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AHC Media

Early elective inductions, C-sections get a no from hospitals

Safety is more important than convenience

Risk managers and patient safety experts across the country are catching on to a dangerous trend: Too many physicians and patients are agreeing to early induction or Cesarean sections, they say, and it has to stop.

On the first day of September 2011, 17 Oregon hospitals — including all nine birthing hospitals in the Portland area — agreed to a "hard stop" on elective inductions and Cesarean sections before 39 weeks. The hospitals agreed to the new policy, which prohibits physicians from scheduling the procedures without proof of medical necessity, in conjunction with a campaign sponsored by the March of Dimes. *(See the story on p. 124 for more on the March of Dimes campaign.)*

The agreement covers about half of the deliveries in the state, says **Scott Berns,** MD, senior vice president of chapter programs for the March of Dimes in White Plains, NY. The number of Cesareans and inductions at 37 and 38 weeks has been growing as women schedule their deliveries for their convenience or to be delivered by their own doctor, she says. Deliveries at those weeks have risen in the United States in the last decade and now account for 17.5% of live births, she says, and about one in three C-sections are done before 39 weeks. *(See the story on p. 123 for more on the increase in early deliveries.)*

A baby is considered full term at 37 to 41 weeks, Berns says, but the March of Dimes believes the longer the term, the better for babies. New research has shown that a baby's brain nearly doubles in weight in the last few weeks of

EXECUTIVE SUMMARY:

More hospitals are banning early elective inductions and Cesarean sections in the interest of patient safety. Improving obstetrical outcomes also might have a positive effect on liability risks and malpractice claims.

- The incidence of early inductions and C-sections has skyrocketed in recent years.
- Babies are at more risk of infection and other complications when delivered before 39 weeks.
- Physicians and patients might resist efforts to ban early deliveries.

pregnancy, he says. Also, important lung and other organ development occur at this time. And, although the overall risk of death is small, Berns notes that it is double for infants born at 37 weeks of pregnancy, when compared to babies born at 40 weeks, for all races and ethnicities.

The March of Dimes has been addressing the issue across the country, and hospitals in California, Texas, New York, and Illinois also have adopted the ban on early elective deliveries, Berns says. Intermountain Healthcare, with 23 hospitals in Utah and Idaho, has prohibited elective early inductions and C-sections for the past decade.

Risk managers should address early inductions and C-sections as a patient safety issue, Berns says. Clinicians and patients will need to be educated, he says. Expect some pushback at first.

When you first broach the topic, clinicians are likely to respond that this is not a problem for them, Berns says. That's when you need to provide the data showing how many babies are delivered early and the corresponding rates of complications, admission to the neonatal intensive care unit, and other factors. *(See the story on p. 124 for more on the growing malpractice risk associated with early births.)*

"There has been this assumption that it's fine to deliver before 39 weeks, and people unfortunately can get very casual about their reasons, trying to work around vacation plans or holidays," Berns says. "But once they see some of this data about the outcomes and how the early delivery affects the child, you can turn them around. The next step after that is the policy change."

Simply declaring that you won't allow early inductions or C-sections is not enough, Berns cautions. There must be a process in place that actually prohibits them. The best method is for administration to make clear to the individuals responsible for scheduling deliveries that they may not schedule an early induction or C-section without proof of medical necessity, he says.

"They just won't schedule it. They have to say no," Berns says. "When the physician gets upset about that, he or she has to take it up with the department head."

Hold physicians accountable

Any policy must carefully distinguish between the necessary but early C-section or induction and the one performed for convenience, says **Georganne Chapin**, president and CEO of Hudson Health Plan, a nonprofit Medicaid insurer in Tarrytown, NY. In response to rising local C-section rates, Chapin has directed Hudson to work with several of Hudson's network hospitals, a large community health center, the Lower Hudson Valley Perinatal Forum, and the perinatology department at the regional tertiary care hospital to examine the high C-section rate among enrollees. *(See the story on p. 123 for one hospital's experience with limiting early deliveries.)*

Chapin's goal is to reduce unnecessary C-sections and to ensure the safety and appropriate level of care for mothers and babies. "This initiative will rely heav-

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ily on data collection in multiple care settings to piece together all episodes of care into one comprehensive overview," she says. "Everybody will win from this initiative: Mothers and babies will be safer, and the community will benefit from lower healthcare costs."

Chapin calls on risk managers to hold physicians more accountable for their delivery practices by requiring them to justify their statistics on early deliveries. She also says risk managers should enact "hard stop" policies on some procedures.

"There is no reason for elective C-sections. They should be forbidden," Chapin says. "There are too many things that happen during labor that are good for the baby and good for the mother, and that is the way the body has been working for thousand years. I believe there is no good reason to have an elective C-section."

SOURCES

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Hard stop cuts deliveries before 39 weeks

Leaders at Summa Akron (OH) City Hospital took a hard look at elective inductions a couple years ago and didn't like what they found, says **John Hutzler**, MD, FACOG, division chief of obstetrics and chairman of obstetrics peer review. There was an inordinate number of women being induced early for a prolonged time, which carried an increased risk of morbidity and mortality for mother and baby. And there was a high number of C-sections at less than 39 weeks.

Hutzler himself was skeptical about whether there was much difference between a delivery at 38 weeks and 39 weeks, but a study of the literature convinced him. To address the issue, Hutzler and his colleagues started educating residents and physicians about a new "39 week hard stop" program for elective induction of labor and elective C-sections. At first the program was strictly educational, but then Hutzler, who heads the peer review program in obstetrics, put some teeth into it.

On Jan. 1, 2009, the hospital began requiring documentation of gestational age and refusing to schedule elective deliveries before 39 weeks, and it implemented a new standardized consent form that prohibited the early deliveries. "If they don't follow those guidelines, and if they managed to sneak through an induction or C-section before 39 weeks, it will go to our peer review process, and they will get negative standards of care for that," Hutzler says. "That's sort of a whip we've got to instigate better quality of care."

The benefits of the hard stop program are clear, says **Tiffany Kenny,** RN, MSN, CEFM, obstetrics informatics administrator at Summa Akron (OH) City Hospital. There have been only three elective inductions that slipped through the system, and those happened with the first version consent form that allowed a procedure to be scheduled before all supporting documentation was provided. The form has since been revised to require the documentation before the procedure can be scheduled.

The policy was not popular at first with physicians or patients, Kenny says. The most common reason cited for early induction or C-section was maternal discomfort, she says, and it was difficult to convince patient and physician to wait, she says. "One thing we have found useful is to provide reports to all the physician groups on their rates of early inductions and C-sections, and their corresponding complications, broken down individually and by group," Kenny says. "We've found that you can count on a little bit of competitiveness between physicians when they see someone else in their practice has a better rate or another practice has better numbers."

SOURCES

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Rate rose dramatically for recent C-sections

Elective Cesarean sections and inductions have become much more common in the past three decades, notes **Roberta Carroll**, ARM, CPCU, MBA, CPCU, CPHQ, CPHRM, senior vice president with Aon Risk Solutions, a consulting firm in Odessa, FL. In 1965, the U.S. cesarean rate was measured for the first time and it was 4.5% (4.5 C-sections per 100 pri-

mary deliveries), Carroll says. In 2002, the C-section rate was 27% and by 2009 it had increased to 34% of single live deliveries. (Some of these C-sections occurred at 39 weeks or later).

Carroll says the rise in C-sections has been associated with many factors including:

• Common labor practices that can increase the likelihood of needing a C-section, such as induction of labor or having an epidural early in labor; convenience in delivery timing for the provider or the mother; increasing willingness of physicians to perform C-sections; limited understanding by the mother of the potentially serious complications of C-section; maternal-requested C-sections;

• Physician fear of malpractice claims if they do not perform a C-section; established physician practice patterns.

