rates at the end of the study, they found that the hospitals had reduced the rate of failures by 69%.

"We were confident that by the end of this process, our patients were safer and subject to far fewer patient care problems from miscommunication at handoffs," Bigham says.

Though the improvement plans were specific to each hospital, all of them followed the four key steps.

Reducing distractions

Akron Children's examined three types of handoffs and saw a 36% reduction in handoff-related failures. The handoff scenarios included:

- The transition of patient care responsibility during shift change for nurses, such as night shift to day shift and vice versa.
- The patient's transition from the emergency department to inpatient.

EXECUTIVE SUMMARY

Improving the process for patient handoffs has helped a group of children's hospitals reduce handoff errors by 69%. Handoffs improved throughout the hospitals.

- The new process standardizes handoff procedures.
- Clear communication is important.
- Distractions were a common hazard during handoffs.

• The temporary transition of an inpatient to and from radiology.

Akron Children's implemented a standard procedure for handoffs designed to eliminate distractions during the handoff process and result in a clear transition of responsibility from caregiver to caregiver, explains Quality Director **Cathy Gustaevel**, who also is responsible for patient safety. Many of the changes encourage face-to-face interactions, rather than leaving notes for other caregivers, Gustaevel explains. *(See the story below for more details on the changes.)*

"I think the impact is going to be huge. The improved process is going to give us some consistency and reliability that what happens in the emergency room as far as handoffs is the same as what happens in critical care," Gustaevel says. "This will increase the safety of the kids because standardization often reduces or eliminates errors. Everyone here knows that the person on the other side of the handoff will do it the same way you've been trained, and they will do it that way every single time."

Some clinicians resisted the handoff improvements at first but warmed to the idea as they saw how the standardized procedure reduced errors, Gustaevel says. Children's Hospital also involves parents in the handoff procedure, with the theory being that they know everything about their child far better than anyone else. The parents listen in and are encouraged to add their own comments or to question the handoff information.

But are the practices developed in the course of the children's hospital study any different from what hospitals already have been trying?

"I'm not sure hospitals have really been trying to improve handoffs. Either hospitals have not improved their processes or what they tried is not working," Bigham says. "This concept of patient handoffs cannot be ignored any longer. Patient handoffs should be just as important to patient safety as the surgical procedure itself and the right settings on the ventilator." ■

Personal communication improves handoffs

These are some of the primary changes made to improve the safety of patient handoffs at Akron (OH) Children's Hospital:

• Whenever possible, unit nurses speak directly to the oncoming shift nurses rather than leaving voicemail messages or written notes. The personal communication improves safety by allowing the oncoming nurses to ask questions or pick up on nonverbal cues, says pediatric critical care doctor **Michael Bigham**, MD. The discussion takes place in the patient's room to reduce distractions and improve focus on that particular patient.

• The hospital developed a "ticket to ride," a standardized form for staff to use when handing off patients to radiology or other departments for testing or diagnostic procedures. The form provides basic information about the patient and his or her condition, along with contact information for the unit where the patient is admitted. The "ticket to ride" helps diagnostic staff know what to do if something goes wrong during the tests and how to manage problems.

• Emergency department staff members now accompany patients up to the intensive care unit when they are transferred and perform the handoffs face to face with staff members there. Previously many of those handoffs were made over the phone. ■

1 in 4 handoffs threaten patient safety

The researchers who studied patient handoffs at 23 children's hospitals found an alarmingly high baseline rate of handoff failure: 25.8% of the handoffs were insufficient or inaccurate.

Twenty-three children's hospitals evaluated 7,864 handoffs over the study period, which was 12 months. *(For more information and access to the full study, see http://tinyurl.com/m56avmq.)*

In the final intervention period, handoff-related care failures decreased from the baseline 25.8% to 7.9%. Significant improvement was observed in every handoff type that was studied. The changes raised the common understanding about the patient from 86% to 96%, having a clear transition of responsibility rose from 92% to 96%, and minimizing interruptions and distractions increased from 84% to 90%.

Overall satisfaction with the handoff went from 55% to 70%. The study's authors made the conclusion that the implementation of a standardized evidence-based handoff process can result in a significant decrease in handoff-related care failures, observed across all types of handoffs. ■

Tailor HIPAA training of your staff to your needs, and avoid generics

There was a time when risk managers and regulators were just happy to see that hospital staff had been trained in Health Insurance Portability and Accountability Act (HIPAA) compliance, and they assumed that what worked for one facility would be fine for the next. That's not the case anymore.

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) has indicated that it now expects healthcare providers to use HIPAA training that is tailored to the specific needs of the employer rather than an off-the-shelf program, says **Edward Buthusiem**, JD, director of the Berkeley Research Group in Philadelphia. He advises clients on a variety of business, regulatory, operational, intellectual property, litigation, transactional, and compliance matters.

"The typical training that people receive from a canned program you bought somewhere is not adequate, and OCR is not going to accept it as sufficient," Buthusiem says. "The main reason for that is those programs do not identify your specific role in the privacy transaction and then train you accordingly."

HIPAA compliance requirements differ according to your role in the transaction, he explains. A generic training program must address all of those players, meaning the hospital staff members must sit through material that does not apply to them, and the material that they most need to hear might not be included at all. That material would drill deeper into the specifics of their own responsibility in the privacy transaction, Buthusiem explains. *(See the story on p. 116 for more on how to customize your HIPAA compliance program.)* "If you're collecting data and aggregating it for treatment purposes, that is different from aggregating that data for research, and if you're collecting it with the intent of selling that information in some form, that's different altogether," he says. "Depending on which one you're doing, different rules will apply."

