Healthcare RISK MANAGEMENT

December 2012 | Vol. 34, No. 12 Pages 133-144

New system would encourage patients to report med errors to feds

Many skeptical about usefulness of such a program

A proposed system that would encourage patients to report medical errors is getting mixed reviews from the healthcare industry and legal professionals, with many expressing concern that the reports would yield little useful information but drive up medical malpractice costs.

The proposed system might be well-intended but could be less useful than expected.

The Agency for Healthcare Research and Quality (AHRQ) is proposing the new effort, which became public when The New York Times revealed it before the government had formally announced the plan. *(The newspaper article is available online at http://tinyurl.com/patienterrors.)*

A flier drafted for the project asks patients: "Have you recently experienced a medical mistake? Do you have concerns about the safety of your health care?" The flier goes on to urge patients to contact a new "consumer reporting system for patient safety. *(See p. 135 for more on how the information is collected.)*

The draft questionnaire also seeks to collect the name and address of the healthcare provider who made the mistake. The reports would be analyzed by researchers from the RAND Corp., a nonprofit institution that helps improve policy and decision-making through research and analysis, and the ECRI Institute, a nonprofit organization that investigates medical errors and evaluates medical devices.

The project could begin collecting information as soon as May 2013, according to the AHRQ. Reporting is voluntary, and federal officials said they would keep the information confidential.

Some healthcare leaders endorse the project, with **Nancy E. Foster**, a vice president of the American Hospital Association, releasing a statement saying, "The idea is welcome." The American Medical Association issued a statement saying it is studying the proposal but does

INSIDE

AHC Media

www.ahcmedia.com

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, has no relationships to disclose.

not yet have an opinion.

The proposed system might be well-intended but could be less useful than expected, says **John D. Birkmeyer**, MD, the George D. Zuidema Professor of Surgery with the University of Michigan Health Systems in Ann Arbor and director of the Center for Healthcare Outcomes & Policy at the University of Michigan. He has served in advisory roles with the Centers for Medicare and Medicaid Services (CMS), the American College of Surgeons National Surgical Quality Improvement Program, and the Leapfrog Group.

Birkmeyer believes a system for enabling patients to report medical errors may nudge provider accountability a little, but that data will be more noise than signal in reflecting the true quality, cost, and patient-centeredness of a given physician or hospital. It certainly won't bring clinicians and patients closer together, he says, and it might do just the opposite.

"It's hard to disagree with the basic concept, because accountability is what we all want in healthcare," he says. "The only mechanism by which it could be a bad thing is if it is just a distraction from things that could really move the needle on hospital safety, or if there are unintended consequences like providing risk managers with unreliable information."

One possible consequence, Birkmeyer says, is that healthcare providers will be less forthcoming about admitting errors to patients if they know that the patient might report that mistake to the database and possibly embellish or mischaracterize what happened.

"That flies in the face of the very strong momentum we have in the risk management world to encourage physicians to be more forthcoming about errors," he says. "The idea of a national database gives physicians hives, so they can only be more reticent about volunteering information to the patient."

The information in the database also could mislead, Birkmeyer says. Given the nature of how the information is reported, it is likely to be a weak indicator of the hospital's or the physician's quality, he notes. "Simply having a database of these error reports is not going to be useful unless you also account for factors like how many difficult, advanced procedures this facility

Executive Summary

The federal government is proposing a new system that would encourage patients to report medical errors to a national database. The information would be analyzed but kept confidential.

- ✦ Patients would provide information through a web site and telephone interviews.
- ✦ The program could begin as early as May 2013.
- ✦ Many healthcare providers and legal experts are skeptical about the program's usefulness and foresee potential problems.

Healthcare Risk Management® (ISSN 1081-6534), including HRM Legal Review & Commentary™, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Healthcare Risk Management®, P.O. Box 105109, Atlanta, GA 30348.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is valid 24 months from the date of publication.

Healthcare Risk Management® is intended for risk managers, health system administrators, and health care legal counsel. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Executive Editor: **Joy Daughtery Dickinson** (229) 551-9195, (joy.dickinson@ahcmedia.com), Production Editor: **Kristen Ramsey.** Senior Vice President/Group Publisher: **Donald R. Johnston.**

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. For approximately 15 CE nursing contact hours, $545. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. Back issues, when available, are $87 each. (GST registration number R128870672.)

Editorial Questions

Questions or comments? Call **Greg Freeman,** (770) 998-8455.

or this physician performs," Birkmeyer says. "This is the same problem we ran into years ago when there was a push for hospitals to report quality measures. A simple number of errors isn't going to be useful by itself."

The reports also are not likely to be accurate, says **Adam Frederic Dorin**, MD, MBA, founder and president of America's Medical Society, a San Diego-based non-profit medical society that advocates for physician rights and patient safety. Collecting useful information on medical errors will be difficult when interviewing people who have little or no understanding of medical procedures or standards of care, he says.

The program could be overwhelmed with people who use it as a sort of complaint line about their healthcare providers, Dorin says. Even if the intent is more specific, chances are the public will see the program as an opportunity to vent about what they perceive as poor care, disrespect by providers, or other issues that do not concern actual errors. *(See the story below for more questions about the program.)*

"I think you're going to have a fair number of people who just don't know what they're talking about, and then you're going to have people who want to manipulate the system," Dorin says. "The people who report that they got in an argument with the nurse but there really wasn't any kind of error, how much is going to cost to ferret out those from the true reports of adverse events?"

Eight U.S. congressmen, seven of them physicians, wrote to **Carolyn Clancy**, MD, director of the Agency for Healthcare Research and Quality, to question how the information collected from patients would be used. *(See the story on p.136 for more on their letter.)*

Details of the program might be altered, but Birkmeyer says he expects the AHRQ will move forward with some version of a patient-reported error database.

"There is enough momentum in the system that I think it's going to happen," he says. "I suspect that its ultimate impact will be the collection of a lot of ad hoc data that doesn't provide hospitals with any useful data to improve patient safety or patients with information that is really actionable. Then it will fade away from lack of impact."

SOURCES

• **Adam Frederic Dorin**, MD, MBA, Founder and President, America's Medical Society, San Diego. Telephone: (858) 344-0083. Email: afdorinmdmba@aol.com.

• **John D. Birkmeyer**, MD, George D. Zuidema Professor of Surgery, University of Michigan Health Systems, Ann Arbor. Telephone: (734) 936-5738. Email: jbirkmey@umich.edu. ✦

AHRQ plan would solicit error reports in hospitals

Under the plan proposed by the Agency for Healthcare Research and Quality (AHRQ), patients and their relatives would report medical errors and near misses through a web site and in telephone interviews. Questionnaires would be made available at kiosks in hospitals, ambulatory care centers, and doctors' offices.