Despite the popularity of C-sections and inductions among patients and physicians, many organizations oppose them and are pushing for the elimination of induced labor and C-section before 39 weeks without medical indication. These groups include the American Congress of Obstetricians and Gynecologists, The Joint Commission, the Agency for Healthcare Quality and Research, the Institute for Healthcare Improvement, and the Leapfrog Group.

SOURCE

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Effort to block births ups malpractice risk

The standard of care is changing

The malpractice risk associated with early inductions and C-sections is growing, as a direct result of the effort to curb them, says **Roberta Carroll**, ARM, CPCU, MBA, CPCU, CPHQ, CPHRM, senior vice president with Aon Risk Solutions, a consulting firm in Odessa, FL. To date there have not been many malpractice cases directly related to early inductions and C-sections, but Carroll says that trend is likely to change.

"There is so much information now saying early induction or early C-section is harmful to the baby, and the standard of care is changing," Carroll says. "What was accepted by everyone years ago is now seen as unacceptable, and if a provider continues with the old way of doing things, that can make you vulnerable to an allegation of malpractice."

That risk can be used to drive change in the organization, she says. If the medical staff keeps vetoing the idea of a pre-39 week ban, the C-suite might overrule them once you show the potential liability and other costs associated with the practice, Carroll says. "Insurers also are going to start asking why this patient was induced or why you did this C-section, and that is going to require additional documentation," Carroll says. "They will start posting your rates and pushing you to reduce them, because it's all tied into money." ■

March of Dimes toolkit encourages minimum

The March of Dimes, based in White Plains, NY, recently began an initiative in New York, California, Florida, Texas, and Illinois to implement a "39-week toolkit" in hospitals to discourage C-sections or inductions before that minimum gestation.

The toolkit is available online at this address: http://tinyurl.com/3nswvwz. The tool specifically discusses how to implement policies and the risks associated with elective early deliveries. It is part of a campaign names "Healthy Babies Are Worth the Wait," which encourages women to allow labor to begin on its own if their pregnancy is healthy.

It aims to dispel the myth that it's safe to schedule a delivery before 39 weeks of pregnancy without a medical need, says **Judith Nolte**, a member of the March of Dimes national Board of Trustees and former editor-in-chief of American Baby Magazine Group, who worked with the March of Dimes to develop the new awareness campaign.

"Some women mistakenly think that the only thing a baby does during the last weeks of pregnancy is gain weight, making labor and delivery more difficult," Nolte says. "When the moms in our focus groups learned about the important brain and organ development that occurs, they were more than willing to put up with their own discomfort so their baby could get a healthy start in life."

Research indicates that only 25% of women know a full-term pregnancy should last at least 39 weeks, Nolte says. ■

Temporary staff can boost liability risk

The key: being oriented carefully

Temporary staff members working in a hospital's fast-paced emergency department (ED) are twice as likely as permanent employees to be involved in medication errors that harm patients, according to new research from The Johns Hopkins University School of Medicine in Baltimore. In addition to minimizing the use of temporary staff, the solution, say some experts, is to devote more attention to choosing the temporary staff you do use.

Results of the Johns Hopkins research raise serious issues related in particular to temporary nursing staff because they already are a substantial and growing part of the healthcare workforce, owing to the national nursing shortage, says study leader **Julius Cuong Pham**, MD, an assistant professor of anesthesiology and critical care medicine and emergency medicine at the school. These fill-ins plug holes in short- and long-term work schedules, and they are seen as a cheaper alternative to permanent hires, Pham notes. They often earn more per hour, but don't receive benefits, he says. *(There also is concern about the risk associated with physician assistants [PAs]. See the story on p. 127, and the story on p. 128 about a teenager who is accused of impersonating a PA.)*

The Johns Hopkins team cautions that while it might be easy to blame the temps themselves for the errors, the problem is probably more diffuse and complex.

"A place that uses a lot of temporary staff may have more quality-of-care issues in general," Pham says. "It may not be the temporary staff that causes those errors, but a function of the whole system."

The Johns Hopkins team says that its findings do suggest, however, that the temp strategy in hospital staffing might be exacting a price in patient harm, and that temp staff's unfamiliarity with the practices and systems of a new hospital could be more costly in the long run in terms of patient safety. *(See the story on p. 126 for more information on the possible malpractice risk related to temps.)* "Our work suggests that if you can, you probably want to avoid hiring temporary staff because they are associated with more severe medical errors," Pham says.

Pham and his colleagues did their study by examining a national Internet-based voluntary medication error reporting system and data from 2000 and 2005, which encompasses 592 hospitals and nearly 24,000 emergency department (ED) medication errors. Medication errors made by temporary workers, they found, were more likely to reach the patient, result in at least temporary harm and be life-threatening.[1]

Pham says that temporary personnel often are not familiar with local staff, care management systems, protocols, or procedures. This lacking of familiarity might hamper communication and teamwork, a situation that causes them difficulty in retrieving important medical information and leaves them unsure of which procedures to follow. In addition, temporary help might be less likely to speak up if they see problems, and they might also lag behind the latest knowledge because they, unlike permanent employees, typically manage their own continuing education.

"You may know the medicine," Pham said, "but you still may get tripped up by the policies and procedures of an unfamiliar system. This can lead to more serious errors."

Pham notes that the ED is a unique environment with a high risk for medication errors, likely due to the increased severity of injury or disease, the rapidity with which lifesaving decisions must be made, the medical complexities encountered, and overcrowding. Many medications are ordered, dispensed, and administered in the ED without the standard pharmacy check that occurs in nonemergency situations elsewhere in a hospital. There is a higher prevalence of verbal orders, and they often are given urgently.

Hospital administrators might not want to use temporary staff but might have no choice but to hire temporary help or be understaffed, depending on the situation, Pham says.

Some temporary nurses and doctors spend a month or two in a city and then move on, not because they can't hold down a permanent job, but because they like to travel to new places, Pham says. While some temporary employees are used in a single department over their stay to give them an opportunity to become more familiar with procedures, others are moved from unit to unit as needed, which gives them fewer

EXECUTIVE SUMMARY:

New research suggests that temporary staff members in the emergency department (ED) might threaten patient safety and increase liability risks. Familiarizing temps with your organization is important in mitigating the risk.

- A high number of temporary staff might signal other problems within the organization.
- Temporary staff members tend to be less familiar with the policies, procedures, and equipment.
- The problem might not be limited to the ED.

opportunities to become properly prepared.

Pham says it isn't known whether a correlation between temporary workers and more serious medication errors exists in other hospital service areas. Further research is needed to determine that connection, he says.

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SOURCE

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ED especially vulnerable to temp risks, doctor says

The emergency department (ED) is perhaps the worst hospital unit in which to have strangers working together, says **Dan Sullivan**, MD, FACEP, JD, president and CEO of The Sullivan Group, a risk and safety consulting group in Oakbrook Terrace, IL, and an associate professor of emergency medicine at Cook County Hospital/Rush Medical College in Chicago.

Twenty years ago, an emergency physician was likely to know everyone working in an ED, which were smaller because the patient volume was much less, he says.

"You knew their routines, their subroutines, and the spirit of teamwork was tremendous. You knew who you could rely on and not rely on," Sullivan says. "Now I work with hundreds of emergency departments around the country, and every single department has PAs, NPs, other physician extenders, and almost every one has temporary staff. I do believe that the temporary people are high quality individuals, but that does not make us immune to the risks of someone who is new to the department."

Although the risks might be most acute in the ED, temp staff pose potential problems in any part of healthcare, says **Ron Calhoun**, managing director for Aon Risk Solutions in Charlotte, NC. "It's a foregone conclusion that pressure on the healthcare delivery system, in the ED and beyond, will only increase if mandated coverage kicks in in 2014, given the shortage of primary care physicians," Calhoun says. "The use of nurse practitioners, PAs, and other physician extenders is going to increase, and the consequence of that will be realized most in the ED."