The amount of time, effort, and money required to customize your HIPAA program properly will depend on the size of your organization, whether it is mostly one central operation or many facilities in a large region, and how much your training needs to be changed from its current state, Buthusiem says. Health systems that have expanded in recent years might be most in need of a thorough analysis and customization program, he says.

"Hospitals grow through acquisition, and every time you take on a new facility, you are taking on that hospital's HIPAA training program," Buthusiem explains. "It's going to be a good process or a bad process — nothing in between. And it is going to be a different process, better or worse than yours."

Tailoring HIPAA education to your needs does not necessarily mean you cannot use an off-the-shelf product, notes, **Jeanne Oronzio Wermuth**, assistant vice president with The Graham Co., insurance brokers and consultants in Philadelphia. If you go that route, however, make sure it covers your specific needs or can be modified to do so, she says. Also check that it addresses technological advances such as the use of mobile devices and social media.

"With those potentially problematic platforms, any education program needs to ensure that employees are aware of the risks and how to avoid them," Wermuth says. "That is different from employees just being aware that the hospital has a policy because you required them to read it. The training should be specific in how those policies apply in your facility and how situations might appear that require them knowing how to respond."

One common problem with off-the-shelf programs is that they lack documentation that individuals were trained, notes **George W. Bodenger**, JD, partner with the law firm of Saul Ewing in Philadelphia. Bodenger often represents hospitals and other

EXECUTIVE SUMMARY

Training in Health Insurance Portability and Accountability Act (HIPAA) compliance should be specific to your organization. Off-the-shelf modules might no longer satisfy the training requirements.

- The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) has indicated that it will expect more organization-specific training in HIPAA compliance.
- Organizations might be able to tailor a generic training module to their needs.
- Emphasize practical matters such as the use of social media.

organizations in cases regarding HIPAA compliance. HIPAA training must be documented with the date and time, and employees should be required to sign in and out.

"OCR takes that very seriously, because otherwise there is no way to prove that someone has been trained," Bodenger says. "The training also needs to be geared to the type of personnel. There will be very different training for nurses and for housekeepers, and if you're providing the same stock training to both groups, you're not serving either one well."

Meeting the bare minimum for HIPAA training never was OCR's intent, Buthusiem says, and it certainly won't pass muster today.

"They don't want to see something off the shelf that you are waiting to hand to them when they come to your institution," Bodenger says. "In order to get credit for having a program, you're going to have to have something far more specific, something that shows you are taking HIPAA seriously."

SOURCES

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How to customize HIPAA training

Whether you use an outside consultant or do it yourself, training staff in Health Insurance Portability and Accountability Act (HIPAA) compliance should be customized to your own needs and situation. Consider this advice on how to provide the training that is right for your organization.

• Understand how your hospital uses protected health information (PHI). The answer might seem obvious and the same as every other hospital, but look deeper than that, advises **Edward Buthusiem**, JD, director of the Berkeley Research Group in Philadelphia. Aside from using PHI in direct patient care, consider where that data goes, in what form, and for what purpose. Relationships with vendors that need feedback on their products might involve some transmission of PHI, for example, or physicians might share data with researchers at other institutions. At other hospitals, those situations might not be applicable.

• Determine your gaps and weaknesses. Assess how well your current compliance efforts address HIPAA as it applies to your particular institution. A gap analysis will show where you need to emphasize training more or need to provide a specific type of HIPAA compliance education that might not be included in a generic program.

• Find a HIPAA expert to customize your education. The specific training for your staff can be conducted by someone in-house if that person is extremely proficient with HIPAA interpretation, Buthusiem says. A high level of expertise is necessary because a person generally competent in HIPAA might not be able to accurately assess the more detailed, situation-specific parts of the law. Don't forget to look for experts throughout your parent health system, and if you hire a consultant for the job, make sure that person has more than a general familiarity with compliance details. ■

Corporate negligence can complicate med mal

Claims of corporate negligence can increase the stakes in a malpractice case, as plaintiffs seek the deeper pockets of the employer who hired and allowed a supposedly deficient healthcare provider to injure a patient.

Corporate negligence claims demonstrate the power of a plaintiff to widen the scope of a malpractice case beyond the physician and the physician's insurer, says **Matthew L. Kinley**, JD, a partner at the law firm of Tredway Lumsdaine & Doyle in Los Angeles. The usual claim is that the hospital or health system should have known the physician

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was unqualified in some way and should pay for allowing him or her to practice.

A current example is the case of Christian Schlicht, MD, a physician hired by the now-bankrupt Gerald Champion Regional Medical Center in Alamagordo, NM. Trial proceedings recently began for 71 plaintiffs suing Quorum Health Resources, a hospital administration company based in Brentwood, TN, that provided top executives and physicians for the hospital. At issue is whether the hospital and Quorum were negligent in hiring Schlicht and allowing him to continue operating even after they were alerted that he was performing experimental back surgery with devastating results.

Attorneys for the plaintiffs are alleging corporate negligence and claiming the employer and Quorum knew the doctor was performing a spinal procedure, not approved by the Food and Drug Administration, that involved bone cement. In opening arguments, one plaintiff's attorney noted that the procedure was not allowed anywhere in the world and amounted to "absolute human experimentation." Schlicht was performing that procedure and others considered just as risky and unsuccessful up to a week before he quit his $450,000 job at the hospital.