The AHRQ also plans to distribute fliers describing the project at pharmacies and to include them with the explanation of benefits sent by insurance companies.

The questionnaire asks why the mistake happened and lists possible reasons:

• "A doctor, nurse or other health care provider did not communicate well with the patient or the patient's family."

• "A health care provider didn't respect the patient's race, language or culture."

• "A health care provider didn't seem to care about the patient."

• "A health care provider was too busy."

• "A health care provider didn't spend enough time with the patient."

• "Health care providers failed to work together."

• "Health care providers were not aware of care received someplace else." ✦

Many unanswered questions about reporting system

There are a number of unanswered questions about the proposed patient report system for medical errors, and one of the most important is how the data would be used, says **George B. Breen**, JD, an attorney with the law firm of Epstein Becker Green in New York City.

As proposed, it is unclear whether the data could be released in response to a subpoena of a Freedom of Information Act request, he notes.

Breen also questions the AHRQ's plan to solicit patient comments through kiosks in hospitals.

"If I were a hospital, I'd have a real concern with these kiosks set up in my place of work," he says. "It almost sends the message that you're going to be subjected to a medical error if you come to this hospital, and here's a convenient way to report it. I don't think that's the impression that you want to leave. You wouldn't want a plaintiff's malpractice lawyer advertising in the lobby of your hospital, and this sends the same kind of message."

The system also would raise questions about when a hospital is obligated to report a case to its medical malpractice insurance carrier, Breen says. Does hearing of a patient's report through the federal system mean the hospital is on notice of a potential claim, obligating a report to the carrier? Would a physician have to divulge such a report during the credentialing process when asked about potential or pending malpractice claims?

"Promoting patient safety is certainly a good idea, but I don't know that this is how you actually get there," Breen says. "We don't know how a hospital can interact with this government system that may make inquiries after a patient report. Can you expect that the information is protected, or do you need to speak as if everything you say can be used in court? Do you need to have a whole structure in place for responding to these inquiries?"

SOURCE

• **George B. Breen**, JD, Epstein Becker Green, New York City. Telephone: (202) 861-1823. Email: GBreen@ebglaw.com. ✦

Congressmen question value of patients reporting errors

In response to news about a possible program that would encourage patients to report medical errors, eight U.S. congressmen wrote to Carolyn Clancy, MD, director of the Agency for Healthcare Research and Quality, to express their concerns.

The letter was signed by Tom Coburn, MD (R-OK), John Boozman (R-AR), Bill Cassidy, MD (R-LA), Ron Paul, MD (R-TX), Phil Gingrey, MD (R-GA), Paul Brown, MD (D-GA), John Fleming, MD (R-LA), and Phil Roe, MD (R-TN). The congressmen question the sample questions that patients would be asked in a questionnaire and the proposed answers for why the error occurred, such as "a health care provider was too busy" or "health care providers failed to work together." Such questions and answers would not provide the empirical data required to improve patient safety, they say.

Here are excerpts from their letter:

• "While the goal of providing greater transparency to patients is a noble one, we have significant concerns that this proposal could undermine that goal by producing inaccurate information."

• "While it is important to understand the subjective patient experience of care, it would be inaccurate to use this information as an objective standard of care. Many patients do not have the medical knowledge to accurately determine when an adverse medical event occurs. If an adverse medical event does occur, there is a likelihood that the patient could mischaracterize it."

• "Additionally, we have concerns that such a reporting system could give rise to greater medical malpractice liability insurance costs. This could increase costs and decrease quality of healthcare for patients." ✦

Court suggests EMTALA could apply to inpatients

The Emergency Medical Treatment and Labor Act (EMTALA) has posed liability risks for hospitals for many years, but EMTALA obligations have been limited mainly to the emergency department (ED). Now a recent decision by a federal district court in Texas suggests that the law could be applied much more broadly to inpatients as well.

The decision reminds hospitals to be extra vigilant in documenting the appropriateness of admitting as inpatients those patients who present in the emergency department and the appropriateness of ultimate discharge following inpatient admission, says **Nathan A. Kottkamp**, JD, a partner with the law firm of McGuireWoods in Richmond, VA.

"This decision suggests that the rule is not as final as many of us thought it was," he says.

The court issued a memorandum opinion and order concluding that, as a matter of law, EMTALA may

Executive Summary

A federal district court has issued a ruling suggesting that the Emergency Medical Treatment and Labor Act (EMTALA) could be applied to inpatients as well as outpatients.

✦ The court's ruling could influence EMTALA-related lawsuits across the country.

✦ The court held that the statute's application does not turn on the administrative status of the patient but on his or her medical status.

✦ An EMTALA claim cannot be barred simply because a patient has been admitted to a hospital as a bona fide inpatient, the court ruled.

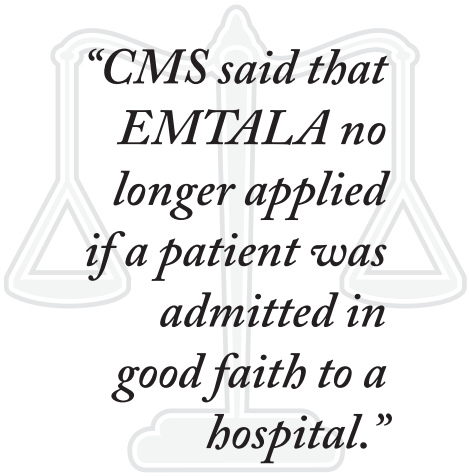
✦ The plaintiff alleged the hospital repeatedly tried to discharge him because he had no insurance.

continue to apply under circumstances in which a patient is seen in an ED and then admitted to the hospital as an inpatient, Kottkamp explains. The patient alleged that after he was admitted, the hospital tried repeatedly to transfer him because he had no insurance and that those attempts violated EMTALA. *(The ruling is available online at http://tinyurl.com/emtaladecision. See below for a summary of the case.)*

"The court denied the defendant hospital's motion to dismiss the plaintiff's EMTALA claim based on the key fact that the patient had been admitted as an inpatient to the hospital," Kottkamp says.

That was a substantial deviation from previous Centers for Medicare and Medicaid Services (CMS) guidance on EMTALA. As recently as Feb. 2, 2012, CMS reaffirmed, in a proposed rule, that a hospital's obligation under EMTALA ends either when the individual is stabilized or when the hospital admits the patient in good faith as an inpatient to continue providing stabilizing treatment. "CMS said that EMTALA no longer applied if a patient was admitted in good faith to a hospital," Kottkamp says. "They made it very clear that you can't just mark someone as being inpatient for an hour and then discharge them. Shenanigans like that wouldn't get around the rule. But if it was a legitimate inpatient admission, EMTALA just stops."