The actual skills of the temporary staff, or lack thereof, are not what increases the risk, Calhoun says. The threat to patient safety and liability comes more from the temporary staff's "systemic unfamiliarity" with the local care management systems, protocols, and procedures. Errors are more closely related to the systems in place rather than the temporary individual's skill level, he says.

"Communication errors are the most insidious. The credentialing of temporary staff tends to be pretty good, but they are dropped into a local environment where communication protocols are already in place," he notes. "I don't care how good the individual is, if they come into a system that has an established communication protocol, both formal and informal, they are at a disadvantage."

Temps often are responsible for their own continuing medical education (CME), which might be out of sync with the local provider's efforts, Calhoun notes. This situation leaves the temp without education on topics that are of special focus for everyone else at the institution, he says. Working with temps who use a CME platform common to your institution or health system can help, he says.

Another potential problem is hiring temps for the ED from other specialties, Calhoun and Sullivan say. When staffing is difficult, there can be a temptation to fill an ED position with someone who — while highly skilled and credentialed in intensive care, for instance, or another field — is not an emergency specialist. "I don't think enough attention is given to that problem," Calhoun says. "It can be highly impactful in these scenarios."

Clinical decision support and clinical assessment are key protections when using temporary staff, Calhoun says. There must be a system in place to provide immediate feedback for the temporary employee from the system level and the individual physician level, he says. Sullivan agrees, and he says that education and orientation to the local systems are critical. "Those systems are critical for bridging this gap as you bring in temporary staff to a local emergency environment," he says.

Individual temps might come and go, but the use of temps is here to stay, Sullivan says. That means healthcare providers might need to adjust their own policies and procedures to make them as homogenous as possible on an industrywide basis. When you could count on your staff being long term, it was easier to justify having your own way of doing things, Sullivan

explains. But with more temps, providers might have to seek uniformity so that the temp doesn't have to learn a new procedure at each facility, he says.

"That may not sound like the ideal strategy, bending to the need of the temps, but it works in your favor," Sullivan says. "If you're seeking improved patient safety and outcomes, it is to your advantage to have the temp merge into your systems as easily as possible. If your system is the same as the one the temp used across the country last month, everybody wins."

SOURCES

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Temps, PAs may be cited in malpractice claims

With the increasing usage of temporary staff and physician assistants (PAs) in the emergency department (ED), it is likely that the healthcare industry will see lawsuits alleging their status was key to alleged malpractice, says **Paul C. Kuhnel**, JD, an attorney with the law firm of LeClairRyan in Roanoke, VA.

"This certainly represents an increased risk. That is clear. How to address is it not so clear," he says. "At a minimum, the potential increased risk to patient safety and the increased risk of malpractice claims has to be considered in staffing decisions. Healthcare providers have a hard time filling positions sometimes, and I'm not unsympathetic to that difficulty, but this risk has to be factored into how you solve that staffing problem."

Kuhnel cautions that risk managers cannot depend on the "independent contractor" status of temporary employees as a safeguard against liability related to their actions. Even if the temp is technically the employee of an outside agency, and even if that agency provides their insurance coverage, the healthcare provider where they work still can be on the hook if things go wrong.

"The argument of ostensible authority would be allowed, and you would end up with liability for their actions, even if you think have hired them simply as independent contractors," Kuhnel says. "In some jurisdictions you can be held liable for the negligent actions of an independent contractor. Having the person on the payroll of another entity won't necessarily insulate the hospital from liability related to their negligent acts."

SOURCE

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ED physician assistants not seen as very risky

While there is general agreement that temporary staff can threaten patient safety and increase malpractice risks, the question is not quite so clear with nurse practitioners (NPs) and physician assistants (PAs) in the emergency department (ED).

NPs and PAs are increasingly being used in EDs, with PAs treating about 10% of the total patient population that visit EDs each year, according to a recent study in the *Journal of the American Academy of Physician Assistants*.[1] The study examined how physicians perceive PAs in the ED and whether they believe PAs to be a malpractice risk. Researchers mailed a 16-item questionnaire to a random sample of 1,000 active members of the American College of Emergency Physicians in 2004 and again five years later. Results from both surveys were fairly consistent.

The percentage of doctors who disagreed or strongly disagreed that PAs are more likely than physicians to commit medical malpractice was 72% in 2004 and 68% in 2009. Similarly, most physicians disagreed or strongly disagreed that PAs were more likely than doctors to be sued as a result of medical malpractice (84% in 2004, 82% in 2009).

According to the survey results, physicians in both surveys thought that the factors that would most significantly decrease the risk of malpractice by PAs were more clinical experience in emergency medicine, completion of a post-graduate residency program, and appropriate supervision by physicians.

Some positive trends were seen during the five-year period between surveys: The number of physicians who reported practicing with PAs increased by 26%, and the number of doctors who were directly supervising PAs in the ED increased by 19%. Even better, the number of physicians who believed that PAs decrease patient wait times in the ED increased by 13%, and the number of doctors who believe that

PAs increase patient satisfaction increased by 10%.

Most emergency physicians agree that the increased utilization of PAs in the ED might improve patient communication, decrease wait times, increase patient satisfaction, and therefore decrease malpractice risk," the authors wrote. In addition, the authors concluded, "as physicians gain both clinical experience and experience working with PAs, their perception of malpractice risk imposed by the PA in the ED significantly decreases."

According to one medical liability study performed by the National Practitioner Data Bank (NPDB) in 2008, there were 1,535 reported medical malpractice payment incidents against PAs between 1991 and 2007. The average payout cost medical providers about $80,003. Although this number was significantly lower than reports and payments for physicians, there were multiple areas in which PAs made medical errors.

According to the NPDB study, the five major categories where PAs received the most malpractice reports were in the areas of diagnosis (55.5%), treatment (24.6%), medication (8.5%), surgery (4.6%) and miscellaneous (3.1%).

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FL teenager arrested for playing PA in ED

Authorities in Kissimmee, FL, report that a teenager has been arrested and accused of impersonating a physician's assistant (PA) in a local hospital's emergency department (ED).

Matthew Scheidt, 17, appeared in court with his mother recently, but the state attorney said charges were pending. Scheidt was a part-time billing clerk at Osecola Regional Medical Center but he obtained a physician assistant badge that allowed him to conduct exams and provide other patient care, according to Assistant State Attorney **Dugald McMillan**, JD.

McMillan said the state is still trying to determine what charges to bring against Scheidt.

The Florida Department of Health issued a statement saying it is investigating the incident. "In light of the arrest of this teenager, we made a site visit to the hospital Sept. 7 through 9. Our report is still being drafted and is under review, so details cannot be discussed," the statement said. "Some of the things we looked at included hospital policies, patient rights, and the security in place when this teenager allegedly had access to patients."

The hospital did not return a call seeking comment. ■

The worst IT threats can come from inside

Imagine the havoc if one day your organization's critical data just … *disappeared*.

It could happen, says **Eric Chiu**, founder & president of HyTrust, a company in Mountain View, CA, that specializes in access control for data. It likely would be caused by someone employed or formerly employed at your organization, he says.

Information technology (IT) security often focuses on the threat of outsiders hacking into your system, but your own employees could pose the biggest threat of all, Chiu warns. He cites a recent incident in New Jersey that he says illustrates the threat posed by insiders: A former employee of the Japanese pharmaceutical company Shionogi was able to hack the organization and effectively take down its virtual infrastructure, which caused $800,000 in damages to the company. *(See the story on p. 129 for more details.)*

"Insider threats are on the rise, whether from malicious or disgruntled employees, data leaks, or mistakes and other unintentional issues," Chiu says. The breach at Shionogi is a great example of how vulnerable virtualization infrastructure and the cloud can be. Critical systems like e-mail, order tracking, financial, and other services were impacted, having been virtualized without the proper controls in place. This was because a disgruntled admin was able to delete the corporate servers with a simple click of a button."

