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Fake CPR certificates show need to check credentials for more than MDs

Hospital finds staff falsifying proof of required training

When the University of California, Irvine (UCI) Medical Center discovered that 22 health care workers had used bogus certificates in cardiopulmonary resuscitation (CPR) to prove they were current with required training, leaders at the hospital were shocked. They immediately launched an investigation and cooperated with campus police.

They found that the problem was serious and required an immediate assessment of their policies and procedures on verifying credentials. What they found also highlights how important it is for risk managers to have proper procedures for verifying the credentials of all staff — not just physicians and nurses.

The problem at UCI was discovered during a routine renewal of a CPR certificate in a training class in May 2007, says **Lisa Reiser**, RN, MN, chief patient care services officer and chief nursing officer. The instructor noticed that an employee's old card looked unusual, unlike any she had seen before even though the cards may appear different depending on where the employee underwent CPR training. Upon investigation, the hospital determined that the card was fraudulent.

That one curious CPR card sparked an internal review of all 2,000

EXECUTIVE SUMMARY

A California hospital recently found that workers were falsifying the proof of required medical training. Results of the hospital's investigation highlight the need for risk managers to verify the credentials of all staff, not just physicians and nurses.

- The liability risk from falsified credentials is high.
- Employees may falsify credentials for convenience.
- The discovery of bogus training certificates is not necessarily proof that your policies and procedures are inadequate.

employees with CPR certification, led by the human resources department. Doctors, nurses, and assistants at UCI Medical Center are required to renew their CPR certification by taking a test every two years. The free course, endorsed by the American Heart Association, lasts less than a day and is offered during work hours at the medical center.

Hospital investigators checked the CPR cards held by all employees and looked for any sign that the cards were bogus, such as poor printing quality or an unfamiliar training provider. They found that 22 employees had fake cards.

UCI Medical Center removed all 22 workers from patient care while the investigation continued with a multidisciplinary team that included human resources, compliance, clinicians, risk management, and the public information office. The first priority was protecting patient safety, but the hospital also wanted to ensure that the investigation was thorough and fair to the employees. "The employees pretty much admitted to what occurred. They said they falsified the cards," Reiser says. "It was an unfortunate incident and a good lesson for us to learn."

Can be difficult to verify cards

Reiser notes that CPR cards and similar certifications held by staff can be more challenging to verify than a physician's credentials because there are so many providers. To verify a physician's education and licensure, the hospital can go to the university and the state database, for example. But for CPR cards and similar training, there are many sources and the employer often relies on the physical proof provided by the employee. As UCI Medical Center found out, that proof can be easy to fake.

The UCI Medical Center found that the employees who faked their CPR cards had some connections within the hospital, but Reiser declines to say exactly how they knew each other. The staff members were from different patient care areas, she says. Because there was some connection and cooperation between the involved employees, the hospital views the case more as one incident in which 22 cards were faked, rather than 22 completely separate and unrelated incidents, she explains.

"That is less than 1% of our employees, which is still enough for us to be concerned," Reiser says. "It would have been worse if we found 22 isolated incidents of this, as opposed to all of them being connected."

Hospital leaders took the incident very seriously, Reiser says, and invited the university police department and the American Heart Association to participate in the investigation. No criminal charges resulted, but the hospital is disciplining the 22 employees found to have fake cards. Reiser says the hospital still is working through the disciplinary process and cannot comment on the specific punishment for any employee.

"We offer the CPR course here and make it really easy for staff to get that certification. In the past year we have had 700 employees get certified through us," Reiser says. "So as far as why these staff members didn't take advantage of that and went this route instead, we can't really say."

Falsified credentials are common in health

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care, says **Mark Anthony Kadzielski**, JD, a partner with the law firm of Fulbright & Jaworski in Los Angeles. Kadzielski works with health care providers facing liability from falsified credentials and those trying to improve their verification processes. He says the problem is less common among medical staff, partly because employers tend to verify their credentials and partly because it is harder to falsify something as substantial as physician licensure, for instance. **(See below article for more advice on how to spot bogus qualifications.)**

"It's easier to falsify something like CPR certification, and employers are usually eager to hire those people. They might be in desperate need for employees for coverage, and you might not go the extra mile to ensure they are as qualified as they say," Kadzielski says. "Corners get cut because you need warm bodies."

Health care providers often focus exclusively on verifying the credentials of medical staff, Kadzielski says, and they ignore the liability risk from staff members who lie about their qualifications. The risk from the staff level is significant, he says.

"The CPR card maybe doesn't sound like a big deal to some people, and maybe that's why they didn't bother taking the class," Kadzielski says. "But the worst case scenario is the employee has to give CPR to someone, it doesn't turn out well, and then the plaintiff's attorney starts waving that fake CPR card in court, asking why the hospital didn't bother to verify it. The argument will be that 'If he had been properly trained in CPR, he could have saved Grandma.'"

The employer would be liable because the hospital, in effect, asserted that the employee was competent in CPR when he or she actually wasn't, and it was the hospital's obligation to confirm the training. An unreasonable expectation? Maybe, he says, but that decision could be left to a jury, and a fake CPR card would be a sensational revelation in court. **(See article, right, for more on the potential liability from falsified credentials.)**

Kadzielski also points out that The Joint Commission and state regulators may check training and certification during site visits. "Imagine if the surveyor asked to see an employee's CPR card, and it looked like a really bad fake," he says. "That's going to be a bad day for you."

Reiser says UCI Medical Center leaders tried to respond aggressively but reasonably to the discovery of the false certifications. The hospital thoroughly investigated and initiated disciplinary action as appropriate, she says, but at the same time hospital leaders did not want to overreact and assume the incident meant current policies and procedures were inadequate.

"This resulted from individual bad judgment," she says. "The immediate response is wanting to put in more controls to make sure this doesn't happen again in the future, but you have to balance that with what is realistic to do."

Source verification can be labor-intensive and time-consuming for CPR cards, Reiser notes. Even if an investigator calls each training provider to verify the card, many providers don't have a database for quick access. They have to go find the paper sign-in sheet to see if the person's name is there, she adds.

"So instead of implementing a verification process that might be unrealistic and unnecessary, we're taking a longer view and looking at our certification requirements and how they might be improved in a way that would make it easier to verify the certification," she says. Possible changes could include requiring staff to be certified in-house at UCI, but hospital leaders first want to be sure the added administrative burden would be justified.

"The take-home lesson from this experience is that you have to balance the response organizationally and the processes you may or may not change, especially when the problem is individuals acting egregiously with no just cause," Reiser says. "We didn't feel that this incident revealed some major flaw in our system, so we don't want to overreact with new policies and procedures." ■

SOURCES

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Exaggeration can be falsification, attorney says

Verifying the qualifications of staff can sometimes mean trying to decide when embellishment crosses the line into falsification,

SOURCE

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says **A. Kevin Troutman**, JD, an attorney with the law firm of Fisher & Phillips in New Orleans, who assists hospitals with risk management projects.

Troutman says risk managers should remember that if patient harm results, plaintiffs' attorneys and jurors will look critically at the decision you made. That means you should have a low threshold for declaring an applicant or employee's submission to be falsified, he says.

"One thing you can do is ensure that your application forms include the warning that any material misrepresentation or omission, when discovered, is grounds for termination," Troutman says. "That sets the groundwork from the beginning, sending the message that you're taking a hard line position on this and you want the complete truth up front."

Without such reminders, employees and applicants can be lax and assume that a little embellishment or a white lie does no harm, he says. Troutman also suggests including the reminder in orientation sessions, and the employee handbook should state that "any information provided to the employer on an ongoing basis must be accurate and complete, and any material omission or misrepresentation is grounds for termination." ■

No shortage of lies on job applications

Once you start checking applicants' qualifications diligently, you may be surprised at just how much people lie and exaggerate, says **Robert Mather**, CEO of Pre-Employ.com, a company in Redding, CA, that conducts background checks for health care providers and other employers.

Mather recommends health care employers check the qualifications of anyone who could potentially put the organization at risk. That checking should include all professional staff such as physicians, but then your budget will determine how far down the pyramid you go with checking an applicant's background, he says.

"If you have the budget for it, check everyone's background and everything they say on their applications," he says. "But in reality, few employers are going to do a complete background check on the janitorial staff and take the time to call and verify everything on their applications. You do have to draw the line somewhere."

Mather recommends asking this question when determining how to use limited resources in verifying qualifications: If this person is lying, what are the potential consequences? The worse the potential outcome, the more you need to verify qualifications, he says.