Quorum contends that the hospital's board of directors was liable for the damage Schlicht caused and that medical staff were responsible for supervising surgeons. The plaintiffs counter that the company should never have hired the surgeon and knew about his repeated failures with experimental surgery. "These cases can get quite complicated because you get into asking, what is the role of the trustees, the board of directors, and the medical staff?" Kinley says. "Corporate negligence also can involve situations like a piece of equipment failing at a critical time. The question then is whether the hospital had policies and procedures in place to respond to that failure in the appropriate way."

In years past, corporate negligence was more difficult to prove in a straight medical malpractice case because the physician generally was considered to be the "captain of the ship" in every way, with ultimate liability falling there, Kinley says. That theory has shifted now so that hospitals and health systems have much responsibility to credential and monitor physicians and more liability if they fail to do so.

That responsibility is partly because healthcare employers have so many more resources now for investigating the background and training of physicians, Kinley notes. Failure to check the National Practitioner Data Bank, for example, would be seen as a major oversight by the employer, he says.

In addition, courts and juries now expect employers to monitor the performance of physicians by randomly auditing patient records and reassessing performance at regular intervals, Kinley explains. Not committing fully to that oversight can lead to large jury awards.

"The courts have ruled that juries get to look at different things in determining the standard of care. So if you have a risk management policy about how and when you are supposed to review physicians, and you didn't, that is almost negligence per se," he says. "Be aware that a jury is going to be looking at your rules and regulations to determine if you met your own standards of care." ■

EXECUTIVE SUMMARY

Corporate negligence is a common claim used by plaintiffs in medical malpractice cases. Successful use of this strategy will make the hospital or health system liable for what otherwise could have been attributed to an individual.

- A current case involves claims of corporate negligence for allowing a surgeon to perform allegedly experimental spine procedures.
- Equipment failures also could lead to corporate negligence claims.
- The surgeon is no longer the "captain of the ship."

Free vaccine app speeds process, documentation

A free app offered by Underwriters Laboratory, based in Franklin, TN, can help risk managers improve their employee vaccination programs. The app can improve compliance rates and documentation, says **Kathleen O'Neill**, RN, BSN, CCM, CPDM, director of employee health and wellness at the University of Texas Medical Branch (UTMB) in Galveston.

The app is available on iTunes at http://tinyurl.com/moyvy92.

As at most hospitals, UTMB is always striving to improve vaccination compliance, for employee health, infection control, and risk management reasons. O'Neill decided

to try the app to streamline the flu vaccination program at her facility and also to create a "technology buzz" around the app that would drive people to be vaccinated. After using the app for five weeks, O'Neill says those benefits have been realized.

"We're conducting flu vaccinations now for our large clinics and our academic medical center on Mondays, Wednesdays, and Fridays," she says. "We have six stations that we run with the IPad. We have utilized the app on an IPad, so it keeps us very mobile. It's easy to set up in the lobby of the hospital."

As O'Neill hoped, the app and IPads have drawn more people to the vaccination offer. "They hear it's all done on the IPad, and I guess they just think that sounds interesting, so they go down to take a look," she says. "If that helps more people get vaccinated, I'm all for it."

In addition, the app frees up staff who otherwise would be needed to key in data on each vaccination from paper forms. Using the app also is much faster than filling out paperwork, so more of the hospital's busiest people – physicians and executives, in particular – are willing to obtain a flu vaccination. The new method means there usually is no line at all, which O'Neill says is important because many employees might see a line and decide they don't want to wait.

"It only takes a couple of minutes for this process, so we're seeing more faculty and people who otherwise would say it takes too long," O'Neill says. "We've compared our early season vaccination rates against the previous three years, and there's a significant improvement."

Flu vaccinations still are available in employee health at any time. The hospital purchased six IPads for the vaccination program, but O'Neill says they will be used for other activities other than vaccinations. UTMB also uses a peer vaccination system, in which employees working overnight or weekends can get a vaccination from someone in their department.

In some cases, departments have chosen to buy their own IPads so they can use the Underwriters Laboratory app."It would be very hard to go back to the paper system," she says. ■

ONC: Electronic health records improve patient safety

Electronic health records (EHRs) can improve patient safety, raise care quality, and reduce potentially serious medical errors, according to a statement from the Office of the National Coordinator (ONC) for healthcare technology.

Healthcare providers that adopt the principles of meaningful use, including computerized provider order entry (CPOE) and electronic documentation, see significantly fewer patient safety events and a 52% reduction in the number

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of adverse drug events, the ONC reports.

The federal office conducted a physician workflow survey found that three times as many physicians reported that their EHRs prevented a medication error than caused one, with nearly 70% saying that lab alerts or medication reminders were helpful in avoiding potential patient harm. Forty-five percent said an EHR feature had alerted them to a potential medication error, while twice as many physicians said EHRs helped them pick the right lab test rather than pick the wrong one.

Fifty-one percent of physicians expressed a positive opinion on EHR alerts, with just 14% saying that they missed something important due to the overwhelming number or distraction of alarms and reminders. Forty-seven percent improved the amount of preventative care they provided due to EHR features, while 39% were more likely to meet clinical guidelines for chronic disease care when prompted by their computers.

EHRs also were associated with improved clinical communication, including easing the ordering of referrals and exchanging data with other providers. ■

Move to ICD-10 could compromise safety data

Transitioning to ICD-10 coding could negatively affect patient safety reporting and perceptions of hospital quality because of inaccurate comparisons between the new codes and those used under the ICD-9 system, according to a study published in the *Journal of the American Medical Informatics Association.*

Physician practices and hospitals are transitioning to ICD-10 code sets to accommodate codes for new diseases and procedures, and they are swapping 14,000 codes for about 69,000 codes. Implementation has been set for Oct. 1, 2015.