To add insult to injury, he was able to do this remotely while sitting at a booth in a Georgia McDonald's, using the restaurant's wi-fi connection, Chiu says.

The $800,000 in damages and multiple days of downtime at Shionogi could have been prevented with the right automated controls in place, he says. IT administrators, such as the man charged with the Shionogi crime, are primary threats because they must be privileged users with extensive access to the system and its controls, he says. "They have credentials and back doors that they have put in place, and in this case, he was able to log in using those credentials long

EXECUTIVE SUMMARY

Employees can compromise information technology (IT) security if you do not take the right precautions. Willful acts by employees can be even more damaging than data theft by outside hackers.

- A recent case in New Jersey shows how easily a data system can be breached.
- The virtualization layer used in many systems can be especially vulnerable.
- Virtual infrastructure often is not protected as well as physical servers.

after he had been fired from the company," Chiu says. "He proceeded to delete all of the servers and virtual machines that the company ran on, which put the company out of business for a week and cost them almost a million dollars in damages."

The damage can be even worse, Chiu notes. In the Shionogi case, the vandal did not use an especially sophisticated method but rather manually deleted 90 virtual machines from the system one at a time. A more determined hacker could destroy 20,000 virtual machines in five minutes using program code, he says.

That "virtualization layer," in which data is stored and managed on "machines" that exist only within the system, is a major trend in IT, Chiu says, and it creates vulnerabilities. "Insider threats are not new, but what is new is that about 50% of servers are running on top of virtualization. You can do much more in terms of attacking or stealing data by going through the virtualization layer," Chiu says. "If you want to steal patient information, it can be as easy as going in through the virtualization layer, copying the virtual machine, and putting it on your laptop. You don't have to go through an elaborate program of sniffing the system for weak points if you can access that virtualization layer."

The virtual infrastructure must be secured just like the physical servers, and that step is where most companies are falling short, Chiu says. In his experience, Chiu says, more than 80% of companies do not have proper controls for securing the virtualization layer. *(See the story, right, for more on considering the risks of virtualization.)*

"We're seeing just the tip of the iceberg because most of these breaches go unpublished," Chiu says. "For every public one like Shionogi, there are probably hundreds that we don't hear about."

SOURCE

- **Eric Chiu**, Co-founder and President, Hytrust, Mountain View, CA. Telephone: (650) 681-8100. ■

Focus on threats, not just ROI of virtualization

The vulnerabilities of a virtual infrastructure are real, but they often are overlooked while healthcare leaders focus on the return on investment (ROI), says **Eric Chiu**, founder & president of HyTrust, a company in Mountain View, CA, that specializes in access control for data.

"Healthcare companies are not focused on the security aspects of virtualizing patient health information, but are focused on the ROI aspects," he says. "They're treating the virtual environment the same way they did the physical data center, so they're securing networks and applications, but they're not securing the underlying technology that all of those applications are sitting on top of."

Chiu says it is only a matter of time before a hospital or health system reports a major breach through its virtualization layer. "Only about 15% of these kind of breaches are done because of a conflict like someone being fired. Most of it is done for personal gain or wanting to expose information like was done with Wikileaks," Chiu says. "The admins can go in and, with the access and free rein they have in the environment, they can steal all sorts of data and never be detected." ■

FBI: Disgruntled admin deleted system info

A Georgia man who allegedly froze the operations of a New Jersey pharmaceutical company where he had worked by deleting portions of its computer network has been federally charged in connection with the attack.

Jason Cornish, 37, of Smyrna, GA, was arrested near his residence by special agents of the FBI on a complaint charging him with knowingly transmitting computer code with the intent to damage computers in interstate commerce, according to a statement from U.S. Attorney **Paul J. Fishman**, JD, of Atlanta.

"The computers on which companies do business are the engines of the 21st century economy," Fishman said. "Malicious intrusions are against the law, regardless of motive. Hacking attacks devised as personal revenge can have serious repercussions for perpetrators as well as victims."

According to the FBI, Cornish was an information technology employee at Shionogi, a U.S. subsidiary of

a Japanese pharmaceutical company with operations in New Jersey and Georgia. In late September 2010, shortly after Cornish had resigned from Shionogi, the company announced layoffs that would affect Cornish's close friend and former supervisor.

In the early morning hours of Feb. 3, 2011, Cornish gained unauthorized access to Shionogi's computer network. Cornish used a Shionogi user account to access a Shionogi server. Once he accessed the server, Cornish took control of a piece of software that he had secretly installed on the server several weeks earlier.

Cornish then used the secretly installed software program to delete the contents of each of 15 "virtual hosts" on Shionogi's computer network. These 15 virtual hosts (subdivisions on a computer designed to make it function like several computers) housed the equivalent of 88 computer servers. Cornish used his familiarity with Shionogi's network to identify each of these virtual hosts by name or by its corresponding Internet Protocol (IP) address.

The deleted servers housed most of Shionogi's American computer infrastructure, including the company's e-mail and Blackberry servers, its order tracking system, and its financial management software. The attack effectively froze Shionogi's operations for several days, leaving company employees unable to ship product, cut checks, or communicate by e-mail.

The FBI's investigation revealed that the attack originated from a computer connected to the wireless network of a Smyrna McDonald's where Cornish had used his credit card to make a purchase minutes before the attack. Cornish also gained unauthorized access to Shionogi's network from his home Internet connection using administrative passwords to which he had access as an employee.

The count with which Cornish is charged carries a maximum potential penalty of 10 years in prison and a $250,000 fine. ■

Stanford responds to breach of patient data

A patient of Stanford Hospital & Clinics in Palo Alto, CA, recently alerted the provider to a disturbing find: Detailed medical and billing records for 20,000 of the hospital's patients were posted on a homework help site. Even worse, the records had been posted for nearly an entire year.

Los Angeles attorney **Bradley I. Kramer**, MD, JD, recently announced that he has been retained in a multi-million dollar class action case against Stanford related to the unauthorized disclosure.

EXECUTIVE SUMMARY

Stanford Hospital & Clinics has confirmed that protected health information of 20,000 patients was accidentally posted online for almost a year. The provider says the breach was caused by a vendor.

- A patient discovered the breach, and the information was removed immediately.
- The hospital notified patients, as well as state and federal authorities.
- A multi-million dollar class action lawsuit may be filed against the hospital.

The breach was discovered in August, and the hospital immediately began an investigation, says **Gary Migdol**, director of communication for the hospital. The information was contained in a detailed spreadsheet posted to a web site called Student of Fortune, where students can pay others for help with schoolwork.

Stanford soon determined that the information was posted by a billing contractor identified as Multi-Specialty Collection Services and first appeared on the site on Sept. 9, 2010, Migdol says. The patient data was in an attachment to a question about how to convert the data into a bar graph.

The spreadsheet included names, diagnosis codes, account numbers, admission and discharge dates, and billing charges for 20,000 patients treated at Stanford Hospital's ED during 2009, Migdol says. The spreadsheet did not include Social Security numbers, birth dates, or credit-card numbers, Migdol says, but to allay fears about potential identity theft, the hospital offered to pay for identity protection services to the patients involved in the breach.

Migdol says, "The information included the patient's name, medical record and hospital account numbers, an emergency department admission/discharge date, diagnosis codes related to the emergency department visit, and billing charges."