The most common falsification is lying about educational degrees, Mather says, followed by licenses. Embellishment and "fudging the facts" are more common than blatant lies, he says. "The same holds true for past employment history as well as licensure and education," he says. "It's less common for someone to say they received a degree from a university where they never sat foot on the campus than it is to say they have the degree when they actually were a few classes short. Either way, it's falsification that you need to know about." *(Editor's note: For more information on background checks for employees, contact Mather at P.O. Box 491570, Redding, CA 96049. Telephone: (800) 300-1821, ext. 124. E-mail: bob.m@pre-employ.com. Web: www.pre-employ.com.)* ■

Adverse events rise, but meaning debated

A new study shows the number of drug therapy-related deaths and injuries reported to the Food and Drug Administration (FDA) nearly tripled between 1998 and 2005,[1] but exactly what those numbers mean is the subject of some dispute. Do they mean that these years of increased attention to preventing drug errors were for naught?

Not necessarily, say the experts, but the number of errors may mean that risk managers should focus on exactly what kind of errors were revealed in the study — particularly, new biotechnology products.

A researcher at Wake Forest University School of Medicine in Winston-Salem, NC, and colleagues reviewed serious and fatal drug events reported in

EXECUTIVE SUMMARY

New research indicates that the number of adverse events related to drug therapy has increased significantly since 1998, but experts disagree on exactly what the numbers mean. Some analysts say the increase is merely the result of better reporting, but some suggest that risk managers should see the report as a warning sign.

- The study specifically addressed serious and fatal drug events, not all adverse events.
- The number of serious adverse drug events increased at a faster pace than the number of prescriptions in the same time period.
- Current risk management efforts may be insufficient for new biotechnology drugs.

that eight-year period to the FDA by consumers, health professionals, and drug manufacturers. They found that serious adverse drug events increased 2.6-fold, from about 35,000 to nearly 89,000, and adverse drug-related deaths increased 2.7-fold, from about 5,500 to more than 15,000.[1] **(For more details on the study, see p. 126.)**

The FDA receives these reports of serious adverse drug events through its Adverse Event Reporting System (MedWatch). This system has been in operation under the same database system since 1998, with consistent regulatory requirements for drug manufacturers.

A few drugs account for many errors

The study also reported serious events increased four times faster than the total number of outpatient prescriptions during that period, and that is an important point, says **Curt Furberg**, MD, PhD, professor of public health sciences at Wake Forest University School of Medicine and a co-author of the report. "It shows current efforts to ensure the safety of drugs are not adequate, and that physicians and patients are unaware of these risks," he says.

Furberg has previously called for far-reaching changes in drug safety regulation, including expanded authority for the FDA, higher priority for drug safety, and new systems to monitor drugs once they are approved by the FDA. For risk managers, a key finding from the study is that many of the adverse drug events involved the same medications, says **Thomas J. Moore**, AB, lead author of the study and a senior scientist for drug safety and policy at the Institute for Safe Medication Practices (ISMP) in Huntingdon Valley, PA.

"The study found that a relatively small number of drugs accounted for the most reported serious adverse drug events," he says. "This represents an opportunity to focus efforts at reducing and preventing adverse events by focusing on those common elements."

More errors or just more reporting?

The study is intriguing, says **Deborah A. Wible**, PharmD, chief pharmacy officer at Beth Israel Medical Center and St. Luke's — Roosevelt Hospital Center in New York City. However, Wible draws a somewhat different conclusion than the authors. While she does not doubt that the number of adverse drug events is high, she says the study's time period coincided with a major push in health care to more fully and accurately report drug errors. Thus, she suspects that the results are skewed by increased reporting.

Furberg says the researchers took into account several factors that might influence their findings. "We saw no evidence that doctors and patients had become more active in reporting events in some across-the-board fashion," Furberg says. "We also tried to eliminate 'noise' in the reporting system, by excluding reports from more than 14 days after a drug was withdrawn. In addition, we excluded events that were not serious and foreign reports to focus on U.S. risks."

Wible says risk managers should not be unduly alarmed by the apparently distressing numbers in the report. But she says there still are meaningful data in the report. "One of the things this does is remind us that when these new drugs come out, they were tested in very controlled conditions on limited populations, and then we start using them on thousands and millions of patients," she says. "Especially with immuno-modulators and new biotech drugs, this is often when we find out a lot more about the effect of these drugs. It's a useful point to keep in mind that we still need to encourage very close monitoring of individual patients even after the clinical trials."

Fragmentation blamed for errors

There is an increased number of errors, says **Bruce Lambert**, PhD, professor of pharmacy administration at the University of Illinois at Chicago College of Pharmacy and an expert on adverse drug events and patient safety. With an

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increase in prescriptions, an increased number of errors would be expected, he says. But the way the number of errors is outpacing the increased drug use is troubling, he says.

"So why is that happening? One reason is that we have more fragmentation of the system, making it harder to manage people's drug therapy," Lambert says. "Patients are seeing many different doctors, being treated at different hospitals, and getting their drugs from different pharmacies."

Another explanation is a trend of patients living longer with more illnesses and more serious illnesses, he says. Patients also receive more outpatient care instead of hospitalization, which means there is less opportunity for close oversight of drug interactions and other potential problems. **(See article, right, for advice on what drugs need more oversight.)**

"In addition, we have more powerful medications being taken," he says. "For many of these new drugs, we need to take blood samples and monitor the effects frequently, but because of fragmentation, sometimes that doesn't get done."

Reference

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Study finds growing risk from drug errors

The recent research from Wake Forest University School of Medicine in Winston-Salem, NC, showing an increase in reported drug errors,[1] was based on data in the Food and Drug Administration's (FDA's) Adverse Event Reporting System, which has been in place since 1998.

This system collects all voluntary reports of adverse drug events submitted directly to the agency or through drug manufacturers. The researchers analyzed all serious adverse drug events and medication errors in the United States reported to the FDA from 1998 through 2005, finding that serious adverse drug events increased 2.6-fold from 34,966 to 89,842. Fatal adverse drug events increased 2.7-fold from 5,519 to 15,107.

Reported serious events increased four times faster than the total number of outpatient prescriptions during the period. In a subset of drugs with 500 or more cases reported in any year, drugs related to safety withdrawals accounted for 26% of reported events in that group in 1999, declining to less than 1% in 2005. For 13 new biotechnology products, reported serious events grew 15.8-fold, from 580 reported in 1998 to 9,181 in 2005. The increase was influenced by relatively few drugs: 298 of the 1,489 drugs identified (20%) accounted for 407,394 of the 467,809 events (87%).

Reference

1. Moore TJ, Cohen MR, Furberg CD. Serious adverse drug events reported to the food and drug administration, 1998-2005. *Arch Intern Med* 2007; 167:1,752-1,759. ■

Watch new biotech and high-alert meds

Unintentional overdose is one of the most common adverse drug events, and it often occurs simply because patients are not monitored closely enough when using new medications, says **Bruce Lambert**, PhD, professor of pharmacy administration at the University of Illinois at Chicago College of Pharmacy, and an expert on adverse drug events and patient safety.

New biotechnology drugs are the culprit in many

adverse drug events, he says, and that means risk managers may want to implement stricter controls and require more pharmacist oversight for them, as well as encouraging more education about how to use these often powerful medications. Many of them can be very dangerous, in that they affect the immune system and cause other systemic damage if not used carefully.

"Doctors, patients, and pharmacists all lack experience with these new drugs," Lambert says. "They may have been approved for relatively narrow applications but used in much larger populations. Until experience accumulates with these drugs, we may not know the best way to monitor them and manage risk, but they should be used very carefully."

Lambert advises risk managers to focus drug error risk management on high-hazard drugs. **(For guidance on what drugs represent the highest hazards, see the ISMP web site at www.ismp.org. Under "Medication Safety Tools & Resources," choose "High-Alert Medication List.")**

"Most of the actual harm comes from a relatively small number of classes of drugs," he says. "These may be opiate analgesics, anticoagulants, paralytic drugs, for instance. Risk managers should look to that list as a guide for where you can focus your prevention efforts. Start where the most problems occur." ■

Acute pain emerging as new area of liability

Liability from pain management is not a new idea for risk managers, but much of the effort in this area has focused on end-of-life issues and elder care, in which providers have faced major lawsuits alleging a failure to provide adequate pain relief.

Now malpractice defense attorneys and anesthesiology professionals are warning about an increase in malpractice claims related to acute pain management, particularly in the postoperative period. Unlike end-of-life care, these claims do not usually allege failure to provide pain relief. Instead, they are more likely to involve death and injury from overdose or improper delivery of anesthesia, says **Mariko Bird**, MD, an anesthesiologist at the University of Washington in Seattle.

Bird has studied the liability risk from acute pain management and says information from the American Society of Anesthesiologists (ASA) indicates there has been an increase in chronic pain management claims over the decades. They formed 8% of anesthesia malpractice claims in the 1990s, she says. The increased risk comes partly because acute pain management is becoming a more common part of the anesthesiologist's practice, Bird says. With more acute pain management comes more opportunity for error and malpractice, she says.

