Healthcare RISK MANAGEMENT

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Positive results coming from apology followed by quick settlements

'Seven Pillars' and similar approaches advocate disclosure, apology, and offer

The idea of full disclosure of adverse events was proposed to the risk management community years ago. Remember how controversial that idea was? Then the next suggestion was that providers should apologize for their errors. More debate ensued.

The next logical idea was to disclose, apologize and then make an offer of compensation without delay. This strategy, proponents said, was not only the right thing to do from an ethical standpoint, but also reduced the amount of money hospitals spend on malpractice litigation.

"When you have the medical society and the trial lawyers association in Massachusetts agreeing on something, that's pretty monumental."

So how's that working out for you?

The recent data suggests it's working pretty well. The approach has developed many names and slight variations as it was adopted by healthcare systems, hospitals and insurance companies across the country, but the original and best known incarnation is the "Seven Pillars," created by the University of Illinois hospital system in 2006. The Chicago system's way consists of these steps:

- Report incidents that could harm patients.
- Investigate those cases, and fix problems before an error happens.
- Communicate when an error occurs, even if no harm was done.
- Apologize and "make it right" by waiving hospital and doctors' fees.
- Fix gaps in the system that can cause things to go wrong.
- Track data from patient safety reports, and see if changes make care safer.
- Educate and train staff how to make care safer.

Only two years after it started, the process led to more than 100 investigations and nearly 200 specific improvements, according to the Agency for Healthcare Research and Quality (AHRQ), which promotes the Seven Pillars program. In those two years, the policy also was the basis for 20 full disclosures of inappropriate care that caused patient harm.

INSIDE

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AHRQ is funding a three-year project in 10 Chicago-area hospitals. The entire process is being tested at five hospitals; the other five will report data only and compare their results to the hospitals using Seven Pillars. Other hospitals and health systems have independently adopted Seven Pillars or variations to the approach, and the initial reports on effectiveness are all universally positive, says **James B. Battles**, PhD, senior service fellow for patient safety and medical errors, AHRQ Center for Quality Improvement and Patient Safety, Rockville, MD.

"We are excited by the results we are seeing so far from not only the Seven Pillars program, but also other programs that use some of the same principles," Battles says. "There seems to be a consensus growing that this is a reasonable, productive way to approach medical errors. When you have the medical society and the trial lawyers association in Massachusetts agreeing on something, that's pretty monumental."

Battles notes that the Seven Pillars approach can be adopted in almost all states without special legislation, unlike some malpractice reform proposals. AHRQ is putting together more resources for healthcare providers interested in adopting the approach, Battle says. Information is available on the AHRQ site at http://tinyurl.com/sevenpillars.

"We are finding that, particularly for hospitals and hospital systems with enterprise liability, meaning they are self-insured, this program really offers benefits," Battles says. "One of the things that is really important is to promote communication among all the parties on the defense side. This whole approach depends on good communication and having all the parties understand that this is an approach that makes sense for everyone."

Disclosure programs of this sort are gaining great admirers among insurers who otherwise would have to pay out larger sums, says **Frank A. Jones**, an 18-year veteran of the insurance industry and partner with Mints Insurance, based in Millville, NJ. "This is the only formidable way for us to see drastic changes in the medical malpractice system," Jones says. "In the University of Illinois system, the claims dropped about 70% and malpractice premiums dropped by several million over a few years. There is a huge, huge positive impact from a disclosure program

Executive Summary

After years of trying the strategy of disclosing medical errors, apologizing, and making a prompt settlement offer, healthcare providers are seeing positive results. The once radical approach appears to save money overall on medical malpractice.

✦ Several variations of the philosophy have been adopted by providers and insurers.

✦ There is no evidence of a downside to the approach.

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Editorial Questions

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

that you cannot get from any type of reform."

Nothing else achieves the same results as a disclosure program, Jones says. Everybody wins when you disclose and apologize quickly, and the settlement offer is almost always less than what it might have been later or what a trial jury would have awarded, he says. "Even with premiums declining, the insurance company wins because the payouts are declining," he says.

A key component for success is to obtain complete buy-in from physicians, Jones says. That buy-in can be challenging because older physicians were taught to deny and defend, and they may steadfastly insist that approach is the right path. "The only way to educate them and get full buy-in is to use hard data that shows disclosure, apology, and offer works every single time it's tried. I have not seen a single bit of evidence that this approach does not work to everybody's best interest," Jones says. "I've never seen an instance where this model failed. But I've seen plenty of other promises for tort reform and the like that amounted to nothing."