Researchers from the University of Illinois at Chicago examined 23 types of patient safety indicators (PSIs) and determined the accuracy of PSIs when comparing those used in ICD-9 and ICD-10 codes. The study found that of the 23 PSIs examined, three PSIs under ICD-9 had straightforward equivalents in ICD-10; 15 PSIs under ICD-9 resulted in convoluted mapping to ICD-10; and five PSIs under ICD-9 had no equivalents in ICD-10.

According to the study, the transition between the systems might inadvertently increase the number of PSIs and make it impossible to compare the two as ICD-10 is implemented. The researchers wrote that such an issue could increase the risks of under-reported safety incidents, unwarranted inflation of PSIs because of ICD-10's more specific codes, and increased variability of calculations.

Access to the study is available at http://tinyurl.com/oh7b7vp. ■

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HEALTHCARE RISK MANAGEMENT™

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CNE QUESTIONS

1. In the case involving a surgeon who used the wrong contrast dye during surgery, what do hospital officials say was the likely cause?

A. The surgeon asked for the wrong contrast medium.
B. The surgeon asked for the correct medium but did not notice that another was delivered.

2. How did Tufts change its policies on medication orders after the incident with the wrong dye?

A. The hospital required written orders for medications, but only in the OR.
B. The hospital required written orders for medications, but excluded the OR because written orders would not be practical.
C. The hospital required the OR to use written orders for medications, a policy that previously applied to other departments but not the OR.

3. In the patient handoff study involving Akron Children's Hospital, what improvements helped achieve a 36% reduction in handoff failures?

A. Involving the unit manager in each handoff.
B. Reducing distractions during the handoff process.

4. How much did Akron Children's Hospital reduce patient handoff errors by implementing new policies and procedures?

A. 36%
B. 17%

CNE OBJECTIVES

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

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

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

Obstetricians' negligence leads to cerebral palsy, $9.6 million verdict for mother and child

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News: The patient, an adult woman, was admitted to a medical center while 39 weeks pregnant in March 2002. On the day of delivery, the patient complained of a lack of fetal movement, and her primary obstetrician referred the patient for a fetal nonstress test (NST) to measure movement, heart rate, and reactivity of the baby. A second obstetrician, who was a member of the hospital staff, administered the NST. The results of the test were indicative of fetal distress; however, the second obstetrician did not personally notify the first obstetrician of the dangerous results and waited 90 minutes until the first obstetrician came to perform a caesarean section. After the child was born, he was treated for cerebral palsy and meconium aspiration syndrome. The patient, individually and on behalf of her son, brought suit against both obstetricians and the medical center, and she alleged that all three parties were negligent with respect to her treatment. The defendants denied that any malpractice had occurred. The jury found both obstetricians and the medical center negligent, and it awarded the patient and her son $9.6 million in damages. Damages were split 65% against the primary obstetrician and the remaining 35% jointly and severally against the second obstetrician and the hospital.

> ...THE SECOND OBSTETRICIAN DID NOT PERSONALLY NOTIFY THE FIRST OBSTETRICIAN OF THE DANGEROUS [TEST] RESULTS....

Background: The patient was a healthy adult woman who was 39 weeks pregnant and sought admission to a medical center in March 2002. On the day of delivery, the patient complained to her primary obstetrician of a lack of fetal movement, and the obstetrician referred the patient for a fetal nonstress test (NST). The test is noninvasive, and it is designed to measure the heart rate of the fetus in response to its own movements. Healthy babies respond with an increased heart rate during times of movement and decreased heart rate during rest. The test was administered by a different obstetrician, a member of the hospital staff. Upon completion of the test, the results were indicative of fetal distress. The second obstetrician sent a nurse to notify the first obstetrician of the NST results and waited 90 minutes until the first obstetrician arrived to perform a caesarean section on the patient. The child was born without further complication, but the damage already had been done. He was treated for cerebral palsy and meconium aspiration syndrome. The syndrome is a leading cause of severe illness in newborns, and it occurs when the baby breathes in a mixture of meconium and amniotic fluid.

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These conditions resulted in spastic quadriplegia, cortical blindness, and an inability to speak. At trial, experts debated the child's life expectancy, with the plaintiffs' experts setting the life expectancy at 50 years or more from the time of trial and the defense's experts setting it at no more than 20 years.

The patient, individually and on behalf of her infant son, brought suit against both of the obstetricians and the medical center. She claimed that all three parties were negligent, in different ways, during the course of her treatment. Against the primary obstetrician, the main claim was that he had failed to properly monitor fetal growth and failed to respond appropriately to symptoms such as high blood pressure and high levels of protein in the patient's urine. The plaintiffs' experts testified that the primary obstetrician should have been able to diagnose a placental problem based on these symptoms. The primary obstetrician, and his medical experts, defended on the basis that there was no reason to diagnose a placental problem prior to the NST. Against the second obstetrician, the main claim was that he should have personally notified the primary obstetrician of the NST results and immediately ordered a caesarian section, so the 90-minute delay caused the child additional harm. The second obstetrician, and his medical experts, testified that the child already had sustained his injuries by this point in time, thus the delay was not the direct cause of any harm. An additional claim against both obstetricians was based on their failure to diagnose placental insufficiency and hypoxia in the time period leading up to the child's birth. After a six-week long trial, the jury deliberated for seven hours and found both the obstetricians and the medical center were negligent. The jury awarded a total of $9.1 million for the child and $500,000 for the mother.