Diane Meyer, SHC/LPCH, vice president, chief compliance officer, and chief privacy offer, wrote a letter to the affected patients soon after the breach was discovered by a patient and reported to the hospital Aug. 22. Meyer says the hospital took "aggressive steps" to ensure that the web site removed the post within 24 hours. Stanford also notified state and federal agencies. The Department of Health and Human Services is expected to conduct its own investigation. The breach was traced to Los Angeles-based vendor Multi-Specialty Collection Services (MSCS). The vendor provided business and financial support to the hospital and was legally responsible for pro-

tecting all patient information needed for its services, Migdol says.

He says, "Stanford Hospital & Clinics sent the data to MSCS for permissible hospital billing support purposes using its secure systems. The data were encrypted and were solely to be used by the contractor for the business service. MSCS's contractor was not allowed to share the decrypted data with others, which apparently was done in this case contrary to law and the hospital's contract."

MSCS had a subcontractor who created the spreadsheet and caused it to be posted, Migdol says. Exactly how and why the data ended up on the homework help site is not clear, he says, but it was attached to a question asking how to create bar graphs and charts from data.

Stanford immediately suspended its relationship with the contractor, Migdol says. The hospital received written assurance that other patient data files would be destroyed or returned securely. ■

CNE QUESTIONS

1. What does Scott Berns, MD, say is the best method for reducing early inductions and C-sections?
   A. Depend on the physician's judgment.
   B. Encourage professional medical organizations to take a stand and educate their members.
   C. Require nurses to report early inductions and C-sections to their supervisors.
   D. Administration should make clear to the individuals responsible for scheduling deliveries that they may not schedule an early induction or C-section without proof of medical necessity.

2. According to Julius Cuong Pham, MD, what is one reason temporary staff may be associated with a higher number of medical errors?
   A. They are often less educated than other staff.
   B. Temporary personnel are often not familiar with local staff, care management systems, protocols, or procedures.
   C. Employers do not take the time to properly credential temporary personnel.
   D. They are less dedicated to their jobs than other staff.

3. According to the FBI, how did the man accused of illegally tampering with the data system of Shionogi obtain access?
   A. He used a Shionogi user account to access a Shionogi server and then took control of a piece of software that he had secretly installed on the server several weeks earlier.
   B. He used a weakness in the employee access format that he had discovered but not reported.
   C. He repeatedly tried to access the system at high speed until the system was overwhelmed.
   D. He worked with a friend still employed at Shionogi to obtain a valid entry password.

4. In the recent privacy breach at Stanford Hospital & Clinics, what do the hospital representatives say was the source of the breach?
   A. A hospital employee mistakenly attached a patient data file to a web site posting.
   B. A patient mistakenly received a file containing the information of other patients and disseminated it.
   C. A hacker entered the hospital's system and stole the patient data.
   D. A vendor's subcontractor created the file in the process of legitimate financial analysis but posted it on a public web site.

CNE INSTRUCTIONS

Nurses participate in this CNE/ CME program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. *First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.*
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

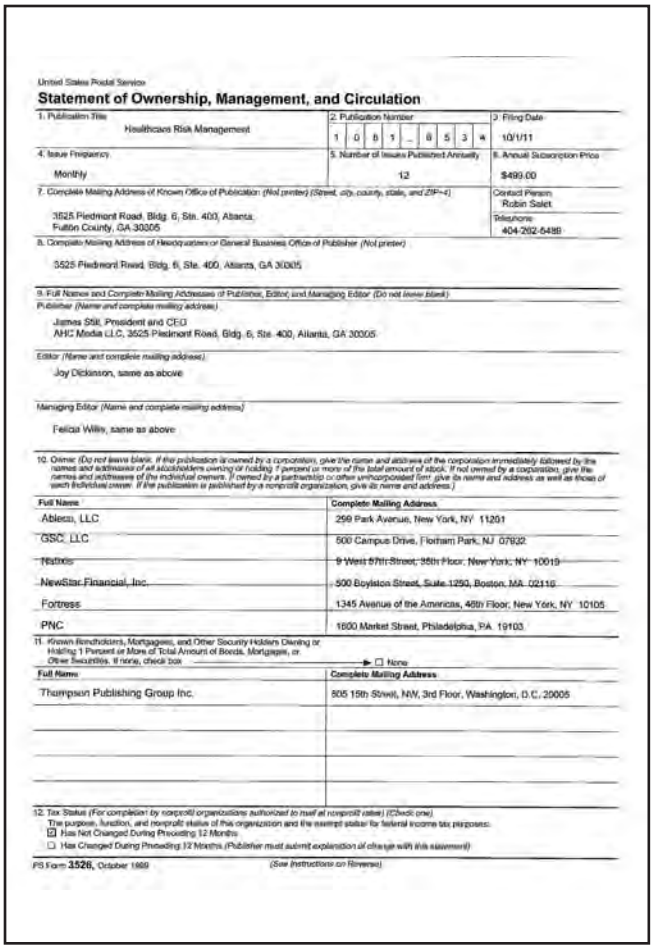
CNE OBJECTIVES

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

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

COMING IN FUTURE MONTHS

- Mandatory reporting of adverse events
- Tips for saving on fleet insurance
- HIPAA reports could aid plaintiffs
- Focus on preventing employee falls



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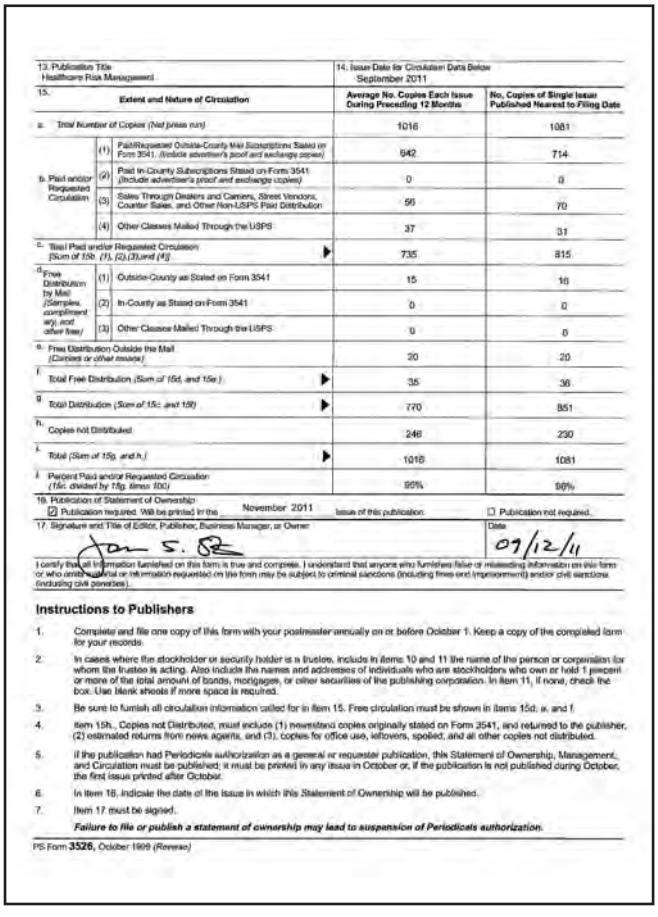

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Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Alleged failure to monitor high fall risk leads to brain injury, $500,000 settlement

By **Radha V. Bachman**, JD, LHRM
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and **Lynn Rosenblatt**, CRRN, CCM, LHRM
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News: A 66-year-old man presented to the hospital with symptoms of alcohol withdrawal. The man was placed on an IV and put in bed. The patient later attempted to get out of bed, but he fell down and struck his head on the floor. The hospital settled with the man for $500,000.

Background: A self-employed 66-year-old man presented at a local emergency department appearing to have alcohol withdrawal syndrome. He was seen by the emergency physician, who placed him on a "banana-pack IV," or an IV containing vitamins and minerals. The bags typically contain thiamine, folic acid, and 3 g of magnesium sulfate, and they usually are used to replenish nutritional deficiencies or correct a chemical imbalance in the human body. The multi-vitamin solution has a yellow color, hence the term "banana bag."