"There is a huge, huge positive impact from a disclosure program that you cannot get from any type of reform."

Jones notes that the approach is becoming so well accepted and the beneficial effects so obvious that insurers are starting to consider it the gold standard for healthcare providers.

"We have made a 100% commitment to the disclosure model, as an agency," Jones says. "We decided to only write policies with a carrier that practices this model fully, as we believe it will be the catalyst to changing this industry."

SOURCES

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Surgeon operates on wrong side of brain — time-out compliance is questioned

Do some team members think they don't have to participate?

A wrong-site surgery resulted in a medical malpractice lawsuit filed recently against SSM Health Care - St. Louis in Missouri and a neurosurgeon, and the plaintiff's attorney suggests that the cause might be a failure of the entire operative team to participate in the time-out.

Regina Turner, 53, of St. Ann, MO, was scheduled on April 4 for a "left-sided craniotomy bypass" at St. Clare Health Center in Fenton, MO, according to a complaint filed in the Circuit Court of St. Louis County in Clayton, MO. Instead, she received a "right-sided craniotomy surgical procedure," the suit alleges. *(See the story on p. 76 for more details about the incident.)*

The hospital issued statements confirming that the sentinel event occurred. A statement from **Chris Howard**, president and CEO of SSM Health Care – St. Louis, said the provider organizations "sincerely apologize for the wrong-site surgery in our operating room. This was a breakdown in our procedures, and it absolutely should not have happened. We apologized to the patient and continue to work with the patient and family to resolve this issue with fairness and compassion."

The hospital immediately began an investigation and has taken steps to prevent such an error from happening again, the statement says. The hospital also confirmed that the neurosurgeon is an employee of SSM Health Care and has staff privileges at St. Mary's Health Center and DePaul Health Center.

A review of the medical record and other investigation suggests that the error was not detected in time because not all members of the operative participated in the time-out, says Turner's attorney **Alvin Wolff Jr.**, JD, of Clayton. "That's my understanding. For something like this to happen,

Executive Summary

Executives at a Missouri hospital confirm that one of its employed surgeons operated on the wrong side of a patient's brain. The patient's attorney suggests that the surgical team did not fully participate in the time-out.

- ✦ The hospital says there was a breakdown in its procedures.
- ✦ Most such never-event cases settle before trial.
- ✦ Some team members might think they do not have to participate in the time-out.

shortcuts had to be made," he says. "There's just no way you follow the proper time-out procedures and have this result."

Wolff is limited in discussing the Turner case because it is still in litigation, but he has handled other wrong-site surgery cases before and says a pattern has emerged. "The time-out procedures were not performed by the entire team," he says. "You've got everyone there who is supposed to be the eyes and ears, looking out for each other and the patient, but some people think they don't have to participate. The CRNAs may think that they don't have to because they're going to be behind the screen anyway, but the more people you have participating, the more eyes you have to see mistakes and prevent them."

In one wrong-site knee surgery case, Wolff settled with the surgery center and the doctor but went to trial with the anesthesiologist and won an award for the plaintiff. "The anesthesiologist felt he didn't need to participate in the time-out despite the universal standard," he says.

Wolff attributes some of the problem to tort reform efforts in recent years.

"If you think you're somewhat bulletproof, you're not going to pay as much attention," he says. "That's the downside to tort reform."

SOURCE

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Patient left with serious disabilities after wrong-site surgery

Wrong-site brain surgery left a Missouri woman unable to speak intelligibly and in need of around-the-clock care, according to a complaint filed in the Circuit Court of St. Louis County in Clayton, MO.

Patient Regina Turner, 53, of St. Ann, MO, received a right-sided craniotomy bypass instead of the scheduled left-sided procedure at St. Clare Health Center in Fenton, MO, the hospital has confirmed. Once the operating team realized they had made an error, a second surgery was performed six days later on the correct side, according to Turner's attorney **Alvin Wolff Jr.**, JD, of Clayton.

"Before the incorrect surgery, plaintiff was mobile, cognizant and able to care for herself," the suit alleges. "After the incorrect surgery, plaintiff requires around-the-clock care for her basic needs. ... Plaintiff will also continue to suffer from emotional distress, anxiety, disfigurement and depression."

Wolff says the woman worked as a supervisor for an Internet service provider and later as a paralegal, but five years ago she began suffering a series of mini-strokes. Her speaking ability already was degraded before the wrong-site surgery, but she could be understood by family members.