What this means to you: In this case, each physician faced liability from different underlying causes, and these reveal lessons which all physicians can learn from. A major issue for the primary obstetrician related to a failure to properly monitor fetal growth and respond to alarming symptoms. Medical professionals must follow strict protocols in monitoring a child's vital signs, and they must take all necessary precautions to help prevent injuries during birth.

The American Congress of Obstetricians and Gynecologists (ACOG) has established guidelines for physicians to follow, including specific guidelines for fetal heart rate (FHR) monitoring. FHR interpretation is the gold standard for diagnosis of fetal distress. The guidelines include a three-tier classification system for FHR tracings: normal, indeterminate, and abnormal.

NST uses fetal heart rate tracings to determine the adequacy of oxygenation from the placenta to the fetus. Immediate action must be taken once determined that the NST is non-reactive and the fetus is not "asleep." Community standard is 30 minutes from decision (the non-reactive NST) to incision (caesarian section), not 90 minutes, and required an urgent call from the second obstetrician to the primary obstetrician.

One difficulty with monitoring fetal growth is the variability in interpreting tracings, which is an issue with certain tests throughout the medical field. If two physicians can look at the same printed results and come to different conclusions, this situation necessarily creates problems with administering treatment. If the case progresses to trial, this situation creates problems with defending against negligence. Objective guides, such as the guidelines established by The American Congress of Obstetricians and Gynecologists (ACOG), can help physicians and hospitals to defend themselves. Proof that the physician followed the appropriate guidelines can be a strong tool in court to prove that the physician acted within the standard of care, because this action is how other reasonable physicians would act in the same or similar situation (assuming that the guidelines are widely accepted in the field). Many hospital obstetrics departments offer FHR tracing classes in an effort to standardize nurse and physician interpretation of fetal monitoring strips, and this education can be very helpful in proving that a hospital adequately taught its employees regarding proper reading procedures.

If a diagnostic test reveals critical information, or relates to an emergent condition, physicians and hospital staff members must act quickly on this information. After performing the NST, the second obstetrician had a duty to the patient to exercise the proper standard of care. The plaintiffs alleged that the physician's delegation of a nurse to inform the primary obstetrician and subsequent 90-minute delay before performing the caesarian section constituted medical malpractice. Unnecessary delays can cause patients serious harm, so in situations in which time is of the essence, physicians must be cautious and prioritize cases to the best of their abilities. If the primary physician had a legitimate reason for his delay, such as a preoccupation with a similarly emergent patient,

then these circumstances could be a defense. However, the second obstetrician here did not have a valid reason for delaying the caesarian section.

Physicians and hospitals must be cognizant of time-sensitive activities, which can occur with great frequency. They must be prepared to act on critical information, rather than unnecessarily delay, as this delay might lead to serious harm to patients.

REFERENCE

Superior Court of Middlesex County, NJ. Case No. MID-L-1853-07. Oct. 11, 2013. ■

State supreme court affirms $4.4 million verdict based on lack of informed consent

News: The male patient fell from a ladder and suffered multiple non-displaced rib fractures, among other injuries. He was admitted to a hospital. While there, he experienced severe chest pain, despite receiving oral pain medication. The physicians requested a consult from a thoracic surgeon who performs a procedure known as the "On-Q procedure." That procedure involves insertion of a catheter to provide continuous analgesic to surrounding tissue and nerves, thus relieving pain associated with the rib fracture. The surgeon discussed the procedure with the patient. However, the surgeon failed to advise the patient that the surgeon had a financial interest in the procedure based on a contract with the On-Q's manufacturer, and the surgeon never gave the patient the option to receive an epidural rather than undergo the On-Q procedure. The patient underwent the procedure, but he suffered from complications that required significant additional time in the hospital and several more surgeries. The patient brought suit against the surgeon and hospital, and he claimed that both parties were negligent. The defendants denied any wrongdoing. The jury found both liable and awarded $4.4 million in damages.

Background: The patient was an otherwise healthy adult who fell from a ladder in December 2009. He suffered multiple non-displaced rib fractures as well as other injuries, and he sought treatment at a nearby hospital. The patient suffered from severe chest pain despite having received an oral pain medication. The physicians requested a consult from a thoracic surgeon associated with the hospital who performs a special pain-relief procedure known as the "On-Q procedure." This procedure involves the insertion of a 5 inch long catheter, which contains several holes, under the patient's skin and over the ribs using a metal tunneling device. After the catheter is in place, a liquid analgesic runs through it and soaks the surrounding tissue and nerves. This process allows for continuous distribution of the analgesic and allows relief from pain associated with the rib fracture. The On-Q procedure has not been approved by the Food and Drug Administration (FDA) and is thus an "off-label" use on the On-Q catheter.

During the consult, the surgeon discussed the procedure with the patient, including the aim of pain relief and risks of bleeding, infection, and injury to adjacent organs or tissues. The surgeon also discussed alternatives. During trial, he testified that he normally informed patients that epidural anesthesia was a very effective alternative, but it was not an option because it has risks and limitations. The patient was not given the choice of having epidural anesthesia. Furthermore, the surgeon failed to disclose his own personal financial interest in the On-Q procedure. Two years prior, the surgeon entered into a contract with the On-Q's manufacturer to give presentations and promote the procedure. The surgeon performance of the procedure increased significantly, and he received approval from the hospital to study the procedure. The patient agreed to and underwent the procedure, but difficulties quickly followed. The day after insertion, the patient inadvertently removed the catheters, which necessitated the insertion of two new catheters. One of these subsequent catheters became displaced and perforated the patient's internal organs, and the patient underwent several surgeries to remove the catheter and repair the organ damage.