Now that might not be the case. "We're looking now at whether the statute, which does not have an inpatient exception, trumps that CMS guidance," he says. "That's pretty scary."



The court stated that an EMTALA claim cannot be barred "simply because a patient has been admitted to a hospital as a bona fide inpatient."

Because the court found that, at this stage of the case, the plaintiff pleaded sufficient facts to state a plausible claim that his condition was never stabilized, it must be left to judge or jury to determine whether the defendant hospital's actions constitute a violation of EMTALA, Kottkamp says.

This recent decision serves as a reminder that the application — or nonapplication, as the case may be — of EMTALA to inpatients is not well settled, Kottkamp says. Therefore, hospitals should be especially careful to document their actions any time a patient presents to the facility through the ED. In light of this decision, hospitals should be doubly sure that they are documenting the reasons for admission through the ED so that, at a minimum, you can prove that it was a good faith admission, Kottkamp says. Once the patient is admitted, if the patient needs to be transferred or there is any other situation in which EMTALA could be raised, the documentation should be exceptional, he urges.

"This is a scary proposition for risk managers that a patient can be admitted to the hospital for a month and if he's unhappy with his discharge in some way, there can be an EMTALA violation," Kottkamp says. "That changes everyone's approach to EMTALA. That's a pretty big deal."

SOURCE

• Nathan A. Kottkamp, JD, Partner, McGuireWoods, Richmond, VA. Telephone: (804) 775-1092. E-mail: nkottkamp@mcguirewoods.com. ✦

Patient alleged transfer attempts violated EMTALA

The recent federal district court decision from Texas involving the Emergency Medical Treatment and Labor Act (EMTALA) concerned an inpatient who alleged that repeated attempts to transfer him from the hospital violated the statute.

Nathan A. Kottkamp, JD, a partner with the law firm of McGuireWoods in Richmond, VA, offers this summary of the Texas case that led to the EMTALA ruling: The plaintiff, an uninsured patient, presented to the defendant hospital's emergency department (ED) and was found to be suffering from bilateral pneumonia, adult respiratory distress syndrome, and significant lung damage. The hospital admitted the plaintiff into its facility as an inpatient, and he stayed until he was discharged home nearly a month later.

The plaintiff alleges that while his condition still was unstable, various doctors and nurses at the defendant hospital attempted to transfer him out of the hospital 18 times because he was uninsured. On one specific occasion, the plaintiff went into cardiac arrest at or near the time he was placed in an ambulance for transfer. After being resuscitated, he returned to the defendant hospital's intensive care unit and was placed on a ventilator. The plaintiff alleges that he later was discharged home improperly because his condition still was unstable.

"The hospital moved to dismiss the EMTALA claim on grounds that the plaintiff was admitted to the hospital in good faith as a bona fide inpa-

tient. After recognizing that there is a split among circuits as to whether EMTALA applies to inpatients, the court denied the hospital's motion to dismiss," Kottkamp explains. In its opinion, the court held that the statute's application "does not turn on the administrative status of the patient but on his or her medical status."

The court rejected the defendant hospital's attempt to throw out the EMTALA claim and said the plaintiff's allegations could be considered by the lower court. The case has not yet been tried or settled. ✦

End-stage renal disease care cited in OIG's Work Plan

The Office of the Inspector General (OIG) recently released its Work Plan for the fiscal year 2013, giving risk managers a heads-up about what topics will be of most interest to regulators over the next year. Some are perennial favorites, such as fraud and abuse, but there are many new areas of focus for 2013.

The Work Plan should be useful for risk managers in directing their resources for the coming year, says **James B. Riley** Jr., JD, a partner with the law firm of McGuireWoods in Chicago.

"The OIG uses the Work Plan in different ways, both to assess the effectiveness of enforcement in some particular areas and also to gather information on some topics that they can provide to Congress," Riley says. "The usefulness for risk managers is that the 240 items identified in the Work Plan, like same-day admissions, tell us that the OIG is gathering information to see whether or not it's a problem they should look into."

Riley suggests that risk managers take a close look at the Work Plan and use it to identify areas in which the government is focusing on what could be inappropriate activities, and then to assess your own hospital's vulnerabilities in those areas.

One of the biggest new areas of interest is end-stage renal disease (ESRD). The Work Plan outlines these three areas in which it will scrutinize ESRD:

1. Medicare oversight of dialysis facilities. The OIG will assess Medicare's oversight of facilities that provide outpatient maintenance dialysis services to Medicare beneficiaries with ESRD. Particularly, the OIG will focus on the oversight function's performance and the complaint processes of dialysis facilities.

2. Bundled prospective payment system (PPS) for renal dialysis services. The OIG will review Medicare pricing and utilization related to renal dialysis services under the new bundled ESRD PPS, which began in 2011. The ESRD PPS has replaced the basic case-mix adjustment composite payment system and the methodologies for reimbursement of separately billable outpatient ESRD services.

3. Payments for ESRD drugs under the bundled rate system. The OIG will compare facilities' acquisition cost for certain drugs to inflation-adjusted cost estimates and determine how costs for the drugs have changed since the last OIG review. The Centers for Medicare and Medicaid Services (CMS) has based the bundled price updates of ESRD care on wage and price proxy data from the Bureau of Labor Statistics, but previous OIG reviews found the bureau did not accurately measure the changes in facilities' acquisition costs for ESRD drugs.

In addition, hospital risk managers can expect more OIG attention in these areas:

• **DRG window.** The OIG will determine how much CMS could save if it bundled outpatient services performed up to 14 days (instead of three days) prior to an inpatient admission into the DRG payment.

• **Readmissions.** The OIG will review Medicare claims to identify trends in same-day readmissions.

• **Non-hospital owned practices using provider-based status.** The OIG will determine the impact of non-hospital-owned physician practices billing Medicare as provider-based. The OIG also will review whether practices billing Medicare as provider-based satisfied Medicare billing requirements.

• **Medicare's transfer policy.** The OIG will review payments to hospitals for discharges that should have been coded as transfers and whether such claims were appropriately processed and paid.

• **Discharges to swing beds in other hospitals.** The OIG will review Medicare payments made to hospitals for discharges that were coded as discharges to a swing bed in another hospital.

• **Canceled surgical procedures.** The OIG will determine the costs to Medicare associated with inpatient claims for canceled surgical procedures. The OIG notes that in a preliminary analysis, it identified

Executive Summary

The Office of the Inspector General (OIG) recently released its Work Plan for the fiscal year 2013, and several new topics are cited. The Work Plan outlines what the OIG will consider its top enforcement priorities for the coming year.