The growing risk from acute pain management is a direct outgrowth of successful claims involving end-of-life care, says **Stuart Hochran**, JD, MD, a practicing physician and an attorney with Garfunkel Wild in Great Neck, NY. "That kind of liability raised the issue of pain management as an issue that can be measured and for which a patient can claim compensation," he says. "The end-of-life issues sometimes were more clearly defined in a way, easier to determine whether the standard of care was met, whereas these acute pain cases can be more complex."

EXECUTIVE SUMMARY

Acute pain management is emerging as a new and growing liability risk. Risk managers may be more familiar with pain management as a liability risk related to end-of-life issues.

- Cases related to acute pain management often involve overdoses, not inadequate pain relief.
- Physicians might feel pressured to refer patients to specialists, but that referral does not release them from liability.
- Acute pain management cases can be more complex than end-of-life cases.

Doctors fear scrutiny on pain meds

Physicians are facing a variety of pressures regarding pain management, Hochran says. On one side, they are being pressured to provide more effective and long-lasting pain relief. On the other side, regulators and legal authorities are scrutinizing their prescribing patterns for signs of abuse.

"Everyone is watching them, and sometimes they feel they're going to be in trouble no matter which way they go," Hochran says. Unfortunately, now they have a growing concern about malpractice liability to add to their worries, he says. "It's kind of a steamrolling, slowly boiling issue," he adds.

Physicians often worry that they will be

scrutinized for having a patient on a narcotic painkiller for more than seven days, and so they think they have to refer that patient to a pain management specialist or another type of specialist for further care, he says. That often interferes with the patient's care and can itself result in liability risks, Hochran says.

"The tendency is for primary care doctors and orthopedists, who typically would care for patients for several weeks, to refer patients on to someone else as soon as the patient asks for another prescription or shows any signs of a risk of addiction," he says. "That can be a reasonable response, but you have to have a system in place that allows that patient to see a specialist without any interruption in care."

The referring physician is not automatically absolved of liability once the patient moves on, says **Ira Fox**, MD, DABPM, FIPP, founder of Anesthesia Pain Care Consultants in Tamarac, FL, and a pain management specialist. If the resulting care is substandard, there is a significant likelihood that the referring physician will be named in the lawsuit.

"Ten years ago, I was one of 150 pain management specialists in the country providing this kind of service; now I'm more like one of 150 in my area," he says. "But are all of them providing the same level of care? I don't think so, and so any physician referring a patient on for pain management needs to know that they will receive quality care."

PCA riskier than many think

Reducing the liability risk from acute pain management will require improving patient-controlled analgesia (PCA), neuraxial opioid administration, and monitoring for respiratory depression, Bird says. She notes that nerve injury associated with regional blocks has long been a significant source of liability for anesthesiologists, and that is where many acute pain management claims will materialize.

The Indianapolis-based Anesthesia Patient Safety Foundation (APSF) recently warned about a significant and underappreciated risk of serious injury from PCA in the postoperative period, Bird says. Her own review of the ASA closed claims found poor outcomes, such as death and brain damage, were common in the PCA group.[1]

"Interestingly, obesity was a factor noted in a number of our respiratory depression claims, consistent with an increased risk of opioid-induced respiratory depression in the obese patient with obstructive sleep apnea," Bird says. "Our review found that the majority of claims in the PCA/other group involved possible or probable respiratory depression. Our results also suggested that better use of monitoring devices may have prevented the complication."

SOURCES

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Policy changes could reduce risk

Bird suggests that risk managers take note of the increased risk and urge anesthesiologists to adopt recent recommendations by the APSF for improving postoperative respiratory monitoring in patients receiving PCA as well as intravenous opioids. APSF has urged additional clinician training in the prevention, diagnosis, and management of opioid-induced respiratory depression as well as appropriate patient selection for PCA and neuraxial opioids.

"APSF also recommended routine use of continuous postoperative respiratory monitoring — pulse oximetry and monitoring of ventilation — in patients receiving neuraxial opioids, PCA, or serial doses of parenteral opioids," Bird says.

Bird says opioid infusion and PCA pumps also can be a risky part of postoperative anesthesia. The APSF has criticized current technology for these pumps; it says users find them too complex and that lethal overdoses are common. Bird does not disagree with that assessment but says her study data could not confirm that assertion.

Hochran suggests that risk managers urge anesthesiology departments and medical directors to formalize policies that permit the use of short-term narcotics after the initial therapy with non-narcotic medications fail. "Much of this

comes down to good clinical decision making, but the risk manager can step in and provide support that makes that possible," he says.

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1. Bird M. Acute pain management: A new area of liability for anesthesiologists. *ASA Newsletter* 2007; 8:71. ■

Closed claim review shows common risks

Mariko Bird, MD, an anesthesiologist at the University of Washington in Seattle, recently studied the malpractice claims related to acute pain management and found 150 cases in the American Society of Anesthesiologists Closed Claims Project database, which has a total of 7,328 closed claims. The database contains standardized information on closed anesthesia malpractice claims from 35 professional liability insurance companies that insure more than one-third of practicing anesthesiologists.

"Our review found that nearly two-thirds of acute pain claims involved nerve damage, abscess, or hematoma, [most of] which were related to the neuraxial or peripheral nerve block," she says. "There is still much room for improvement to prevent nerve injury in acute pain patients and to understand why nerve injury occurs."

In analyzing the acute pain management cases, Bird categorized them as probable respiratory depression, possible respiratory depression, or no confirmed respiratory depression.[1] The proportion of claims associated with acute postoperative pain management increased between the 1980s and the 1990s, with most postoperative pain management claims from the 1990s (86% from the 1990s, 8% from 2000 or later, and 6% from the 1980s). A payment was made in 55% of claims, and the median payment, when a payment was made, was $211,650. The range was $627 to $14.8 million. Forty percent of claims were for nerve damage, and one-third of all claims were for death and brain damage.

Evidence for probable or possible respiratory depression was present in a quarter of all acute pain management claims, Bird says. She found that 20% of neuraxial block claims involved probable or possible respiratory depression and in many of these claims, there was multimodal administration of opioids. Sixty-six percent of patient-controlled analgesia claims involved death or brain damage resulting from possible

Case shows risk from acute pain care

To illustrate how acute pain management can lead to a malpractice lawsuit, **Mariko Bird**, MD, an anesthesiologist at the University of Washington in Seattle, cites the example of a 71-year-old obese female smoker with hypertension and diabetes who underwent a total knee replacement under epidural anesthesia with intravenous sedation. Bird studied the case from the American Society of Anesthesiologists (ASA) Closed Claims Project database, and it was recently highlighted as a safety case study by the Anesthesia Patient Safety Foundation (APSF).[1]

Postoperatively, an epidural infusion (bupivacaine 0.25% and fentanyl 2 mcg/ml) was started at 10 ml/hr. She was discharged to a ward without any continuous monitors and with vital signs to be taken every hour for four hours and every four hours thereafter. Several hours later, she was in severe pain for which the anesthesiologist administered 100 mcg fentanyl and 10 ml of 0.25% bupivacaine via the epidural. Three hours later, the patient still was complaining of pain, and the epidural concentration was increased to bupivacaine 0.375% with 3 mcg/ml of fentanyl and the infusion rate was increased to 15 ml/hr.

Two-and-a-half hours later, the anesthesiologist ordered hydromorphone (2 mg IM) due to continuing pain. About four hours later, she was given another 2 mg of IM hydromorphone. Her level of arousal and vitals were not assessed for four more hours until she was found unresponsive and pulseless.

The patient was resuscitated but suffered severe brain damage. The cause of the injury was determined to be postoperative opioid-induced respiratory depression. A lawsuit was settled for $135,000 against the anesthesiologist and $15,000 against the hospital. *(More information on the ASA's Closed Claim Project can be found online at depts.washington.edu/asaccp. For more information on the APSF and resources, see the group's web site at www.apsf.org.)*

Reference

1. Weinger MB. Dangers of postoperative opioids. APSF workshop and white paper address prevention of postoperative respiratory complications. *APSF Newsletter* 2007; 21:61, 63-67. ■

or probable respiratory depression.

Reference

1. Bird M. Acute pain management: A new area of liability for anesthesiologists. *ASA Newsletter* 2007; 8:71. ■

Police investigating suspicious insulin deaths

The Chicago Police Department and the patient safety team at the University of Chicago Medical Center are investigating suspiciously high levels of insulin that left two elderly female hospital patients dead and a third in a coma earlier this summer.

The *Chicago Tribune* reports that police are looking into whether the unusually high insulin levels were the result of an intentional act after the patients were admitted to the hospital for unrelated illnesses. According to the hospital, two of the elderly women had insulin levels thousands of times higher than normal. The third woman, who did not have her insulin levels tested, showed signs of hypoglycemia, a deficiency of sugar that can result from too much insulin, the hospital said.