Upon receiving the IV, the man was placed in the care of the floor nurse. The nurse apparently instructed the man to remain in bed or request assistance if he needed to get up from the bed, but despite these instructions, the man attempted to get out of the bed by himself. The nurse tried to intervene, but the man fell and struck his head on the floor. Following the accident, he was diagnosed with a subdural hematoma and underwent emergency neurosurgical evacuation. The man remained in the ICU for four weeks before beginning two months of inpatient neurocognitive treatment. The man remains mildly to moderately brain damaged.

The man's appointed guardian sued the hospital for negligence. The guardian argued that the patient presented a very high fall risk and that strict fall precautions should have been employed. The plaintiff further contended that the fall precautions should have been fully communicated to the patient and his family, which was not adequately done in this case.

In its defense, the hospital argued that it was compliant at all times with the standard of care. In calculating potential damages, the plaintiff proffered evidence that the man was making about $125,000 per year and that he would have continued working as a heavy equipment broker until age 72. The hospital's experts countered that the man's abuse of alcohol would have limited his ability to work. The parties ultimately entered into a settlement in the amount of $500,000.

What this means for you: This patient had been identified as having alcohol withdrawal syndrome, which certainly alerts the staff to the

Financial Disclosure: Author **Greg Freeman**, Executive Editor **Joy Daughtery Dickinson**, and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Radha V.Bachman**, guest columnist, have no relationships to disclose. **Lynn Rosenblatt**, guest columnist, has no relationships to disclose. **Leilani Kicklighter**, guest columnist, discloses that she is owner of The Kicklighter Group and is course coordinator and lecturer on healthcare risk management at the University of South Florida.

probability that he would experience delirium tremens (commonly known as the DTs) to some degree.

Delirium tremens is a severe form of alcohol withdrawal that involves sudden and severe mental or nervous system changes. Symptoms most often occur within 72 hours after the last drink, but they may occur up to 10 days after the last drink. Symptoms may get worse quickly and can include body tremors as well as changes in mental function. Significant to a patient's presentation is agitation, irritability confusion, disorientation, and decreased attention span.

The patient might experience periods of delirium, hallucinations with which he or she sees or feels things that are not there, quick mood changes with restlessness, and agitation. The patient also might be overly fearful, in a stupor, and overly sensitive to noise, light, and touch. Seizure activity is also possible, but more likely within 48 hours of the last drink.

Obviously such a patient is at an extremely high risk for falls, as any of the above symptoms could induce the patient to get up unexpectedly, roll out of bed, or merely not have the cognitive ability to follow directions. Such patients are incredibility impulsive, which defies personal safety.

Instructing a patient suffering from delirium tremens to remain in bed and use a call light is in the same vein of giving such instructions to a 4-year old. They are either quickly forgotten or totally ignored. The impulses to get up for whatever reason is the driving force, not safety restraints.

Hospitals have policies that dictate a fall assessment on admission, but those policies might be limited to higher risk units and not universal across all services. While there are standardized assessment instruments, some might be irrelevant to certain classes of patients for whom falls are more likely based on the diagnosis or patient's presentation at the time the assessment is administered.

While the patient might be alert and responsive on assessment at the time of admission and score within a safety zone, in terms of fall risk, the underlying diagnosis might be of greater value in determining what safety precautions might be needed. In this case, the patient's alcoholism predisposed him to the DTs as he was being detoxified. With each successive hour without a drink, the potential for cognitive dysfunction, confusion, and agitation increased. These are all high risk areas that predispose falls.

Fall prevention strategies are varied and should be specific to the patient's cognitive presentation and behavioral indicators. For those who are alcoholics and in withdrawal, they frequently display disruptive behaviors that are poorly controlled. The nursing staff should be trained to expect and anticipate such behaviors and the inherent risks.

It is to be expected that the patient will try to get up. Balance is also a problem for drinkers and the root of the expression "falling down drunk." Patients who are delirious and have visual hallucinations will exhibit agitation and perhaps fall out of bed.

Researchers and medical professionals already know that chronic, excessive alcohol consumption causes cognitive and motor deficits. Operating as a central nervous system depressant, alcohol produces a dose-dependent decrease in cognitive and motor functioning, which is another indicator of potential falls. It is also an indication that personal safety must extend beyond the patient to the family, as they will be more compliant than one could ever hope the patient to be.

For those who are alcoholics in withdrawal, they rarely have family with them and usually go it alone. Or if the family is available, there are frequently emotional barriers to witnessing the withdrawal symptoms, and they stay remotely attached but nonetheless supportive.

While the plaintiff contended that the fall precautions should have been fully communicated to the patient and his family, which was not adequately done in this case, any instructions given were not going to be effective if not coupled with strong preventive measures. In this case, the patient should have been under close observation at all times to ensure that should he attempt to get out of bed, someone could immediately intervene. Documentation should include the number and frequency of attempts to get up, so that increased activity is noted and so that measures can be taken promptly to address escalating behaviors. A bed alarm should be in place. All four rails should be in the up position, with nurses ensuring that the patient is given the opportunity to get up to the bathroom as needed.

The Joint Commission states that four rails constitute a restraint, so an order must be obtained, and the patient must be observed at

scheduled intervals. While this situation requires manpower, it is certainly preferable to a serious injury fall and the resulting liability.

Hospitals have fall prevention policies, but risk managers need to question whether those policies are sufficient for every population group and investigate how those policies are disseminated across all services and staff. In this case, it does not appear that anything was done to anticipate that the patient would not act as a coherent responsible adult.

REFERENCE:

Superior Court of California, Confidential. ■

Settlement for alleged failure to diagnose

Confidential settlement reached in NC

By **Radha V. Bachman**, Esq.
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Tampa, FL
and **Leilani Kicklighter**, RN, ARM, MBA, CHSP, CPHRM, LHRM
The Kicklighter Group
Tamarac, FL

News: After returning to North Carolina following a trip, a young man presented at his local hospital feeling ill. The man was seen by a physician, and a chest radiograph was ordered. The physician ordering the test and the radiologist interpreting the test noted different findings, and there was later a disagreement as to whether the two physicians met to discuss the contrary findings. Within two months, the man had died as a result of an apparent fungal lung infection, which had developed during the man's trip to California. The man's estate filed a lawsuit, and a confidential settlement was reached with the hospital after a jury found the hospital liable but before the damages phase of the trial commenced.

Background: Shortly after returning to North Carolina after visiting family in California, a 24-year-old man began to feel ill and went to his local hospital. The man was seen by an internist who ordered a chest radiograph. The test was read by the internist and the hospital's board certified radiologist. The internist diagnosed the man with pneumonia, and the radiologist saw a "diffuse micronodular pattern . . . associated with tuberculosis or acute histoplasmosis," which required clinical correlation with the internist's diagnosis. The radiologist later claimed, at trial, that he met with the internist to discuss the findings, but this allegation was denied by the internist.

Ultimately, the man's condition worsened, and he died two short months later from a fungal lung infection. The infection apparently was caused by exposure to fungal spores that cause coccidiodycosis, a lung disease known as "Valley Fever," while in California.

The man's mother brought suit on behalf of her son's estate and claimed that the failure to timely diagnose and treat her son for a fungal lung infection was the proximate cause of his premature death. The mother alleged that the failure of the physicians to adhere to hospital policy requiring the radiologist to fill out a discrepancy report was a breach of the standard of care. The radiologist admitted at trial that he had not filled out such a report.

The defendants countered the plaintiff's allegations by arguing that no treatment could have prevented the man's death, as the infection already had moved from the patient's lungs to his brain at the time he presented to the hospital.