✦ Fraud and overpayments continue to be a primary focus, as in recent years.
✦ Dialysis facilities will get a closer look from OIG in 2013.
✦ The OIG will review payments for end-stage renal disease (ESRD) under the new bundled rate system.

significant occurrences of hospitals receiving two payments for cancelled surgical procedures [i.e. an initial inpatient PPS (IPPS) payment followed by a second IPPS payment for the rescheduled procedure].

• **Mechanical ventilation.** The OIG will review Medicare payments for mechanical ventilation to determine the appropriateness of the diagnosis-related group (DRG) assignments and the payments. The OIG will specifically review whether patients received fewer than 96 hours of mechanical ventilation.

• **Graduate medical education payments.** The OIG will review data to identify whether providers have claimed duplicate or excessive graduate medical education payments.

• **Acquisition of ambulatory surgery centers (ASCs).** The OIG will identify the extent to which hospitals acquire ASCs and the effect of such acquisitions on Medicare payments and beneficiary cost-sharing.

• **Long-term-care hospitals and interrupted stays.** The OIG will assess the extent to which Medicare made improper payments for interrupted stays in long-term-care facilities, identify readmission patterns, and determine the extent to which they readmit patients directly following the interrupted stay period.

• **Claims submitted by error-prone providers.** The OIG will determine the validity of claims submitted by error-prone providers, project the results to the provider's population of claims, and recommend to CMS that it request refunds of projected overpayments.

• **Use of commercial mailboxes.** The OIG will review the extent to which the practice locations of Medicare Part B providers and suppliers matched commercial mailbox addresses in 2011.

• **High cumulative Part B payments.** The OIG will assess controls that identify high cumulative Part B payments to physicians and suppliers and whether controls are in place to identify such payments.

• **Anesthesia services.** The OIG will review Part B claims for personally performed anesthesia services to determine whether the claims satisfied Medicare requirements. The OIG will also review whether payments for services reported with the "AA" modifier satisfied Medicare requirements.

• **"Incident-to" services performed by non-physicians.** The OIG will review billing for incident-to services to identify whether payments for such services had a higher error rate than other services. The review stems from prior OIG findings regarding unqualified non-physicians performing such services.

The full 2013 Work Plan can be found online at http://tinyurl.com/2013workplan.

SOURCE

• James B. Riley Jr., JD. Partner, McguireWoods, Chicago. Telephone: (312) 750.8665. Email: jriley@mcguirewoods.com. ✦

'Safe Count' effort aimed at overlooked items in delivery

Retained objects are a constant worry in any invasive procedure, but the risk has gone overlooked in obstetrics. A project from the Minnesota Health Association (MHA) is changing that situation and has practically eliminated the problem statewide.

The SAFE COUNT campaign aims to prevent objects such as sponges from being retained after a patient gives birth. The SAFE COUNT Roadmap to Preventing Retained Objects in Vaginal Deliveries provides a detailed list of recommended actions that are organized under the SAFE COUNT acronym:

• **S**afe Count teams;
• **A**ccess to information;
• **F**acility expectations;
• **E**ducate staff;
• **C**ount sponges, sharps, and other items;
• **O**btain post-delivery imaging;
• **U**se of white board or other visual documentation;
• **N**ever use anything but radiopaque;
• **T**ime-out: "pause for the gauze."

The effort was initiated after Minnesota passed a law mandating the reporting of adverse events in 2003, explains **Julie Apold**, director of patient safety with the MHA in St. Paul. As Apold and her colleagues began to study the data generated by the mandatory reporting, they were surprised to see that the most common retained object was a sponge in labor and delivery.

"That's not what we expected to see. We thought it would be sponges after complex abdominal surgeries," Apold says. "Retained objects were a top

Executive Summary

A project sponsored by the Minnesota Health Association is aimed at reducing the number of retained items during delivery. The project has practically eliminated the problem in recent years.

✦ A specific protocol promotes best practices for avoiding retained objects.
✦ Post-delivery imaging is required in all cases.
✦ The delivery team must take a time out to account for all objects.

adverse event, and the sponge in labor and delivery was at the top of that list, so we decided to address this specific problem."

By studying the root cause analyses from the adverse event reports and best practices, MHA was able to put together a program specifically aimed at retained objects in labor and delivery. The SAFE COUNT campaign was launched in 2008.

The campaign promotes education for labor and delivery team members and a specific protocol for ensuring that no objects are left behind. Team members must always use post-delivery imaging to look for retained objects, for example, and they must take a timeout at the end of the procedure to account for all sponges and other objects. *(For the SAFE COUNT roadmap, which outlines the entire process, go to http://tinyurl.com/safecountroadmap.)*

Most of the hospitals that deliver babies in Minnesota are participating in the campaign. Participation begins with a baseline assessment of how the hospital is complying with the best practices outlined in the campaign, followed by webinars and other educational efforts to bring the delivery team up to speed. "We've seen wonderful results. Sponges in labor and delivery went from the most often retained object to zero," Apold says. "We haven't had a retained object in labor and delivery in over two years now."

Apold encourages risk managers to use the SAFE COUNT roadmap to implement the same program in their own facilities.

"This is an effort that has been extremely successful for us in practically eliminating what was one of our most persistent adverse events," Apold says. "Minnesota hospitals have really benefitted, and we'd love to see hospitals across the country enjoy the same improvements."

SOURCE

• **Julie Apold**, Director of Patient Safety, Minnesota Hospital Association, St. Paul, MN. Telephone: (651) 641-1121. Email: japold@mnhospitals.org. ✦

Transition to accountable care brings major risks

The healthcare industry's transition to accountable care will require significant cultural and operational shifts, bringing new risks that many organizations have yet to fully identify and manage, according to a new white paper from Marsh, the insurance broker and risk management consulting practice based in New York City.

Healthcare organizations are steadily moving to form or join accountable care organizations (ACOs), as encouraged under the Patient Protection and Affordable Care Act (PPACA). ACOs are networks of health care organizations that aim to deliver cost savings and better patient outcomes through coordination across the healthcare continuum.