The first patient, 82-year-old Ruthie Holloway of North Kenwood, was admitted to the University of Chicago Hospitals in May 2007 for treatment for a urinary tract infection (UTI) but, according to the newspaper, died three weeks later after registering an insulin level of 2,680 micro international units (units) per microliter. A normal insulin level ranges between 10 and 50 units per microliter.

Later that month, a 68-year-old woman fell into a coma when, less than a week after being admitted (also for treatment of an UTI), she began showing similarly extreme levels of insulin, at one point registering a level of 2,670 units.

The third patient, 89-year-old Jessie Sherrod, died reportedly displaying signs of insulin overdose after entering the hospital in late April because of complications from Alzheimer's disease. The results of blood tests to measure Sherrod's insulin levels have not yet been released.

Alarmed by the abnormal blood test results, the medical center's patient safety team launched an investigation on June 6 to determine if a medication or laboratory error had occurred. Doctors feared the product integrity of medications had been threatened. But on June 22, when no cause had been detected, they notified the police, as well as the Food and Drug Administration, The Joint Commission, and the Illinois Department of Public Health. "We will do everything we can to discover the cause," **David S. Hefner**, MD, president of the medical center, said in a press release. "The safety of our patients is our highest priority."

The Chicago police assigned homicide detectives to the case, while the hospital instituted several new safety measures, including keeping insulin in locked compartments and double-checking and documenting insulin doses with two registered nurses. ■

Leapfrog Top Hospitals raise bar on safety

Forty-one U.S. hospitals have been named 2007 Leapfrog Top Hospitals, based on results from the Leapfrog Hospital Quality and Safety Survey, a rating system that assesses a hospital's quality and safety.

The survey by The Leapfrog Group, a patient safety organization based in Washington, DC, collects data from hospitals on their progress toward implementing practices in four categories: computerized physician order entry (CPOE), ICU physician staffing (IPS), evidence-based hospital referral (EBHR), and the Leapfrog Safe Practices Score (SPS), which measures how well hospitals are progressing on 27 other safe practices endorsed by the National Quality Forum.

Seventy-four percent of participating hospitals have fully implemented the practices in at least one of these four safety and quality categories. The 2007 Top Hospitals list is based on 1,285 hospitals that responded to the Leapfrog Hospital Quality and Safety Survey as of Aug. 31, 2007. The survey results from those hospitals revealed these significant findings about the state of health

care quality and safety in the nation's hospitals:

• **CPOE.** Only 10% have fully implemented CPOE. Another 4% plan to implement it by 2008, which represents slow progress since Leapfrog began tracking implementation in 2002, when the figure was 2.5%.

• **IPS.** Among hospitals with one or more ICUs, 29% enlist intensive care specialists to manage patients in the ICU, and another 6% plan to do so by 2008. This is a significant jump since 2002 when just 10% met the Leapfrog standard.

• **EBHR.** Thirty-two percent have neonatal intensive care units that meet Leapfrog's specifications for certain high-risk deliveries, 24% meet the standard for bariatric surgery, 7% meet the standard for pancreatic cancer resection, 5% meet the standard for esophageal cancer surgery, 3% meet the standard for percutaneous coronary interventions, and 1% meet the standard for aortic valve replacement.

• **SPS.** Twenty-five percent fully meet the standard for the SPS, which means that these hospitals have implemented the vast majority of each of the 27 National Quality Forum Safe Practices that comprise the SPS.

In addition, 44% have implemented procedures to avoid wrong-site surgeries, 36% have an adequate hand-washing policy for employees, 35% have a satisfactory policy for preventing pressure ulcers, and 29% require a pharmacist to review all medication orders before medication is given to patients. **(For more on the results of the Leapfrog survey and the list of top hospitals, go to the Leapfrog Group's web site at www.leapfroggroup.org and select "2007 Leapfrog Top Hospitals and Survey Results" on the home page.)** ■

CE objectives

After reading this issue of *Healthcare Risk Management*, the CE participant should be able to:

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and other hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

CNE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

17. When hospital leaders discovered a fraudulent CPR card at the University of California, Irvine Medical Center, how did they respond?
A. The first discovery sparked an internal review of all 2,000 employees with CPR certification.
B. The hospital reviewed the CPR certification only for staff in the same unit.
C. The hospital reviewed the CPR certification for everyone hired within the past year.
D. The hospital decided no further investigation as needed.

18. What does Mark Anthony Kadzielski, JD, say about falsified credentials?
A. Falsified credentials are extremely rare in health care.
B. Falsified credentials are common in health care.
C. Falsified credentials are found mostly with physicians.
D. Falsified credentials are found mostly with entry-level staff.

19. According to research from Wake Forest University School of Medicine regarding serious and fatal drug events reported to the FDA from 1998 to 2005, which of the following is true?
A. Serious events increased four times faster than the total number of outpatient prescriptions during that period.
B. Serious events increased at the same rate as the total number of outpatient prescriptions during that period.
C. Serious events held steady and did not increase along with the total number of outpatient prescriptions during that period.
D. Serious events decreased while the total number of outpatient prescriptions increased during that period.

20. According to research by Mariko Bird, MD, which of the following is true of claims regarding acute postoperative pain management?
A. No payment was made in any of the claims.
B. A payment was made in less than 10% of the claims.
C. A payment was made only in claims that did not involve patient-controlled analgesia (PCA).
D. A payment was made in 55% of claims.

Answers: 17. A; 18. B; 19. A; 20. D.

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HIPAA Regulatory Alert

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

Should HIPAA's privacy rule be revised for today's technology? It depends on who you ask

Does the HIPAA privacy rule need to be revised to meet the needs of the current changing health care environment involving health information exchange? The answer depends on who you ask.

When the American Health Information Community's workgroup on confidentiality, privacy, and security held a daylong meeting to consider a "working hypothesis" that the HIPAA privacy rule, and especially its scope of coverage, is inadequate for today's health information technology needs, members heard a variety of opinions. Privacy advocates and some vendors said the rule needs to be changed, while representatives of an existing health care data exchange and a coalition of providers, drug companies, and drug distributors suggested things are fine the way they are.

The privacy rule, which was drafted in 2000 and significantly revised in 2002, does not allow patients to control use and transmission of sensitive health care information. And its protections only apply to HIPAA-covered entities — payers, providers, and claims clearinghouses.

Part of the workgroup's hypothesis is that there needs to be one or more "enforceable mechanisms" to ensure that privacy and security requirements are met. The group noted that the Department of Health and Human Services (HHS) Office for Civil Rights had received more than 27,000 complaints of possible HIPAA privacy rule violations through April 2007, and has not issued a single fine against a HIPAA violator.

Another element in the group's hypothesis is that any organization handling protected health information should be required to meet privacy and security criteria at least equivalent to any relevant HIPAA requirements, and that rules should apply to them directly rather than through business associate agreements with covered entities.

Some of the harshest criticism came from University of Louisville (KY) Institute for Bioethics, Health Policy, and Law director **Mark Rothstein**, a member of the National Committee for Vital and Health Statistics.

"It is debatable whether the HIPAA statute and its privacy rule ever provided an effective framework for regulating health policy," Rothstein declares. "It is not debatable that new developments in health IT render the HIPAA privacy rule obsolete and incapable of providing meaningful health privacy protection to consumers. Consequently, a new, comprehensive regulatory approach is necessary, and Congress will need to enact new legislation to provide HHS with the statutory authority to promulgate more far-reaching regulations."

Privacy not the main focus

Rothstein contends HIPAA was drafted with claims simplification in mind and that health privacy was an afterthought. A significant concern, he says, is that tens of thousands of providers that deal with individually identifiable health information are not subject to HIPAA because they don't submit electronic claims for payment.

"A health care provider's legal obligation to protect the privacy of personal health information should not turn on whether or how the provider is paid," he says. "The harm to be avoided has nothing to do with the method of payment, and individuals' health privacy should not vary based on the irrelevant criterion of method of claims processing. Furthermore, members of the public are already confused about the extent of protection of their health information, and they should not be put in the position of relying, perhaps to their detriment, on a federal rule of limited applicability."

According to Rothstein, the privacy rule also does not apply to many nonhealth care entities that

routinely receive and consider information contained in individually identifiable health records, including employers, life insurers, disability insurers, long-term care insurers, financial institutions, and other public and private entities. In some instances, he says, disclosure of health information is permitted without any consent or authorization, and once information is released to an organization that is not a covered entity, HIPAA does not apply to any subsequent uses and disclosures.