The patient brought suit against the surgeon and hospital. He alleged multiple bases for negligence. One was that he claimed the surgeon failed to obtain informed consent and negligently performed the procedure. He claimed that the hospital was liable because the surgeon was its agent, along with the hospital's negligent management of the surgeon's On-Q study and negligent "expedited review" of the surgeon's

application to conduct the study. Following an eight-day trial, the jury returned a verdict for the plaintiff and awarded $3.75 million in damages to the plaintiff plus $650,000 to the plaintiff's wife for loss of consortium. The jury found the surgeon and hospital liable, and it apportioned 65% liability to the surgeon and 35% to the hospital. Upon appeal, the state's supreme court affirmed the judgment.

What this means to you: Several important issues arise from this case, which is consistent with the number of bases upon which the plaintiff alleged negligence. The first claim addressed by the court, and one of great importance to all physicians and hospitals, was the lack of informed consent. In general, physicians must fully inform their patients about the risks involved in any proposed procedure or treatment and possible alternatives to the procedure. Different jurisdictions might articulate the rule slightly differently, but the overall theme is the same: Physicians who fail to disclose important information to patients who are deciding about procedures may be found negligent for that failure. In this case, Delaware had a statute defining "informed consent" that required the healthcare provider to inform the patient in a "reasonably comprehensible to general lay understanding" of information regarding the nature and risks, as well as alternatives, to the treatment that a reasonable patient would consider "material" to the decision. This provision of course leaves room for debate regarding whether something is "material," but physicians and hospitals can err on the side of caution and prevent any debate by informing patients in the first place. The court here found that the failure to inform about alternatives and the surgeon's relationship with the manufacturer were relevant. The court found that this information was particularly relevant because, since the surgeon was earning money from the On-Q procedure, he had a "strong incentive to play down the risks of the On-Q procedure and play up the problems with alternative treatments." It is important to note that this law does not preclude physicians and hospitals from having a financial interest in treatments or procedures, but if such is the case, patients must be informed of this fact to satisfy informed consent.

Physicians often can be seduced by private companies to use their product or drug on patients without ensuring that these are FDA-approved to treat the issue at hand or that, if not, the hospital medical staff and/or pharmacy leaders have approved the off-label use. Any time a product or drug is used in a study, regardless of by whom, the hospital or regional institutional review board has absolute oversight. A physician or principal investigator may ask for an expedited approval from the institutional review board (IRB), but it should not be approved if it involves a device or drug not FDA-approved for use on a patient. Hospital IRBs should not be pressured by physicians to push through expedited approvals. Finally, any patient or subject participating must be asked to sign an IRB-approved informed consent form, which by law requires that all elements of informed consent be present along with additional elements related to being part of a research study. This process is above and beyond the usual informed consent a patient is given for more routine procedures, and it can go a long way toward protecting physicians and hospitals involved in disputes regarding informed consent should the issue arise later. Without going through appropriate research study protocols, there exists the possibility of kickback law violations as well.

Another important issue raised by this case is the different treatment that expert witnesses and fact witnesses receive by courts. Expert witnesses play an extremely important role for plaintiffs and defense in medical malpractice cases, as the knowledge required is typically beyond that which a layperson knows. Such scientific, technical, or otherwise specialized knowledge may be presented only by expert witnesses who have been qualified as such by the court prior to giving their expert opinion. This qualification process can be quite involved and include days of hearings to determine the expert's qualifications and reliability, so the complete scope goes beyond the purview of this article. However, of importance here is the fact that the trial court did not allow the defense's "fact witnesses" to opine on the fact that the procedure was "experimental" in nature, while it allowed the plaintiff's expert witnesses to testify about this fact as they possessed "specialized knowledge about what treatments for rib fracture pain were generally accepted in the medical community and what treatments were not." Choosing experts thus plays a critical role in litigation because if the court finds your "experts" are not properly qualified, this decision can be a death knell for your case without the experts' required testimony regarding medical subject matters.

REFERENCE

Supreme Court of Delaware, DE. Case No. N11C-06-092 MJB. Aug. 7, 2014. ■

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

Handwritten notes can be weak link in your compliance with HIPAA

With all the talk about encryption and other high-tech ways to safeguard protected health information (PHI), Health Insurance Portability and Accountability Act (HIPAA) violations still can be traced to the simplest task: jotting down notes about a patient on a piece of paper.

The risk posed by handwritten notes was illustrated recently when AccessHealthCT, the health insurance exchange in Connecticut, announced a HIPAA breach traced to an employee of a contractor. The employee left a backpack containing the PHI of 400 of the state's residents on the street. The PHI was written on a notepad and included various combinations of the customers' names, birthdates, and up to 200 Social Security numbers. AccessHealthCT said the contractor apparently was using the data to work away from the office.

The contractor who employed the owner of the backpack is Maximus, the firm that operates the exchange's call center. On the day of the breach, AccessHealthCT CEO Kevin Counihan said they were working with Maximus to address the situation, including the possibility that the employee left the backpack intentionally as part of a plan to steal the PHI. Maximus leaders put the suspected employee on an administrative leave while it investigated the incident further, and they soon announced their conclusion that the employee unintentionally left the backpack.