However, several activities associated with the transition to ACOs have the potential to expose organizations to new reputational, legal, and compliance risks. These include establishing provider networks, entering into new at-risk payer contracts, developing transitional care models, sharing data, and physician integration, Marsh warns in its report, A New Risk Management Frontier: Accountable Care Organizations. *(The full Marsh report is available online at http://tinyurl.com/ACOreport. See the story on p. 141 for more details from the report.)*

The movement to ACOs will bring changes that risk managers are not prepared for, says **Donna Jennings**, a vice president in Marsh Risk Consulting's Clinical Healthcare Consulting Practice and one of the authors of the report. Aon's 12th annual Hospital and Physician Professional Liability Benchmark Analysis, also released recently, concurs with that assessment. *(See the story on p. 142 for more Aon's report.)*

"The new accountable care model holds great promise for the industry, but many organizations have yet to explore the full impact of the transition to accountable care on their operations and risk management programs," Jennings says. "The key to mitigating the risks inherent in this transition lies in strengthening the culture of safety that supports risk management across the enterprise and in greater communication

Executive Summary

The movement toward accountable care will bring important new risks to hospitals, according to a new report. Risk managers should review current insurance coverage to assess whether the new challenges will require coverage updates.

✦ Entering into provider networks and new payer contracts will open the door to many additional risks.
✦ Sharing data across the network will expose the hospital to more security breaches and their related liability.
✦ Hospitals might take on more medical malpractice liability risk by affiliating more closely with physicians in an accountable care model (ACO).

and coordination among risk managers, quality managers, and business leaders."

While many of the exposures relating to ACOs also can be addressed through existing insurance solutions, organizations should ensure that any current insurance programs effectively protect them through the transition to accountable care, Jennings says. For example, risk managers should determine whether existing directors' and officers' liability policies respond to wrongful acts related to the selection of care models and whether existing cyber/data privacy policies address exposures for affiliated providers' access to patient data. Underwriters, meanwhile, have demonstrated a clear interest in ensuring that the organizations they are insuring have well-defined plans for their transition to accountable care, says **Holly Meidl**, U.S. leader of Marsh's HealthCare Practice and an author of the report.

"Now is the time for risk managers, working closely with their insurance advisors, to engage with underwriters to explain their strategies and objectives for accountable care," Meidl says. "Communication early in the transition process will help to eliminate many ambiguities and uncertainties and ease underwriters' doubts."

SOURCES

- **Donna Jennings**, Vice President, Marsh Risk Consulting's Clinical Healthcare Consulting Practice, Atlanta. Telephone: (404) 539 8018. Email: donna.jennings@marsh.com.
- **Holly Meidl**, U.S. Leader, Marsh HealthCare Practice, Nashville, TN. Telephone: (615) 340-2446. Email: hollis.d.meidl@marsh.com. ✦

Many risks will come with shift to ACOs

No matter the precise structure of the accountable care organization (ACO) or network that they are joining or forming, it will be critical for hospital risk managers to carefully manage the risks associated with the transition to ACOs.

Some of the risks are outlined in a report from Marsh, a healthcare consulting company based in New York City. These are some highlights from the report, A New Risk Management Frontier: Accountable Care Organizations:

• **Establishing provider networks.** Decisions about which organizations to partner with in the ACO structure — whether a joint venture, formal partnership, series of alliances, standalone entity, or another format — and how to share payments and expenses can carry significant risks.

Errors in the provision of nonmedical professional services, including the distribution of shared savings across the network, and other risks could lead to antitrust allegations; contractual liabilities; and lawsuits from patients, competitors, and regulators. If mergers and acquisitions are involved in the formation of the network, participating organizations also could face transactional risks.

• **Entering into payor contracts.** Depending on the structure of reimbursement agreements with the government and various benefit plans, an ACO could assume additional risks. Examples include the risks related to the pricing of medical services, contract mismanagement for member providers, or incurring medical expenses in excess of agreed capitation levels.

• **Developing transitional care models.** Transitioning to accountable care will require new behavior on the part of healthcare professionals to ensure coordination of care — including moving patients from one part of the network to the next — and sharing of information across the network. In the long run, this sharing of information is likely to benefit patients and improve the quality of care provided. But in the short term, realigning organizational resources (including personnel), redefining measurements to track patient care and expenses, and establishing new processes and best practices could increase the risk of errors in delivery of medical services.

• **Sharing of data.** A critical component of achieving better patient outcomes through an ACO is the sharing of electronic medical records and other data across the network. But with more parties handling such data, including service providers outside of the formal network, the risk of a data breach grows. Even before the push toward accountable care, healthcare organizations that had been victimized by data breaches were well aware of the costs related to a data breach, including those related to patient notification, potential government fines imposed under the Health Information Technology for Economic and Clinical Health Act (HITECH) and the Health Insurance Portability and Accountability Act (HIPAA), and litigation.

• **Physician integration.** Whether through direct employment, provider service agreements, or loose affiliations, a key component of the transition to accountable care is the integration and alignment of physicians with hospitals. Depending on the nature of their agreements with physicians, hospitals and the ACOs in which they participate could face added risks, notably medical professional liability (medical malpractice) exposures. ✦

Med mal management for integrated systems more critical than ever

It is estimated that 50% to 60% of physicians and hospitals are exploring ways to team up. Aon Risk Solutions, the global risk management business of Aon Corp., expects this trend to lead to significant collaborative activity, including mergers, acquisitions, joint ventures, and additional developments across the United States.

Those changes will bring new risks that risk managers should plan for now, according to a new report from the American Society for Healthcare Risk Management (ASHRM) in Chicago and Aon Risk Solutions, the global risk management business of Aon Corp. The impact of these new liability risks should not be underestimated cautions, says **Ron Calhoun**, managing director and Health Care Practice leader for Aon Risk Solutions in Charlotte, NC.

"This expected increase in hospital and physician collaboration can be directly linked to the Patient Protection and Affordable Care Act, which is motivating a shift in the marketplace," Calhoun says. "Hospitals are moving from volume-based reimbursement methodologies to outcome-based solutions. This requires a more integrated approach to care delivery to achieve the cost efficiencies necessary to compete in today's evolving market."

Health systems will face significant risk management challenges associated with integrated physician-hospital medical malpractice and professional liability risks. In addition to regulatory scrutiny, Calhoun says these risk-related issues must be considered:

- experience rating variables;
- allocation strategies;
- tail coverage issues;
- capital requirements;
- increased premium flow;
- financial reserve methodologies;
- coordinated defense strategies;
- clinical risk management efficiencies.

"Our findings reflect that when hospitals team up with physicians, they are effectively doubling down on medical malpractice risk."

The 12th annual hospital and physician professional liability benchmark analysis found that 73% of systems surveyed will self-insure the combined hospital-physician malpractice risk. That increased responsibility for the actions of physicians will have a major impact on hospital liability, says **Erik Johnson**, FCAS, MAAA, author of the analysis and Health Care Practice leader for Aon Global Risk Consulting in Charlotte, NC.