Shortcomings Rothstein sees under HIPAA include: 1) the lack of coverage and enforcement of business associate arrangements; 2) individuals not being given an opportunity to opt in or opt out of a network; 3) individuals having no ability to segregate sensitive elements of their health records; 4) the lack of provisions for establishing contextual access criteria or role-based access criteria to restrict the scope of disclosures; 5) loose standards for disclosure of protected health information to law enforcement and other third-party requestors; and 6) inadequate enforcement, research, oversight, outreach, and education.

"In a real sense," Rothstein says, "the shortcomings of the HIPAA privacy rule will be magnified with the establishment of a national health information network. The foremost shortcoming of HIPAA is its limited applicability. If Congress fails to address this fundamental issue, all of the other, needed revisions of the privacy rule will be largely irrelevant. Comprehensive health information exchange demands comprehensive privacy and security protection."

'Effective privacy rule'

Taking the opposite position was Health Leadership Council president **Mary Grealy**. She says the five years of deliberations that led to the privacy rule "carefully weighed the competing interests in our extraordinarily complicated health care system . . . The result of these deliberations we believe to be an effective privacy rule."

She says the Health Leadership Council has chaired the Confidentiality Coalition, a broad-based group of organizations that support uniform national privacy standards. The coalition, she says, sought a rule that would strike a balance between protecting the sanctity of a patient's medical information and ensuring that necessary information is available for providing quality health care and conducting vital medical research. It also advocated for a rule with effective confidentiality safeguards that would not burden providers and patients with unnecessary paperwork or delays in treatment. "We believe that the privacy rule, to a great extent, achieved this balance and has increased consumers' confidence in the privacy of their medical records," Grealy says.

While recognizing that dialogue about health information technology and standards for the electronic transaction of health care has raised questions about the privacy and security of electronic health information in an electronic context, Grealy says it is important to remember that it was concern about the impact on patient privacy of the health system widely adopting electronic transactions that spurred the HIPAA privacy rule.

"The current HIPAA regulations are very restrictive and health care organizations like our members have taken a very conservative compliance approach in their business practices . . . We understand that many believe that the HIPAA privacy rule must be revised in light of electronic transfer of data and web-based access to personal health records, so that patients may trust that the system will keep their data private. We share the belief that patients' confidence in health information technology systems is of the utmost importance in order for them to be successful.

"We believe that it is vitally important that patients understand the protections contained in the HIPAA rule so they can be confident that their records are and will be protected. We also need to do a better job informing patients and consumers how appropriate access to their health information will improve the quality of their health care and the care of future generations."

State variations could be changed

While defending HIPAA, Grealy also says it is too restrictive in that it permits "significant state variations that we believe will create serious impediments to interoperable sharing or sending of health information, particularly across state lines." She says many state laws provide for more restrictive handling of patient records for treating mental health, substance abuse, and HIV/AIDS. Also, in the original privacy rule released by HHS in 2000, patient consent was required for exchange of health care information for treatment, payment, and other health care operations. That consent provision was removed in the 2002 revision. Grealy says her council opposed the consent provision and warned that proposals to add a consent requirement for health information exchanges "would be unnecessary and harmful."

She says if patients are able to direct where information may flow within the health care system, "it will upset HIPAA's careful calibration designed to facilitate providers having all the necessary facts for proper diagnosis and treatment."

(Editor's note: AHIC working group meeting information is available on-line at www.hhs.gov/healthit/ahic/confidentiality/cps_archive.html. ■

HIPAA should trump other privacy laws

Multiplicity of rules makes compliance difficult

The American Hospital Association says the multiplicity of privacy rules from local, state, and federal governments, accrediting bodies, and other organizations makes compliance difficult and can interfere with patient care. In testimony before the House Science and Technology Committee Sept. 26, HCA Inc. senior vice president **Noel Williams** said that simply identifying all the relevant rules can be a monumental task, let alone determining how to comply when the laws may conflict.

"A single set of privacy rules is needed to facilitate the use of IT and ensure access by health care providers to needed information at the point of care," Williams said. "Specifically, federal privacy laws as laid out in the Health Information Portability and Accountability Act should preempt state and local privacy laws."

The hearing was held to consider the need for interoperability and information security in health IT and HR 2406 sponsored by Rep. **Barton Gordon** (D-TN), the committee chairman.

Williams reported that in a survey of 1,500 hospitals, more than two-thirds said they had either fully or partially implemented electronic health records. Large, urban, and teaching hospitals were more likely to have fully implemented electronic health record systems.

She also said adoption of information technology and information sharing will increase when health information and IT applications are more standardized. Currently, she said, hospitals devote considerable staff and financial resources to creating interfaces between systems or other IT "workarounds." The problem, she testified, is a need to select a single set of standards and get consensus among health care stakeholders to use those standards.

Also commenting on the need for generally accepted standards was American Health Information Management Association CEO **Linda Kloss**, who noted that throughout the United States, other industries are sharing data and cutting administrative costs because they are using uniform standards.

Health care has not followed other industries

"This has not been the case in the past in health care," she said. "For instance, today we use standards required by HIPAA. We, therefore, adopted an X12 standard for claims, the X12-837. Unfortunately . . . there are now over 1,000 different instructions for the use of the X12-837 in the health care industry. If we are to achieve interoperability and use standards like other industries, this should not happen or be allowed to happen.

"The health care industry has over 1 million providers, thousands of health plans and payers, a potential consumer base of over 300 million individuals, and some 1.44 million employees offering some level of health care, along with numerous government agencies. Achieving consensus on complex standards and understanding of their uniform application is a monumental task even with shared vision."

To date, according to Kloss, the U.S. health care system has had only limited success with adopting and using standards. She said the standards chosen to be included under HIPAA were reviewed by the National Committee for Vital and Health Statistics (NCVHS), which takes considerable public comment but is not a public/private entity that engages the industry and government. The result has been a limited adoption of several of the HIPAA standards and an inconsistent use of the more common claims standard and remittance standard.

Barriers to uniform standards

Kloss discussed several barriers to uniform standards adoption, including reimbursement issues as many physicians indicate they will not even consider adoption of health information technology and standards until the Medicare and Medicaid reimbursement formulas are corrected and they are paid adequately.

Gordon opened the hearing by noting that the biggest barrier to broad implementation of health IT systems is the lack of technical standards to

support interoperability while protecting data security. "It is wasteful to start investing in technology until we know it is interoperable, as the cost to upgrade to new systems would eat up any immediate cost savings," he said.

Gordon's HR 2406 would authorize the National Institute of Standards and Technology (NIST) to increase its efforts to support the integration of the health care information enterprise in the United States. It instructs NIST to advance health IT integration while working with health care representatives and federal agencies to develop technical roadmaps for health IT standards. It also requires NIST to create or adopt existing technology-neutral guidelines and standards for federal agencies. ■

HIMSS backs development of interoperable ePHRs

Group says ePHRs should use HIPAA standards

The Healthcare Information Management and Systems Society (HIMSS) says it supports development of interoperable electronic personal health records (ePHR) that are interactive and use a common data set of electronic health information and e-health tools. HIMSS says it envisions ePHRs that are universally accessible and layperson-comprehensible, and that may be used as a lifelong tool for managing relevant health information.

"The ideal ePHR would receive data from all constituents that participate in the individual's health care, allow patients or proxies to enter their own data (such as journals and diaries), and designate read-only access to the ePHR or designated portions," a HIMSS position statement says.

HIMSS says it supports ePHR applications with the following characteristics:

- provide for unique patient identification;
- allow secure access to the information contained in the ePHR;
- permit receipt of e-mail alerts that do not reveal protected health information;
- allow patient proxy to act on behalf of the patient;
- permit designation of information to be shared electronically;
- provide technical support to ePHR constituents at all times.

Current forms of ePHRs in the market mainly involve three basic models: 1) software used by individuals to enter and maintain their personal health information; 2) web sites maintained by third parties that allow patients to enter and access their information; and 3) web sites that allow patients to view information from other applications, such as an institutional electronic health record/electronic medical record or from an application that maintains the individual's health insurance claims data.

Adopt HIPAA standards even if not covered

To the extent that an entity offering an ePHR is not a HIPAA-covered entity, or is not covered by other privacy and security laws, HIMSS encourages the entity to adopt at a minimum the privacy and security standards of HIPAA as if the organization were a covered entity.

Although there is currently a lack of universal data element standards for ePHRs, HIMSS supports development of ePHRs with this minimum data set — personal identifier, clinical summary, results/reports, histories, contact and registration information, and current and historical insurance information.

HIMSS acknowledges there are many legal barriers that impede widespread ePHR adoption and recommends development of national standards to ease burdens placed on constituents due to variances in state law and/or development of national and uniform state rules, regulations, and/or standards to address legal concerns raised by ePHRs. ■

Senators say HHS needs medical privacy office

Sens. **Edward Kennedy** (D-MA) and **Patrick Leahy** (D-VT) say they will introduce legislation to create an office within the Department of Health and Human Services to interpret and enforce medical privacy.