Maximus sent 395 letters to those affected offering them options to help protect their identity at the company's expense. *(See the story on p. 3 for advice on contractors and HIPAA security.)*

Even in the age of electronic records, handwritten notes still are common and pose a significant risk, says **Timothy B. Adelman**, JD, an attorney with LeClairRyan in Annapolis, MD. In addition to contractors and others who might jot down notes as part of their work, Adelman points out that nurses and other clinicians routinely make written notes. Nurses often write notes about patients just before a shift change, for example, so they can refer to them when briefing the oncoming staff. Those could contain PHI, but don't always.

Written notes common

Limiting the use of handwritten or printed records should mesh with a hospital's overall privacy policy, particularly the admonition to use the "minimum necessary" PHI, says **Patricia Wagner**, JD, an attorney with Epstein Becker Green in Washington, DC.

That "minimum necessary" phrase will mean that handwritten notes should never include more information than is strictly necessary to achieve the task, and Wagner says it rarely would be necessary for a note to include information such as a patient's full identification and Social Security number.

Jotting down a patient's lab value so it can entered in the electronic record later is a common habit, Adelman notes. That information probably would not rise to the level of PHI unless the note contained enough information for another party to figure out the identity of the patient, Adelman says.

"If it only says `Room 1' and notes about the patient's condition, that might not be PHI, but if the note includes the patient's initials or full name, the room number and date, that might be enough to make it PHI," Adelman says. "Nurses may take these notes home with them at the end of the day, in their bag or the pocket of their scrubs, and that could lead to a breach."

The solution is to require that nurses leave those

notepads at the hospital, in a secure location such as their lockers or a locked cabinet on the unit, Adelman says. Destroying the notes, preferably by shredding, also is an option.

Completely prohibiting such handwritten notes is not practical, Adelman says. It is wise, however, to include education about the risk of handwritten notes in all HIPAA training and to have a policy that restricts how much information can be written down and how the notes are stored or destroyed, he says. "You also should expect any contractor or independent provider to adhere these policies as well," Adelman says. "It's important that you not just give it lip service by saying in the contract that they must adhere to your policies and procedures. There should be a mechanism by which they acknowledge that they receive these policies and procedures and that they agree to abide by them."

Adelman has handled several cases involving shift change notes written by nurses, which can be important in proving what was or wasn't conveyed to the other nurses and physicians. For HIPAA security and risk management concerns, Adelman always has recommended policies that prohibit taking those notes home.

"We've also handled a case in which a physician had his car stolen, along with a lot of paper patient records he had in the trunk. The Office for Civil Rights has made it clear that losing that kind of document, whether in paper or digital form, is a violation," Adelman says. "We strongly encourage people not to take paper records anywhere that makes them vulnerable."

Handwritten notes are not the whole problem, notes **Brad Rostolsky**, JD, an associate with Reed Smith in Philadelphia. Any hard copy record can lead to a HIPAA breach, he says. In one case with which he is familiar, a hospital employee accidentally left a stack of printed records on a subway train.

"The biggest issue with printed out, hard copy records is that you just don't know whose information is at play," he says. "With electronic records, there is a backup somewhere, and you know what is lost or accessed. With handwritten records or printed copies, the tough question is, who do you notify?"

The answer usually will be "everybody" or at least a very liberal estimate of whose information might have been included, Rostolsky says. That broad notification means the impact of the breach could be much larger than if the data were electronic, he explains.

If a healthcare provider needs to use paper records – handwritten or printed – in some instances because going electronic is not feasible for that data, Rostolksy says there should be policies and procedures on how to track that information. Institutional pharmacies create paper records when delivering prescriptions, for example, and it would be nearly impossible to eliminate them. Those records can be protected with policies that require the records to be safeguarded at all times and not treated like just any other piece of paper. *(The loss of paper records accounts for nearly a quarter of HIPAA breaches. See the story on p. 3.)*

"If that kind of policy gets in the way of people taking home a stack of paperwork to work on in the evening, it might be time to move toward a system that allows them to log in to the system from home and work that way," Rostolsky says.

HIPAA education efforts should include pointing out that the notepads and other written materials can lead to a breach. It is easy for people to dismiss a notepad as harmless, with just casual notations that don't really constitute PHI, she says.

"Unfortunately many healthcare organizations will not recognize the danger posed by paper records until they have a breach of that type," Wagner says. "Then they will be alarmed and wonder why they have so much paper floating around."

EXECUTIVE SUMMARY

Writing down protected health information (PHI) on paper poses a significant risk of violating the Health Insurance Portability and Accountability Act (HIPAA). Many healthcare employees and contractors still jot down PHI and bypass all the digital protections.

- HIPAA breaches have been traced to handwritten notes.
- Completely prohibiting the use of handwritten notes might be impractical.
- Some types of information could be banned from handwritten notes.

SOURCES

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Specify quick notification in vendor agreements

Business associate agreements are one of the tricky parts of complying with the Health Insurance Portability and Accountability Act (HIPAA). The reason? You must trust that the vendor will act responsibly with your protected health information (PHI). Requirements for notification of a possible breach should be strict and clear, says **Timothy B. Adelman**, JD, an attorney with the law firm of LeClairRyan in Annapolis, MD.

If a contractor loses information in a way that even suggests a possible HIPAA breach, the hospital's contract should require the contractor to notify the hospital immediately. That contract provision encompasses more situations than a contract requiring notification if there is a breach.