The judge bifurcated the trial into two phases, the first dealing with the defendants' liability, and the second focusing on the plaintiff's damages. The bifurcation was ordered due to a question surrounding the rightful heirs of the man's estate. The initial phase jury found liability on the part of the hospital but cleared the internist in its verdict. Before the damages phase of the trial commenced, the hospital and the plaintiff reached a confidential settlement.

The lawyer who represented the man's estate was quoted in "Lawyers Weekly" as saying, "The major significance of this case involves the corporate negligence theories we advanced and supported with the evidence, and which the jury clearly based its verdict upon." Other lawyers in the case saw the claim as one where the plaintiff relied strictly on the failure of a hospital to follow its own policies and procedures for reporting important information from radiographs to the appropriate physician.

What this means to you: A healthy young

man comes in for a chest X-ray that shows abnormalities. There is a discrepancy between the ordering internist and the radiologist as to what the films reflected. From there, things went awry and ended in the death of the patient. What a sad outcome.

It is unclear if the internist was the patient's private physician, the emergency department (ED) physician, or the on-call internist. It is further unclear if the internist read the film as a "wet read" — a preliminary read in the ED — or if the internist went to the radiology department and read the films. If the films were read in the ED, the usual procedure is for the ED physician to note the preliminary read on the film that is considered by the reading radiologist against the official reading. If there is a discrepancy between the official read, done by the radiologist, and the ED physician's wet read, the radiologist usually calls the physician who did the initial wet read to advise of the discrepancy and documents in the dictation that the physician was contacted. Part of this process is to track the discrepancies for trends and patterns by type of film and physician as a component of the quality improvement program.

There is also a reference to the radiologist's failure to complete a discrepancy report, but we have no further information regarding this program. One wonders exactly what such a report would provide in this situation, to whom the report would be sent, and how it would have provoked a timely patient care intervention.

This situation is another example of how important documentation, or in this case, lack of documentation, can be. The hospital and radiologist were held responsible in this case, but not the internist. Discussion in this scenario relates to failure to follow established hospital policy and procedure to document the discrepancy. The radiologist claims he did discuss his findings with the internist, but that discussion was not documented. Documentation by either physician might have addressed this particular issue in this lawsuit, but one wonders whether it would have been the basis of a correct diagnosis.

A root cause analysis of this situation would determine why the communication between the internist and the radiologist failed and how the process can be emphasized. However, this case begs the question why the patient's signs, symptoms, and history, over the last two months of his young life with a diagnosis of pneumonia, didn't lead to the correct diagnosis and treatment. If this patient were followed by the internist and the pneumonia was not resolving, why wasn't another chest X-ray taken or an infectious disease specialist brought in to consult? It would be appropriate for the risk manager to refer this case to peer review and to medical grand rounds to be addressed from the medical treatment perspective.

The internist testified that the Valley Fever had progressed to the patient's brain by the time he presented to for treatment. This diagnosis seems questionable, as we have no evidence of further X-rays being taken or what neurological signs and symptoms were presenting.

Valley Fever, like Lyme's Disease, can be very difficult to diagnose depending on the time of exposure, the development of the signs and symptoms, and the time the patient presents to the physician. In these and other such regional diseases, the diagnosis often is missed unless the physician is attuned to the signs, symptoms, and history of travel.

This case raises the issue of corporate negligence liability. Risk managers and middle and senior management should become familiar with corporate liability such as in this case for failure to follow established policy and procedures. Management and staff should be advised and re-enforced the need to follow policies and procedures. Risk management should be an advocate to facilitate that policies and procedures follow practice, and practice follows policies and procedures. Staff is held to the established policies and procedures but often do not know all applicable policies and procedures in the manuals. When one looks at the number of manuals of policies and procedures in a facility, it is understandable that many staff have never read them all.

Risk management should facilitate a system that allows and supports easy and ready access to policies and procedures to staff to review. Furthermore, steps should be taken to ensure that the members of the medical staff are familiar and abide by the organization's established policies and procedures.

REFERENCE:

Jackson County Superior Court (NC), Case No. 09 CVS 261 ■

HIPAA Regulatory Alert

Supplement to *Healthcare Risk Management* and *Hospital Access Management*

Will your patients have more access to laboratory results? It's proposed

New rule will enable patients to bypass physicians

As hospital compliance officers prepare for a proposed increase in patient access to medical records' information, another proposed rule increases access to laboratory results. Comments on the laboratory proposed rule must be received by Nov. 14. (For more information, see "Proposed rule allows patients to see record access details," HIPAA Regulatory Alert, August 2011, p. 1)

The latest proposed rule related to medical records allows patients to access test result reports directly from labs as opposed to receiving the information from their physicians. Under existing Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, a laboratory may release patient test results directly to the patient only if the ordering provider authorizes the laboratory to do so at the time the test is ordered, or state law allows for it. Although the HIPAA Privacy Rule allows patients access to their medical records, the privacy rule defers to CLIA regulations in the case of laboratory results, explains Jane Pine Wood, Esq., an attorney at McDonald Hopkins, in Dennis, MA. This difference means that in the 26 states without laws authorizing direct disclosure of test results to patients or the 13 states that expressly prohibit it, patients do not have direct access to their laboratory results. (For more information about how state laboratory access laws differ, see resource box, p. 3.)

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Bill Wilson, administrative director of the laboratory at Stamford (CT) Hospital, says, "Patients should be able to get their test results directly from the lab. The Internet makes it easy for people to understand what their cholesterol results or blood sugar levels mean." Laboratories in Connecticut can release reports directly to the patient with the ordering provider's approval. "We ask for the patient's identification, verify that it is their information, and give them a printed copy of the results when they request one," he adds.

Although ac-

EXECUTIVE SUMMARY

Increased patient access to personal health information is a key focus of proposed HIPAA rules affecting hospitals. Hospital laboratory managers and compliance officers have until Nov. 14 to comment on the latest proposed rule that will give patients the right to receive laboratory test results directly from the laboratory rather then only through the physician.

- The most significant concern is the inability for patients to understand the implications of many test results without the consultative advice of a physician.
- Hospital labs must determine protocols to ensure proper identification of person requesting information as well as how to distribute results to patients.
- Because Medicare and most insurance will not cover the cost of providing additional reports, hospitals must determine if and how they will charge patients for the expense.

cess to lab results can help patients ask more specific questions of their physicians and make informed choices about lifestyle changes, the challenge that needs to be addressed is related to the more complex tests that may be ordered, says Wilson. "Without a physician's interpretation and explanation of the results, the patient won't know what to do with them," he explains.

Rodney W. Forsman, president of the Clinical Laboratory Management Association in Chicago and assistant professor emeritus of laboratory medicine and pathology at Mayo Clinic in Rochester, MN, says, "A significant issue that must be addressed is the fact that the role of the physician's interpretation and consultation with the patient will be subverted when patients get the results directly from the lab."

It will be important for labs to develop a cover letter for all results given directly to patients that instructs them to call their physician to discuss the meaning of the test results, Forsman suggests. "Lab personnel will need to make it clear that they cannot explain the meaning of results," he adds. "Other issues that must be addressed include the method of delivering results to patients, how to verify the patient's identity when making a request, and how to cover costs associated with providing results directly to patients. Some hospitals already give patients access to lab results through a secure web site, so it will not be an issue for them."

> ***"The best place to get information on what test results mean is the physician."***

Other hospitals will need to develop a protocol that addresses whether to provide print copies of reports that are mailed to the home address or electronic copies of reports that are transmitted through e-mail, he points out.

Wood says, "Some reports may be as many as 30 pages, and even if the report is short, staff time is needed to find the report, print it, and mail it. Hospital billing departments will not want to handle charges of $5 or $10 for producing and mailing the report, and insurance will not cover the cost, so hospitals will have to decide if they are going to provide the service free."