"In this electronic era, it is essential to safeguard the privacy of medical records while ensuring our privacy laws do not stifle the flow of information fundamental to effective health care," said Kennedy, who was a sponsor of the original HIPAA legislation. He said he is unhappy with what he called the "bizarre hodgepodge" of regulations under the law and with HHS' failure to provide "adequate guidance on what is and is not barred by the law." ■

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

Shoulder dystocia during delivery of 10-pound baby leads to $700,000 settlement

By **Jon T. Gatto**, JD
Blake J. Delaney, JD
Buchanan Ingersoll & Rooney
Tampa, FL

News: A pregnant woman with a fetus weighing nearly 10 pounds was admitted to the hospital for induction of labor even though she was never told of her baby's large size or given the option of a cesarean. During delivery, a shoulder dystocia occurred, and the baby suffered permanent Erb's palsy on his left side. The mother sued the obstetrician for medical malpractice, and the physician defended the suit by claiming that he did not act negligently and that shoulder dystocia can occur in any delivery. Prior to trial, the parties settled the case for $700,000.

Background: A pregnant woman was admitted to the hospital for induction of labor due to macrosomia, meaning that her baby was large in size, although the mother was never informed of this diagnosis. She also was not made aware of the risks associated with a vaginal delivery of a macrosomic fetus, including shoulder dystocia, brachial plexus paralysis, brain damage, or fetal demise, nor was she given the option of a cesarean.

During delivery of the 9-pound, 13-ounce baby, a shoulder dystocia occurred. The mother, on behalf of her baby, sued the attending obstetrician and claimed that the maneuvers required to perform the delivery safely were not used and that failure caused her son to suffer severe and permanent brachial plexus paralysis of the left arm, shoulder, and hand, known as Erb's palsy. The plaintiff also alleged negligence relating to the defendants' failure to inform her of the macrosomia diagnosis and failure to give her an option of cesarean delivery. Arguing that future surgeries, physical therapy, and vocational rehabilitation would be required, the plaintiff sought damages of $805,200 for future medical costs, $288,200 for lost earning capacity, and $250,000 for pain and suffering.

The defendant maintained that there was no negligence and that shoulder dystocia can occur in any delivery, regardless of the estimated fetal weight and regardless of whether proper maneuvers are used to deliver the shoulder dystocia. As a result, he argued, offering a cesarean as an option was not warranted.

The plaintiff demanded $1 million in damages, which the defendant countered initially with an offer of $200,000 and then $500,000. The parties ultimately reached a $700,000 structured settlement providing for a college fund and periodical lump-sum payments to the child until the age of 35.

What this means to you: "Lawsuits arising from shoulder dystocia-related injuries cost millions of dollars each year and constitute the second-highest category of payments in obstetrical medical professional liability claims," says **Ellen L. Barton**, JD, CPCU, a risk management consultant in Phoenix, MD. "In addition, such injuries

cause untold pain and suffering for babies and their families."

The physician in this case defended on the grounds that shoulder dystocia is rare and has a high false-positive rate. Therefore, argued the physician, it is impossible to develop a workable clinical protocol to assess the risk. While this defense may have been persuasive in the past, that is no longer the case, according to Barton. There are now better tools for assessing the risk of shoulder dystocia thanks to advances in informatics and other disciplines. (*See* Dyachenko A, Fahey J, Mighty H, et al. Prediction of risk for shoulder dystocia with neonatal injury. *Am J Obstet Gynecol* 2006; 195:1,544-1,549; Hamilton E, Wright E. Labor pains, unraveling the complexity of OB decision making. *Crit Care Nurs Q* 2006; 29:342-353.) Accordingly, due to these advances, obstetricians can and should share more information with the expectant mother so that she can make a fully informed decision.

Barton observes that the physician in this case was overly paternalistic in dealing with this patient. He dismissed the diagnosis of macrosomia, which is a term usually used to describe a baby weighing more than 9 pounds. He never informed the mother of the diagnosis. Accordingly, he never made the mother aware of the risks associated with a vaginal delivery, nor did he make her aware of alternative delivery options such as a cesarean. "Clearly this case also involves a lack of informed consent," says Barton.

While there is concern regarding an increased rate of cesarean, she does not believe that it should affect a physician in providing this type of advice to expectant mothers. Barton contends that the use of appropriate screening and assessment protocols will result in an "appropriate" rate of cesarean.

Barton observes that, in addition to the lack of informed consent issue, there was a clear mismanagement of the shoulder dystocia once it occurred. Thus, it was wise for the defendant to settle the case.

With the emphasis on patient safety, physicians and hospitals would be well advised to investigate comprehensive screening programs for shoulder dystocia and to utilize universal implementation of shoulder dystocia prevention (management) protocols. Particularly, joint physician-nurse training in shoulder dystocia management could yield positive results by encouraging the use of common terminology and team building.

This case underscores the need for health care practitioners to: 1) develop protocols based on scientifically validated risk factors for shoulder dystocia; 2) universally screen patients for such factors; and 3) present options for patients whose risk factors place them at greater risk for shoulder dystocia. Such programs must be monitored, audited, and the data collected and shared to increase evidence-based practice.

Reference

• San Diego County (CA) Superior Court, docket information withheld. ■

Ectopic pregnancy goes undiagnosed, patient dies

Jury awards $1.7M verdict

News: A woman who had an ectopic pregnancy and suffered from paranoid schizophrenia went to the hospital complaining of a two-week history of vaginal bleeding. Unable to detect any fetal heart tones or recognize a fetus *in utero*, an on-call obstetrician/gynecologist discharged the woman. The woman returned to the hospital a couple of days later, but again was discharged when she said she had started to feel better. The woman was subsequently found dead at home. She had bled to death from a ruptured ectopic pregnancy. The woman's estate and the baby's father sued the OB/GYN and the hospital, and a jury awarded damages of $1.712 million, with nothing attributable to the hospital, 40% attributable to the physician, and the remainder attributed to the woman's primary OB/GYN who was not a defendant in the suit.

Background: A 26-year-old woman suffering from paranoid schizophrenia was pregnant. She went to the hospital complaining of a two-week history of vaginal bleeding, although her vital signs were normal and she was not complaining of pain. The triage nurse was unable to detect any fetal heart tones, and she contacted the doctor who was on-call for the woman's obstetrician/gynecologist. The physician performed an ultrasound showing an empty uterus, which led him to believe that the woman was not pregnant. He discharged her with instructions to follow up with her regular OB/GYN physician when he

returned from vacation in a few days.

A couple of days later, however, the patient went to the emergency department of another hospital, where she was treated for severe abdominal pain. A urine test revealed pregnancy. After the woman began to feel better, she was again discharged with instructions to follow up with her regular physician the next day. That night, however, the woman was found dead in her home. Doctors discovered she had an ectopic pregnancy. The woman bled to death as a result of an apparent ruptured ectopic pregnancy.

The woman's parents filed suit against the on-call OB/GYN and the hospital, and they alleged negligence in their failure to diagnose and treat the ectopic pregnancy. The father of the fetus also joined in the suit. A jury found no negligence on the part of the hospital, but they did assign 40% liability to the physician. The remaining 60% of liability was assessed against the patient's regular OB/GYN, although he was not named in the suit, perhaps having settled with the plaintiffs earlier. The jury assessed damages of $1.712 million, only $7,000 of which was attributed to the father. The award was reduced for comparative fault to $684,800 against the on-call physician.

What this means to you: "Some of the facts in this story seem a bit odd, and it is not difficult to understand why the jury awarded such a large verdict," says **Lynn Rosenblatt**, CRRN, LHRM, risk manager at HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL.

A woman goes to an emergency department with a history of vaginal bleeding over two weeks but without pain. The woman apparently knew she was pregnant, but the narrative does not say how far along the pregnancy was. The nurse checked for fetal heart tones, but heart tones most likely would not have been discernable at an early stage of pregnancy. The ultrasound came up empty, indicating that she was not at that moment pregnant, at least with an intrauterine fetus. At this point, says Rosenblatt, the emergency department personnel should have questioned the source of the woman's vaginal bleeding and determined whether other tests could be performed to confirm the woman's claim that she was in fact pregnant.

One obvious conclusion could have been that the woman miscarried, but that possibility was apparently not fully explored. In fact, the narrative does not address whether the ED staff at the first hospital even performed a vaginal exam on the patient or a visual physical assessment.

The ultrasound came up empty . . . . At this point, says Rosenblatt, the emergency department personnel should have questioned the source of the woman's vaginal bleeding and determined whether other tests could be performed to confirm the woman's claim that she was in fact pregnant.