"Some business associate agreements say the contractor will notify the hospital within 30 days of a breach, but we'd rather see a contract that requires the vendor to notify the hospital promptly whenever there is an unauthorized disclosure or access to PHI," Adelman says. "We don't want to leave it up to the vendor to decide whether a loss of PHI is a breach, because they may not have the background and resources to make that decision. We want the hospital to be involved in that decision." ■

Errors by employees are at the root of most data breaches, but not the most costly

The two most common sources of Health Insurance Portability and Accountability Act (HIPAA) breaches are unintended disclosure, such as misdirected emails and faxes (31%) and the physical loss of paper records (24%), which is particularly prevalent among healthcare organizations.

Those findings come from Beazley Breach Response (BBR) Services, an Atlanta company providing breach response insurance. It recently announced findings from an analysis of more than 1,500 data breaches at a meeting of the International Association of Privacy Professionals (IAPP). Breaches handled by the company have affected more than 14 million people.

> " DUE TO HEAVY FORENSICS COSTS ... THESE [MALWARE OR SPYWARE] BREACHES ARE ON AVERAGE 4.5 TIMES MORE COSTLY THAN THE LARGEST LOSS CATEGORY...

These are expensive

Among the data breaches serviced by Beazley in 2013 and 2014, breaches due to malware or spyware represented only 11% by number of breaches in 2013 and 2014. However, they have been increasing, with the total number of breaches in this category growing by 20% between i2013 and 2014. Due to heavy forensics costs (money spent to find out exactly how the breach occurred), these breaches are on average 4.5 times more costly than the largest loss category, unintended disclosure, explains **Katherine Keefe**, JD, head of Beazley Breach Response.

"With more information being stored electronically and in the cloud, the risk of data breaches is growing," Keefe says. "Consumers expect their privacy will be protected, and a data breach can have serious reputational and financial impact."

Most breaches are avoidable with appropriate training and security measures, says Keefe, noting the particular need for encryption services for large-scale computer networks and mobile services. *(See p. 4 for tips on avoiding a data breach.)* ■

EXECUTIVE SUMMARY

Most HIPAA data breaches are tied to misdirected emails and faxes, but the costliest are the result of malware and spyware. The findings come from a company that offers insurance for data breaches.

- The loss of paper records accounted for 24% of the breaches.
- Malware and spyware breaches are costly because of the research necessary to unravel them.
- Breaches from computer hacking are on the rise.

5 ways to avoid a data breach

Most data breaches are fully preventable, and Beazley Breach Response (BBR) Services, an Atlanta company providing breach response insurance, offers these five ways to avoid them:

• Encrypt your devices.

More than 73% of the breaches serviced by Beazley Breach Response in 2013 involving portable devices could have been prevented if the devices were encrypted. Encryption is a safe harbor under virtually every breach notification law.

• Automate patch management.

From 2013 to August 2014, Beazley has seen a 20% increase in breaches due to malware or hacking. Staying on top of the latest available software patches and moving to automated patch management can protect against a breach.

• Enforce password complexity.

Computer systems can systematically cycle through all permutations of potential passwords. Do not allow the use of passwords that are easy to crack. Dictionary words are capable of being deduced with an algorithm.

• Be alert to phishing.

Training is a critical step in breach preparedness. Train employees to spot the indicators of a phishing email. From 2013 to 2014, Beazley Breach Response has seen a 10% increase in breaches attributable to someone inside the company, either an employee or contractor. Most breaches occur because of human error.

• Double-check before hitting send.

Thirty-one percent of the breaches serviced by Beazley in 2013-2014 were due to unintended disclosure. It might be simple, but double-checking the contents of a file, email address, or mailing details can make a difference, especially when sending data to outside contacts. ■

Act expands breach notification requirements

Any healthcare organization with a presence in Florida will be affected by the Florida Information Protection Act of 2014 (FIPA), which expands the requirements on covered entities that acquire, maintain, store, or use personal information of Floridians.

As part of a growing trend in state legislatures, Florida's new data breach and security law expands notification requirements on covered entities that experience a breach of security, according to McGuireWoods.

The new law repealed Florida's prior data breach notification statute and made significant modifications to Florida law that can reach entities far beyond the state's borders, the firm explains. Providers need not be based in Florida for the law to apply; any business presence in the state will trigger the law.

William J. Cook, JD, partner with McGuireWoods in Chicago, offers these explanations of the new Florida law:

• Any commercial or governmental entity that acquires, maintains, stores, or uses personal information of individuals in the state is subject to this law. Although this is a Florida statute, companies in other jurisdictions should assume this statute will apply in the event they experience a breach of security affecting any individuals in Florida,

• Under FIPA, like its predecessor statute, personal information includes an individual's first name or first initial combined with the individual's last name, in combination with social security number, driver's license number, or other similar number of a government-issued ID, or a financial account number or credit or debit card number combined with the required security code. New under FIPA, personal information also will include any information about an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a healthcare professional; or an individual's health insurance policy number or subscriber identification number, plus any unique identifier used by a health insurer to identify the individual.

• FIPA also expands the definition of personal information to include any personal login information that would permit access to a person's online account. Notably, this expansion, which might be the first of its kind in any state data breach notification law, would include login information to social media sites or applications, regardless of whether such sites include more traditional forms of personal information.

• Personal information excludes information already made public or information that is encrypted.

• FIPA reduced the time period for report of breaches to 30 days from the time the breach is discovered, compared to 45 days under the previous Florida statute. FIPA authorizes the Department of Legal Affairs to grant up to 15 additional days to provide notice if good cause is provided in writing to the department within 30 days of the determination of a breach. ■