"We believe this report to be the most comprehensive analysis of self-insured risks in the health care industry. Our findings reflect that when hospitals team up with physicians, they are effectively doubling down on medical malpractice risk," Johnson says. "As a result, medical malpractice for new physician-hospital arrangements will be a critical issue."

Johnson offers these examples from the report:

- Smaller regional and local hospitals might find themselves without the capital, infrastructure, or expertise to develop as an Accountable Care Organization (ACO).
- Regional hospital systems might not own the assets needed to be competitive and could be looking to buy specific physician practices to fill the gaps.
- Middle market hospital systems are looking to develop capabilities to help drive efficiencies in specific clinical specialties, such as radiology and orthopedics.
- Integrated health systems might be rethinking relationships with home health agencies, home infusion companies, hospice agencies, and behavioral health firms to achieve a more seamless delivery of service post-discharge.

The "2012 Hospital and Physician Professional Liability Benchmark Analysis" is available for purchase at http://tinyurl.com/ashrmreport. The cost is $269 for ASHRM members and $369 for non-members.

SOURCES

- **Ron Calhoun**, Managing Director and Health Care Practice Leader, Aon Risk Solutions, Charlotte, NC. Telephone: (704) 343-4128. Email: Ron.calhoun@aon.com.
- **Erik Johnson**, FCAS, MAAA, Health Care Practice Leader, Actuarial and Analytics Practice, Aon Risk Solutions, Raleigh, NC. Telephone: (919) 786-6246. E-mail: erik.johnson@aon.com. ✦

Senator questions hospitals over 340B drug funds

Sen. **Chuck Grassley** (R-Iowa) is asking three North Carolina hospitals to explain their use of a federal discount drug program after news reports described how the hospitals charge their patients a big mark-up on certain drugs, such as cancer-fighting drugs.

"The discount drug program is meant to help the poorest, uninsured patients," Grassley said in a statement. "It's not meant to subsidize other hospital services and build up hospital sur-

pluses. If hospitals aren't passing drug savings on to patients, they're abusing the system. They're also abusing the taxpayers, including those who already subsidize the massive tax breaks given to tax-exempt hospitals. I'm looking for some answers about program use."

Grassley, the ranking member of the Senate Committee on the Judiciary, wrote to Carolinas Medical Center, University of North Carolina Hospital, and Duke University Health System about their participation in the federal 340B program. The 340B program is meant to help the poorest, uninsured patients who receive treatment through entities including hospitals, qualified health centers, and children's hospitals. The program is meant to lower outpatient drug prices for the uninsured.

Increasingly, the program is under scrutiny as it gains popularity. In a September 2011 report, the Government Accountability Office (GAO) noted an inadequate level of oversight by the Health Resources and Services Administration and a lack of necessary direction on program requirements. Of greatest concern to Grassley is the GAO finding that "the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater."

"As the improper use of the 340B program increases, so does the financial liability to the federal government," Grassley said.

The letters are only the latest effort from Grassley concerning the 340B program. In March 2012, Grassley and three other senators and a member of the House of Representatives asked a wide range of stakeholders for a detailed accounting of how they operate the 340B program. The letters were triggered in part by a recent article in The News & Observer, a Raleigh newspaper, suggesting that certain North Carolina nonprofit hospitals are making excessive profits from markups on cancer drugs. The newspaper article and letters from Grassley highlight examples of significant differences between the amounts hospitals paid for cancer drugs compared to the amounts billed by those hospitals for the drugs and the payment amounts allowed by Medicare.

The letters follow a recent announcement by the HRSA Office of Pharmacy Affairs, the federal agency charged with managing the 340B Program, that it will begin audits of 340B Program participants. The audits will focus on 340B eligibility status, preventing diversions and duplicate discounts, and other program violations.

The requests for information included in the letters could be instructive for 340B participants. These are some issues raised in the letters that could trigger increased scrutiny by the government:

- total revenues received by the participant from participation in the 340B Program;
- the amount of reinvestment of 340B savings in benefits for the uninsured;
- differences in pricing of drugs across different third-party payers;
- the characteristics of a hospital's indigent care population and composition, and its policies on charitable care;
- the frequency of Health Resources and Services Administration (HRSA) audits of the 340B Program. ✦

COMING IN FUTURE MONTHS

✦ Health system pays $9.3 million for false claims

✦ Avoid hires with bad records

✦ Hospital wins nurse's FLSA lawsuit

✦ Career prospects in risk management

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 healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

CNE INSTRUCTIONS

Nurses participate in this CNE 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 QUESTIONS

1. Under the adverse event reporting system proposed by the Agency for Healthcare Quality and Research (AHRQ), how would patients and their relatives report medical errors and near misses?

A. They would report them through a web site and in telephone interviews. Questionnaires would be made available at kiosks in hospitals and doctors' offices.
B. They would report them to their primary caregivers, who would forward the information to the government.
C. They would report them to hospital administration, who would forward the information to the government.
D. They would submit written accounts to a newly created government office.

2. According to John D. Birkmeyer, MD, the George D. Zuidema Professor of Surgery with the University of Michigan Health Systems and director of the Center for Healthcare Outcomes & Policy at the University of Michigan, what is one possible consequence of the adverse event reporting system proposed by the AHRQ?

A. Patient safety will be greatly improved.
B. Doctors may be less forthcoming about admitting errors to patients.
C. Hospitals will be less likely to settle malpractice cases.
D. Patients will be less likely to speak candidly with their doctors.

3. In the federal district court ruling suggesting that the Emergency Treatment and Labor Act (EMTALA) could apply to inpatients, what was the plaintiff's complaint?

A. The hospital refused to treat him in the emergency department (ED).
B. The hospital refused to admit him after initial treatment in the ED.
C. The hospital attempted to transfer him multiple times because he did not have insurance.
D. The hospital admitted him for only an hour to get around EMTALA requirements.

4. In the SAFE COUNT campaign sponsored by the Minnesota Health Association, what adverse event is the focus?

A. Retained objects in labor and delivery
B. Retained objects in any surgical procedure
C. Wrong-site surgery
D. Misidentification of patients

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

$21 million jury verdict issued for victim of birth injury

By **Jonathan D. Rubin**, Esq.
Partner
Kaufman Borgeest & Ryan
New York, NY

Elizabeth V. Janovic, Esq.
Associate
Kaufman Borgeest & Ryan
New York, NY

Bruce Cohn, JD, MPH
Vice President
Risk Management & Legal Affairs
Winthrop-University Hospital
Mineola, NY

News: A woman prematurely gave birth to an infant in 2002. The woman's labor was induced, and she experienced a prolonged vaginal birth. The fetus was under distress during delivery. Plaintiffs claimed the infant should have been delivered by caesarean section, because an umbilical cord was wrapped around the infant's neck causing oxygen deprivation and resulting in cerebral palsy. In 2012, a jury awarded $21 million to plaintiffs and their 9-year-old, wheelchair-bound infant who suffers with cerebral palsy and a host of disabilities.