"Pregnancy brings with it changes in a woman's body that are the result of hormonal interaction. Those telltale signs most likely would have still been discernable even if the miscarriage had occurred two weeks previously," says Rosenblatt. Moreover, in most ectopic pregnancies, there is some tenderness within the abdomen that should have shown itself on palpation, and the signs of pregnancy would have been evident.

Rosenblatt notes that it is difficult to deduce from the facts given whether the woman actually saw a physician on her first trip to the ED. "It appears that she was interviewed by a nurse, who then contacted a physician who had assumed responsibility for another obstetrician. There is no indication that the on-call physician actually saw the patient. The physician may have instead reviewed the details of the nurse's assessment and the results of the ultrasound over the phone," says Rosenblatt.

Because the woman was not technically his patient, he apparently overlooked the degree of responsibility he had for her well-being. "In other words," says Rosenblatt, "he decided he would rather not be bothered by someone with a history of mental illness who clearly was not pregnant [in his mind], but thought she was." In Rosenblatt's opinion, the physician made a fatal mistake in not pursuing the woman's symptoms further.

The on-call physician decided that given the patient's schizophrenia, the negative ultrasound, and the absence of pain, the woman was not pregnant. "But that does not address what was causing the bleeding and if anything needed to be done about it," observes Rosenblatt. If the patient had miscarried, for example, a minor surgical procedure to ensure that the uterus was empty of the products of conception generally

would be undertaken. And if the physician is absolutely sure that the patient never was pregnant, then he should have made a more definitive determination as to the nature of the bleeding. "Under those circumstances, how prudent was it to have the patient wait several days before seeing her regular OB/GYN?" questions Rosenblatt.

She also wonders why the patient did not test positive for pregnancy at the first hospital given that she had a positive urine test confirming pregnancy at the second hospital. "Perhaps the first hospital did not administer a test," she says.

When the woman chose to go to a different hospital for follow-up treatment, Rosenblatt questions what, if anything, the patient told the physician at the ED about her experience a few days before. If the woman still had vaginal bleeding, the second hospital should have taken blood work to establish possible internal bleeding. The physician at the second hospital also should have performed a vaginal examination and repeated the ultrasound. And Rosenblatt wonders whether the second hospital was able to rule out a miscarriage and whether an ectopic pregnancy was considered.

"All of these questions should have been answered given that the woman's pregnancy test was positive and she was in extreme pain," says Rosenblatt. "The second hospital should have considered any number of very serious complications before releasing her."

Rosenblatt contends that the second hospital was responsible for providing a more comprehensive assessment of the patient. "A patient with severe pain and bleeding of unknown etiology most likely should be admitted for observation to ensure that the situation is resolving without further complications," she says. Rosenblatt further states that it is inexcusable that this observation did not occur in this case and that the patient then died several hours later from something that is generally considered treatable.

As for the lawsuit, because the scenario does not reveal the particulars of why the attending OB/GYN physician was not named, it is speculative to say why 60% of the negligence was attributed to him. "Most likely there were facts not put forth here that made the jury find against him," says Rosenblatt. "Perhaps it had to do with the inadequacy with which the physician who covered for him handled the case. Either way, the jury apparently felt that the woman's primary attending physician had an obligation that he did not meet."

The second physician was charged with the remaining 40% of the responsibility because he clearly failed to satisfy the standard of care that is commonplace in dealing with the potential complications of pregnancy. "Had he proceeded to answer some of the most basic questions that are always on the forefront when dealing with a pregnant woman who is bleeding," Rosenblatt says, "this woman may have survived a real emergency that generally has positive outcomes."

And finally, the hospital was spared from liability most likely because the jury chose to focus instead on the conduct of the physicians, who were apparently independent contractors with no employer-employee relationship with the hospital. "Had that not been the case, though, the hospital could have also been found liable," says Rosenblatt. Hospitals, after all, are responsible for overseeing the actions of contracted employees, common examples of which are teaching hospitals or where the ED physician is actually in the employ of the hospital.

"This is a sad case for several reasons, not the least of which is the inadequacy of the care provided. But even more, this case speaks to the plight of the mentally ill and the credibility they receive when they present to emergency personnel who have neither the time nor the patience to adequately sort out their stories," Rosenblatt says.

Reference

• Jefferson County (TX) District Court, Case No. A-167868. ■

Healthcare Risk Management™

There is plenty of opportunity if you position yourself correctly, say leaders of risk managment society

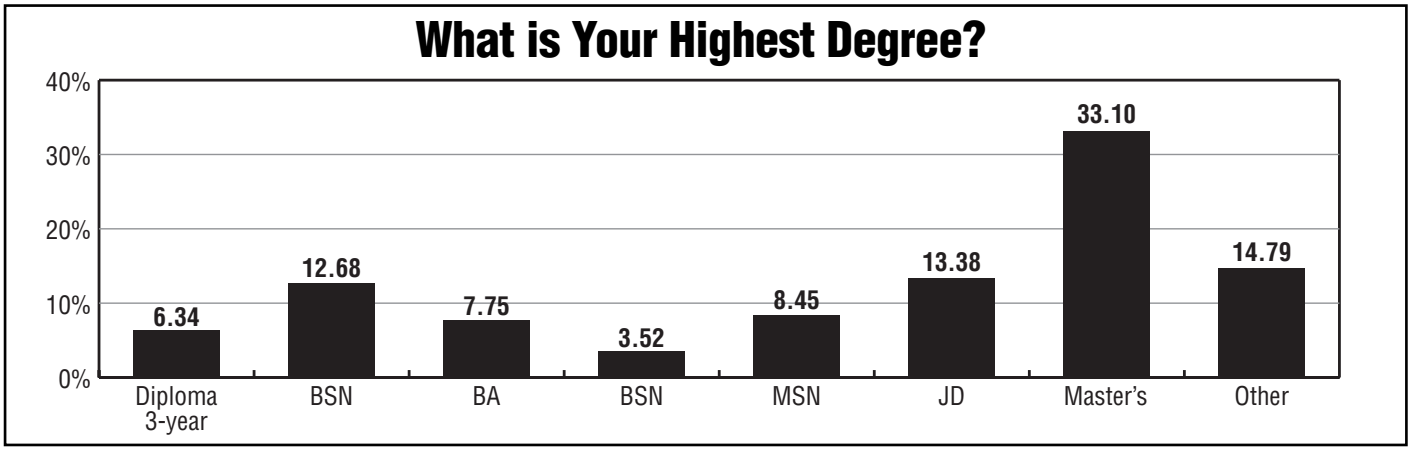
Health care risk management continues to be a promising career field even as the industry faces challenges, says **Douglas J. Borg**, MHA, ARM, CPHRM, director of insurance for Duke Health System in Durham, NC, and president of the American Society for Healthcare Risk Management (ASHRM) in Chicago.

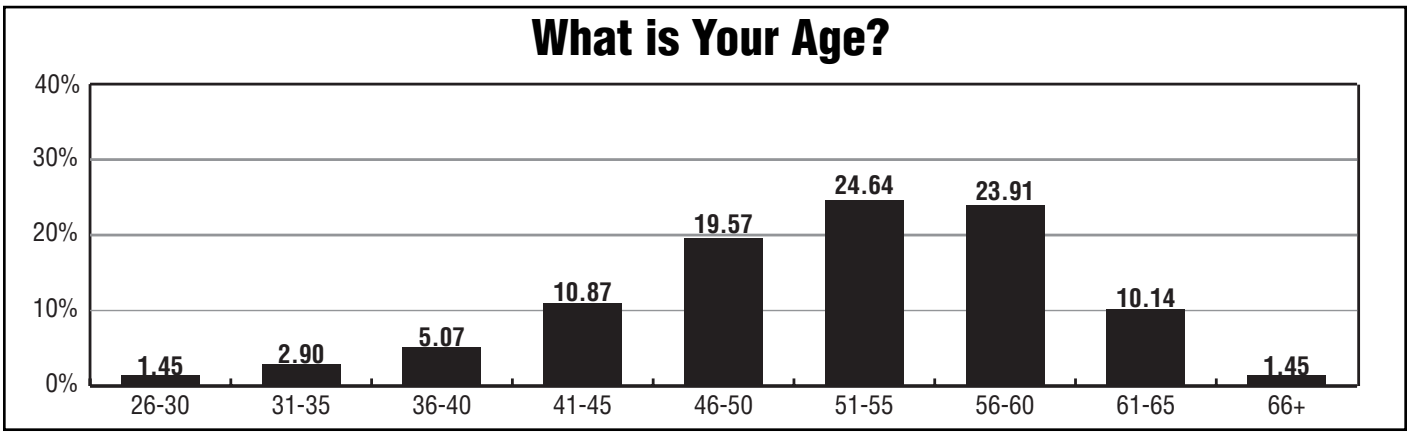
The continued emphasis on patient safety in health care means there is more for risk managers to do, and that can be a double-edged sword, Borg says. On one hand, there is more in your "to-do" box. But on the other hand, people may notice you more.