At Stamford Hospital, reports to the physicians are automatically sent to a secure fax line identified by the physician, so no staff time is involved to produce and send the report, Wilson says. "We can set up the system to generate a report for the patient, but at this time, the only way to send it electronically is to a fax," he says. "We don't use e-mail for reports because we don't have a way to be sure the transmission is secure."

Concerns about e-mailing reports should not be an issue, says Wood. "If the patient instructs a lab to send the report by e-mail and provides the e-mail address, it does not violate any privacy regulations," she says. Some states may require that the lab encrypt the message that is sent, but there is no requirement that the receiver take any security measures, Wood adds.

While hospital lab managers and compliance officers should be thinking about protocols that might need to be developed, be aware that comments on the proposed rule are being accepted until Nov. 14, she points out. There may be changes to the proposed rule that might affect actual procedures the lab must take, Wood adds.

Forsman says, "Hospitals have always been required to provide the patient's medical record when requested, and although CLIA regulations prohibited the release of lab results to patients, many hospitals either do not take time to delete lab reports in the record or are unaware that they are supposed to do so. So patients have been receiving lab reports in their medical records." The change that the proposed rule represents is that it supersedes state regulations and existing CLIA regulations that prevent release of reports directly to patients, he explains.

Overall, the proposed rule is a good step, says Forsman. "Information can help patients make positive changes in their lifestyle to improve their cholesterol or blood sugar levels, and a lab test can reinforce the benefits of their efforts," he says. "It can also help patients prepare to ask questions of their physicians."

The most important task of all labs will be to find a way to keep the physician in the loop, admits Forsman. "The best place to get infor-

mation on what test results mean is the physician," he points out. "We may need to develop procedures to notify physicians when their patients ask for results to be given directly to them, so they can follow up, because unfortunately, not all patients will go back to the physician if they think they have their answers."

SOURCES/RESOURCES

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• To see a copy of the proposed rule and to see information on how to submit comments, go to www.gpo.gov/fdsys. On the right-side navigational bar under "Featured Collections," select "Federal Register." Then select "2011" and choose "September" and September 14." Scroll down to "Health and Human Services." Under "Proposed Rules" select "CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports Pages 56712 - 56724 [FR DOC # 2011-23525]" Comments about the proposed rule must be submitted by Nov. 14, 2011.

• To access a free copy of "Electronic release of clinical laboratory results: A review of state and federal policies" go to www.chcf.org. Under "Browse" and under "Topics," select "Health IT." On the left side of the page, under "Health IT," select "PHRs and Privacy." Scroll down to ""Electronic Release of Clinical Laboratory Results: A Review of State and Federal Policy." n

HHS reports complaints and breaches to Congress

Data breaches impact almost 8 million people

More than 57,000 complaints of Privacy Rule violations were received by the Health and Human Services' (HHS) Office for Civil Rights (OCR) between April 2003 and December 2010. More than 250 large data breaches, defined as those involving the protected health information of more than 500 individuals, occurred in 2009 and 2010.

These are just a few of the statistics reported to Congress by HHS as mandated by the Health Information Technology for Economic and Clinical Health (HITECH) Act. More than 19,000 of the Privacy Rule complaints were investigated, with no violation found in 34% of the cases. Of the 800 complaints about Security Rule violations received, nearly half of the 290 complaints investigated were not found to be violations.

The most common compliance issues with the Privacy Rule that the OCR investigated were the following, in order of frequency:

• impermissible uses and disclosures of personal health information (PHI);
• lack of safeguards of PHI;
• denial of individuals' access to their PHI;
• uses or disclosures of more than the minimum necessary PHI;
• inability of individuals to file complaints with covered entities. The most common areas for which entities failed to demonstrate adequate policies and procedures or safeguards, as required under the HIPAA Security Rule, include the following, listed by frequency:
— response and reporting of security incidents;
— security awareness and training;
— access controls;
— information access management;
— workstation security.

A separate report on data breaches in 2009 and 2010 showed that covered entities notified a total of 7.8 million people that their protected health information (PHI) was compromised in a data breach. The most common cause of data breaches in both years covered by the OCR report was theft of paper records or electronic media containing patient information. Other top causes of breaches included unauthorized access, use or disclosure of protected patient information, and human error.

In addition to the large breaches, covered entities reported more than 30,500 smaller breaches to HHS in 2009 and 2010. The OCR report indicated that most of those breaches affected just one individual and were caused by misdirected communications, such as mistakenly mailing or faxing clinical or claims data or test results to the wrong person. (Editor's note: To see a copy of the full reports presented to Congress, go to www.hhs.gov/ocr/privacy. Under the "Reports to Congress" section on the right navigational bar, choose "HITECH Act Reports to Congress, 9/1/11.") ■

Study says e-mail is source of data leaks

Unencrypted mobile devices contribute

E-mail practices and mobile e-mail cause the most concern for data protection and regulatory compliance, according to the 830 individuals whose responses were included in a study conducted by the Ponemon Institute and Zix Corp., an e-mail encryption service.

When examining everyday e-mail practices, the study found:

• The majority of respondents strongly agree or agree that the use of e-mail by employees is one of the main sources of data leakage in their organizations.

• 70% of respondents are concerned about the loss of information via e-mail on mobile devices.

• Based on survey results, respondents believe employee behavior continues to place organizations at risk.

• Nearly 70% believe employees ignore policies about e-mailing unencrypted sensitive or confidential documents through insecure channels.

• More than 60% believe employees mistakenly send unencrypted confidential information to other recipient(s) outside the workplace.

• More than 60% believe employees send unencrypted confidential information through insecure e-mail channels, such as personal web-based e-mail.

As more business is conducted outside the office, mobile security has gained considerable attention as a potential threat to data protection and compliance. The study revealed 70% of respondents are concerned with data loss via mobile e-mail. As a result of this concern and the complexity of e-mail encryption on mobile devices, less than one-third of respondents have ever opened an encrypted e-mail on a mobile device.

To see a copy of the full report go to survey.zixcorp.com/downloads/ZixCorpPonemonE-mailEncryptionSurveyReport.pdf. ■

Leon Rodriguez to head up OCR

Leon Rodriguez, the new leader of the government's HIPAA privacy and security enforcer, last served as chief of staff and deputy assistant attorney general for the Department of Justice Civil Rights Division.

"Leon Rodriguez brings a strong record of integrity, leadership, and judgment with his outstanding expertise as a state and federal prosecutor," said HHS Secretary Kathleen Sebelius. "He has devoted his career to ensuring that individuals have access to healthcare, including children and families, the elderly, and people with disabilities. He will also spearhead the department's continued work to ensure greater consumer confidence through strong and effective enforcement of the privacy and security of protected health information."

Rodriguez' background includes serving as the county attorney for Montgomery County, MD, as a shareholder in the Health Law Department of Ober, Kaler, Grimes & Shriver, and was the first assistant U.S. attorney, serving in Pittsburgh, PA, assigned to the prosecution of healthcare fraud cases. ■

Timeline widget for HIPAA 5010

Interactive tool keeps you on track

Beginning Jan. 1, 2012, providers must use the new HIPAA 5010 transaction standards to conduct certain administrative transactions such as claims, remittance, eligibility and others, but not all providers are ready for the transition to new standards, and that lack of preparedness could affect transition to ICD-10 as well.

A free timeline widget to help hospitals stay on track for transition to the new standards is available on the Centers for Medicare and Medicaid Services web site. The interactive tool gives healthcare providers a plan to implement HIPAA Version 5010 as well as ICD-10. To download the widget, go to www.cms.gov/ICD10. On the homepage, in the first sentence of the "Welcome," click on "timelines." This selection will take you to page with the timeline tools and instructions on how to download and use them. ■