Background: Plaintiff's estimated date of delivery was Nov. 6, 2002. However, on Sept. 6, 2002, plaintiff was admitted to the hospital with preeclampsia. The fetus was at 31 and 2/7 weeks gestation. Plaintiff was evaluated by a maternal fetal medicine specialist who determined that a vaginal delivery was appropriate as long as plaintiff and the fetus remained clinically stable. The specialist warned that if plaintiff became unstable or if non-reassuring fetal heart tracing remote from vaginal delivery was detected, then a caesarean section should be performed. On the morning of Sept. 7, 2002, plaintiff was started on oxytocin and dinoprostone to induce labor.

Plaintiff said the hospital never discussed this issue with her, nor was the option of a caesarean section offered.

An obstetrician/gynecologist evaluated plaintiff at 11:10 a.m. and noted that plaintiff was 4 cm dilated, 100% effaced, and the fetus was at -1 station. The fetal heart rate became non-reassuring with late and prolonged variable decelerations after noon. At 5:13 p.m., the infant was born. He was pale and required positive pressure ventilation because of bradycardia and poor respiratory effort. His initial Apgar scores were 4 at one minute and 7 at five minutes after birth.

Plaintiffs filed suit on Feb. 18, 2011. They argued that the hospital failed to recognize the signs of a serious medical condition, failed to monitor during the delivery, and failed to perform a caesarean section delivery. A physician testified at trial that the infant was at risk for periventricular leukomalacia. The physician said it was caused by periods of oxygen deprivation due to the infant's umbilical cord that was wrapped around his neck throughout the delivery. Plaintiff said the hospital never discussed this issue with her, nor was the option of a caesarean section offered. Plaintiffs claimed that the infant, who was 9 years old at the time of resolution of this case, suffers from neurological injuries, spastic diplegic cerebral palsy, receptive language and expressive language delay, developmental

Financial Disclosure: 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. **Elizabeth Janovic**, **Patrick A. Dolan, Bruce Cohn,** and **Jonathan D. Rubin**, co-authors, have no relevant relationships to disclose.

disabilities and delays, respiratory distress syndrome, perinatal depression, apnea, apraxia, hypoxia, cerebral palsy, and hypertonia. Plaintiff also argued that the infant's earning capacity has been severely diminished. The infant has a fully functioning mind, but the combination of cerebral palsy and limited mobility, use of his hands, and speech has trapped him inside a broken body. He will likely be in a wheelchair for the rest of his life.

The hospital stood by all of the care provided by the nurses and doctors in this case. Defendants claimed that post-birth ultrasounds showed no swelling in the infant's brain, which should have presented if there was oxygen deprivation during the delivery. Additionally, they said that blood tests performed on the infant's blood acids showed no signs of oxygen deprivation. The hospital claimed that the infant's premature birth was the ultimate cause of his current condition.

The trial began on July 16, 2012, and ended on July 31, 2012. The jury held in favor of the plaintiffs and awarded $21 million. The award breakdown is: $18 million for the infant's medical care, $2 million for lost potential wages, and $1 million for non-economic pain and suffering. The family most likely will receive $20.62 million, due to a state cap on non-economic damages.

What this means to you:
Impaired infant cases are very dangerous due to the significant damages and the difficulty of getting a jury to accept the fact that the child is impaired when nothing was done wrong. This case illustrates the classic dilemma of not waiting to perform a caesarean section and put the baby at risk vs. moving too quickly to a caesarean section that has some risk to the mother and might be disappointing to the woman who wanted to deliver naturally.

Several issues are present in this case report. Although the due date was November, the patient presented with preeclampsia in September. At 31+ weeks, the fetus was clearly mature enough to be delivered, and the obstetrician induced labor. Consider the "warning" issued by the maternal-fetal medicine (MFM) specialist: if plaintiff became unstable or there were non-reassuring fetal tracings, then a caesarean section should be performed. Unfortunately, the clinical staff called in an appropriate consult and then chose to ignore the advice that they sought.

The infant has a fully functioning mind, but the combination of cerebral palsy and limited mobility, use of his hands, and speech has trapped him inside a broken body.

The fetal tracings became non-reassuring with late and prolonged variable decelerations after noon, yet the infant was not delivered until 5:13 p.m., some five hours later. We don't know from the information presented whether the fetal heart rate tracings subsequently became more reassuring, but what is clear is that the attending obstetrician chose not to go to a caesarean section to get the baby out. From a defense standpoint, the obstetrician is at greater legal peril having called for the MFM consult and then discounted the recommendation. Surely this consult was shown to the jury members, who probably had difficulty understanding the obstetrician's thought process. The patient and her family also were never given the option of proceeding to a c-section.

As a general proposition, the likelihood of success of these cases is more tenuous than medical malpractice cases in other specialties. The jury is presented with complex testimony and conflicting opinions, then left to decide what really happened. Two or more experts banter with opposing counsel over the cause and effect of peri-ventricular leukomalacia (PVL) and the significance of blood gas analysis. Assuming that member of a lay jury even understand the concept of what PVL is and the finer points of acid base balance of the blood gases, they still are faced with a 9-year-old child who has significant and devastating injuries.

Contrasted with the highly complex nature of the defense, which relies on the lack of swelling in the brain and blood chemistry, the plaintiff has a simple argument: All they had to do was perform a caesarean section, a procedure well understood by lay people and generally thought of as a simple procedure. The case summary also refers to the umbilical cord wrapped around the neck, another apparent clear cause and effect of the damages easily understandable by the jury. Also consider that this patient was induced because of a diagnosis of preeclampsia. This condition by its very nature puts the woman and the unborn child at risk and would seem to argue in favor of the safest delivery, which according to the plaintiff's expert was a caesarean section.

The child is born with less than stellar APGAR scores and poor respiratory effort, requiring supplemental oxygen, and subsequently experiences cerebral palsy and delayed development. While clinical authorities will argue over whether cerebral palsy is truly

caused by malpractice, the damage is apparent. Unless the defense can come up with another plausible explanation for the child's condition, the likelihood of successfully defending the case is small.

So what does this mean to me? If your physicians are going to call consults, they should listen to the advice or at least document in the record why they didn't. Patients who present precisely because of a complication such as preeclampsia warrant consideration for more aggressive early intervention than other patients. Consulting with the patients is a must and, in high-risk situations, the patient and their family members should be kept informed and consulted as to the plan. Finally, some cases have such a high risk at trial that early reasonable settlement should never be automatically discounted.