"The focus on patient safety raised our profile, allowing us to get involved in activities that maybe we didn't do in the past, and creating more attention for the kind of activities we've always done over the years," he says. "We see that particularly concerning the data that we collect. The value of that data has gone up."

The same data that risk managers have collected for years — information on medical errors, for instance — are now of much more interest beyond the walls of the risk management department, he says. Other departments and top executives have more of an interest in patient safety and quality than they did in years past, Borg says, so that interest means that the risk manager who gathers and analyzes that information is a more valuable member of the team.

"The demand for the data I collect has gone up significantly in the past two or three years," he says. "That, in turn, makes me more aware of the quality of those data. So we need to pay attention to any ways we can improve the quality of data that might be used for accreditation or other purposes. Providers are under a lot of scrutiny right now, and the data supplied by risk management





often plays a big role."

To position yourself better for the future, risk managers should recognize that their value in the organization will be judged partly by the amount and quality of the data they provide to other key players in the organization, Borg says. "It's an opportunity for the risk manager to prove your worth, or to participate in ways that you might not have in the past," he says. "The demand for the information is strong, so can take advantage of that to improve your career."

Don't be pushed out by others

Borg cautions that there is a potential downside to the growing emphasis on patient safety in health care. If patient safety, or data collection related to safety and quality, becomes a high-profile position within your organization, others may want the spotlight. Borg says other departments can do much of the same type of data collection and analysis as risk managers, so it is imperative that you protect your turf and show your organization how you do more with the data than just put them in a nice folder and pass them on.

"There is a danger of being pushed aside if you're not careful," Borg says. "Patient safety is getting a lot of press; it's very high profile, and we have to be careful not to be marginalized within our own organizations."

Proactive use of the data can be what distinguishes risk managers from others who seek to stake a claim on patient safety, Borg says. Others may want the data and know how important they are, but risk managers should have the edge in knowing what to do with them, he says. "It's important to keep a strong voice and not take a back seat to others just because they suddenly want a piece of what you've been doing for years, long before it became the hot topic in health care," he says.

Maintaining your position in the organization, not to mention advancing, may require developing leadership skills in addition to pure risk management. "It's not enough to know that you're a good risk manager and to just do your job well and hope somebody notices," he says. "If you really want to advance beyond where you are now, you have to keep growing as a leader in the organization."

Baby boomer wave moves on

Borg points to another trend he's seen developing in recent years. Baby boomer risk managers are beginning to retire and make way for a younger generation of new talent. As the wave of baby boomers moves forward, those still working will begin to see more young people coming into the business.

"That will mean more need for continuing education, but it could also mean that these young people bring new ideas and new ways of doing things," Borg says. "It will be an interesting trend to watch."

The future looks optimistic for risk managers as long as they take advantage of the opportunities,

SOURCES

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says the immediate past president of ASHRM, **Paul English Smith**, JD, FASHRM, CPHRM, vice president and general counsel at Cabell Huntington (WV) Hospital. The field continues to evolve as health care organizations consider ways to combine traditional risk management with patient safety and quality improvement, he says.

"We've seen a number of organizations looking at ways to roll those into one position or one department, so that could be something we'll see more of in the future," he says. "It makes sense to some organizations when they see the overlap between these positions."

That change would not necessarily be good or bad for risk managers, because the risk manager would be a top candidate for any such newly created position, Smith says. The way to prepare is to let organization leaders know what you are capable of beyond the traditional role of the risk manager, he says. "Like any employee, a risk manager can be pigeonholed so that leaders think you're capable of doing just one thing, even if you do it very well," Smith says. "You can become known as the person who does risk financing, or clinical risk management, and that's how they think of you. If you have more skill sets than that, you have to find a way to show that."

Investigations, finance are key skills

The ability to conduct an objective investigation is one key skill set that can help a risk manager break out of the stereotypical mold, Smith says. Investigations will be needed throughout the organization, and an experienced risk manager often has insight and skills not found in other departments, he adds.

Courses in finance would be a good move for any risk manager who wants to operate with the top leaders in the organization, Smith says. The higher up you go, the more the topic always turns to managing financial resources, he notes. "At my level, with 22 years' experience, the push is for more enterprise risk management," he says. "I'm being asked for input on benefits and workers' compensation, employment liability, looking at the nontraditional risks."

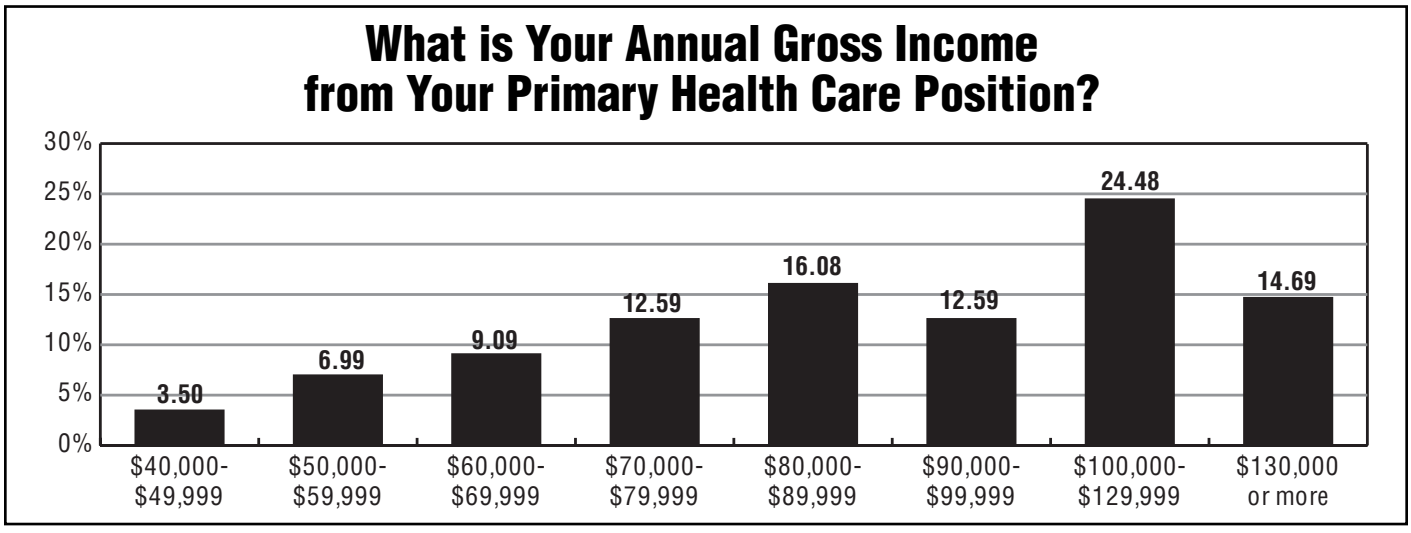
Salary survey shows income rising this year

You might have more money in your pocket this year, but if so, you worked hard for it. Data from this year's *Healthcare Risk Management* Salary Survey suggest that salaries for health care risk managers are on the way up, but there is some letup in the workload.

The exclusive 2007 *Healthcare Risk Management* Salary Survey was sent to about 1,187 readers in the June 2007 issue. A total of 143 were returned, for a response rate of 12%. The results were tabulated and analyzed by AHC Media, publisher of *HRM*.

The median income for health care risk managers in this year's survey is $95,000, up from $85,000 in last year's survey. **(See the chart, below.)** The 2006 figure represented no increase from the year before, so the current increase gets risk managers back on track with steady increases each year. In the years prior to 2005, health care risk managers had seen their incomes climb modestly but steadily each year.

Consistent with the increase in median income, respondents this year also report a median salary



increase over the past year of 4%-6%, much more than the 1%-3% reported most commonly in previous years. **(See the chart, below.)** Thirty-seven percent report increases in the 4%-6% range, up from 32% reporting that amount last year.

Only 13% reported that their salaries had not changed this year, down from last year's 1% and consistent with the previous year's 13%. The worst figure for this category has been the 20% reported in 2004. But at the same time, 1% reported a decrease in their income, the same as last year.

Number of work hours plateaus

Hours worked per week continues to be an interesting data point to watch. In previous years it seemed health care risk managers were working longer and longer hours. This year's survey results show you're still working long and hard, but the number of hours may be reaching a plateau. **(See the chart, right.)** Thirty-three percent reported working 46-50 hours per week, down from last year's 39% and approaching the previous year's 30%. Twenty percent reported working 51-55 hours per week, down from last year's high water mark of 28% and closer to the previous year's 16%. Fewer risk managers are working 56-60 hours a week, 11% this year, down from 16% in 2006 and the previous year's 13%. Less than 1% report working 61-65 hours. ■