Reference

Circuit Court of Maryland, Baltimore City: 24C11001080 (2012). ✦

$15 million verdict awarded to victim of overdose death from propofol

By **Jonathan D. Rubin**, Esq.
Partner
Kaufman Borgeest & Ryan
New York, NY

Patrick A. Dolan
Law Clerk
Kaufman Borgeest & Ryan
Garden City, NY

Bruce Cohn, JD, MPH
Vice President
Risk Management & Legal Affairs
Winthrop-University Hospital
Mineola, NY

News: The patient was a 45-year-old woman who had been experiencing chest discomfort. Her primary care physician told her to obtain a complete heart check-up at the hospital. The heart check-up revealed that the patient required triple bypass surgery immediately. After a successful surgery, the patient lay recuperating with a breathing tube in stable condition. While recovering, the nurse on shift injected an anesthetic amount of propofol that caused the patient to lapse into a coma, experience unstable blood pressure, and eventually die. A wrongful death action was commenced in malpractice against the hospital by the patient. The jury returned a verdict for $15 million.

Background: The patient began feeling short-winded and was experiencing chest discomfort. Despite the generalized nature of the symptoms, the patient's primary care physician recommended she receive a full heart work-up. She visited the hospital for cardiac testing. Immediately following the hospital's examination of patient, doctors informed the patient that a triple bypass was necessary. The hospital determined that the patient's risk in undergoing such a procedure was 3%. The triple bypass surgery was performed without any complications. Success of the revascularization was confirmed by a post-surgery Doppler flow study. The patient then was sent to rest in the hospital's Cardiac Recovery Unit. She recovered there for approximately six hours and remained in stable condition. About 7 p.m., family and friends visited the patient. Also at this time, the nurses on duty changed shifts. The new nurse administered propofol to the patient. According to the anesthesiologist, propofol was to be provided as a light sedative only in case her breathing tube caused her difficulty. Even though the patient's ventilator was set only to assist breathing, the new nurse administered an anesthetic amount of propofol to the patient. This amount caused the patient to immediately lapse into a coma. She experienced respiratory depression and falling blood pressure. While the patient's condition was spiraling out of control, the nurse waited over 20 minutes before calling for help from any physician or the rapid response team. She repeatedly silenced the alarm bells on the monitor and ventilator. Eighteen minutes after help had been summoned, the patient suffered cardiac arrest and died.

According to the anesthesiologist, propofol was to be provided as a light sedative only in case her breathing tube caused her difficulty.

The patient's estate commenced a wrongful death suit against the hospital in medical malpractice.

Plaintiff alleged that the nurse should never have been hired by the hospital in the first place. The nurse had absolutely no experience in caring for cardiac bypass recovery patients, as this was only her second month on the job. Not only did she not have experience, but she was not trained and her skills were not tested in caring for cardiac bypass recovery patients. The nurse also had no experience or proficiency in administering propofol. Eight senior nurses at the hospital testified that they had never mentored or taught the nurse in any capacity. Plaintiff alleged that the nurse improperly provided care by overdosing the patient with propofol and then, once admittedly realizing the effect it had on the patient, waited 20 minutes before calling for help.

The hospital attempted to justify the care it provided the patient. However, the wrongdoing on the part of the hospital most certainly muddied its defense. First, the nurse disposed of the bottle of propofol, all of the intravenous tubing, and deleted the memory of the computerized intravenous pump immediately after the incident. Also, before litigation, the patient's husband obtained her medical records from hospital. After the commencement of the suit, a different set of medical records was provided to defense counsel through discovery. Numerous false records were noted in the subsequently provided records. This behavior, combined with the attempted justification of the hospital's employment of the nurse and her care in light of patient's 3% risk level, appeared to play against the hospital with the jury.

After a two-week trial and only one hour of deliberation, plaintiff was awarded $15 million. This amount was surprising as the venue is known to be conservative in its awards and because the patient only asked for an award between $5 million and $10 million.

What this means to you: This is a case involving a 45-year-old woman who was unexpectedly diagnosed with coronary artery disease, underwent surgery that was incredibly successful, and then succumbed to a medication overdose due to clinician error.

There is no defense to this case due to a number of issues. What this means to you is that credentialing is of the utmost importance. Proper training of staff cannot be taken lightly either, and the worst thing you can do after a negative outcome is to cause spoliation of evidence and attempt to absolve yourself by altering documentation.

...when the patient was obviously dying, no rapid response team or other assistance was called for by the nurse.

Most cases don't get worse than this. The surgery was a resounding success, but the patient passed away. A young, relatively well patient who had an isolated cardiovascular issue that was correctable was done in by a drug error. The anesthesiologist ordered propofol for discomfort due to the endotracheal tube. Propofol (Diprivan) is a potentially dangerous drug and well within the conscious of jurors due to the Michael Jackson case. It is a great medication when used in competent hands, but it has a mechanism of action that can go from light sedation to heavy sedation to general anesthesia. It is also not a controlled substance, and it might be viewed as less dangerous than it should be by providers. It is used extensively, not only in the operating room, but in procedure rooms, in post anesthesia care units (PACUs), and in intensive care units (ICUs).

The nurse was clearly not credentialed to use propofol, which was an absolute necessity in this case. She had no real experience in caring for these types of patients, and she should not have been assigned to this area. Compounding the problem was the fact that alarms were purposely silenced, and when the patient was obviously dying, no rapid response team or other assistance was called for by the nurse. The lesson here is that members of the hospital staff must be certified and trained to work in the specialty areas where they are placed. Also, documentation of that training and certification must be up to date.

Perhaps the worst part of the case was the nurse's disposal of the bag of medication, which erased the memory of the monitoring equipment and changed the records. The hospital then compounded the blunder by participating in covering up. This cover-up clearly escalated the value of the case for the jury and, while it was not defensible before, this situation made it exponentially worse. Jurors might forgive a mistake but they will not forgive an intentional act.

Had this case been handled properly and the mistake disclosed immediately, the case would have cost money, but not at the level seen in the obviously punitive verdict.

Reference

Mobile County Circuit Court: CV-10-900421 (Alabama). ✦

Healthcare RISK MANAGEMENT

2012 Index

When looking for information on a specific topic, back issues of Heatlthcare Risk Management *newsletter, published by AHC Media, may be useful. To obtain back issues, contact our customer service department at P.O. Box 740060, Atlanta, GA 30374. Telephone: (800) 688-2421 or (404) 262-7436. Fax: (800) 284-3291 or (404) 262-7837. E-mail: customerservice@ahcmedia.com.*