The craniotomy bypass surgery was intended to prevent future strokes, but the woman is now in significantly worse condition than before her surgery, Wolff says. ✦

6 ways to improve your root cause analysis

Risk managers routinely use a root cause analysis (RCA) to determine the true source of an adverse outcome or other event, but are your RCAs as good as they could be? There is no single way to conduct an RCA, but one experienced investigator explains how you can improve your results by following a few tips and avoiding the most common mistakes.

No two RCAs are ever the same, says **Kathryn Schulke**, RN, principal with the consulting firm Booz Allen Hamilton in Baltimore, MD. Each one must be tailored to fit the circumstances of the incident being investigated and the people involved, Schulke says.

"Most risk managers could improve their RCAs," she says. "I think a lot of people know that, but are unsure what might be lacking or how they can make their RCAs better."

There is no one way to conduct an RCA, Schulke says. However, some RCA best practices apply to all situations, so Schulke offers these tips for improving your RCAs:

• Do not include in your RCA the parties who were involved in the adverse event. This is one of the most common mistakes that Schulke sees

Executive Summary

Most risk managers could stand to improve the way they conduct root cause analyses (RCAs). Proper use of this vital tool will yield more useful results.

- ✦ Avoid including those involved in an adverse event in the RCA.
- ✦ An RCA must be tailored to each individual event under review.
- ✦ Rely on the medical record, not interviews, for the timeline.

with an RCA. A better process is to interview those individuals one-on-one and capture the information they can provide, but do not include them in the RCA exercise or meeting. Instead, bring in people from their service line and other relevant areas.

"If that person is from dietary or pharmacy, for instance, you make sure you have people from those departments involved in the exercise, but not the person who was directly involved with the error," Schulke explains. "People can't help but be defensive and try to speak for themselves when they were part of the error, so it makes the exercise more objective when they are not involved in the actual RCA."

• Frame your questions on facts, not a hypothesis. This distinction is important, Schulke says. Do not ask, "Was the lack of proper equipment a contributing factor to this error?" for example, because that is a hypothesis, and you could lead the person into answering yes. Instead, ask factual questions about what equipment was available, what was needed, and what was used. Those participating in the RCA, particularly those from risk management or quality improvement who might take the lead in the investigation, should be properly trained on this point.

• Involve physicians and hospital leadership. Too often, Schulke says, the RCA is conducted by other parties, and then the results are presented to the physicians and hospital leaders as a final conclusion. Involving those parties in the RCA will result in more substantial and sustained process improvements stemming from the RCA results, she says.

"The physician community is key to looking at some of these sentinel events and the serious harm that has occurred," Schulke says. "Getting them involved early on, along with the C-suite at the hospital, is a superior way to conduct a root cause analysis."

The cause relates to the steps that were taken, not taken, or missed, whereas the problem is the resulting adverse outcome.

• Focus on the cause, not the problem. The cause relates to the steps that were taken, not taken, or missed, whereas the problem is the resulting adverse outcome. With a patient fall, for example, the problem is that the patient fell, but the cause is that the floor was wet.

• Use a multidisciplinary team for the RCA. Schulke cautions that many hospitals will build a multidisciplinary team related to the event in question, but they stop there. A pharmacy error, for example, might prompt a multidisciplinary team that includes representation from pharmacy, physicians, and nursing, because those are the fields involved in that incident.

"You really should involve people from areas that were not necessarily involved in that error, but who might have a perspective or point of view that is useful," Schulke says. "Everyone brings a different perspective and a different history to the analysis, and that's what you're looking for in an RCA: insight that is not immediately apparent to those involved."

• Build your timeline from documentation, not personal recollections. The medical record should be considered the reliable source of factual data such as time points. The statements of people involved most likely will contradict because memories are imperfect and sometimes because the parties involved have a vested interest in skewing information such as the timeline to their advantage.

"If it is in the medical record, you should be able to rely on that as the accurate source," she says.

SOURCE

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Include families in patient safety efforts, education

When risk managers try in so many ways to improve patient safety, patients' family members are an often overlooked partner, says **Karen Curtiss**, president of PartnerHealth system based in Boston and founder of Campaign Zero — Families for Patient Safety.

Curtiss created Campaign Zero — Families for Patient Safety to help educate people on how to help their loved ones stay safe in the hospital.

"It's become a well-known adage now that if you go to the hospital, you should take someone with you to watch out for you and be your advocate," she says. "But people don't know what to do when they get there. They want to protect their loved one, but they don't know how."

Curtiss urges healthcare risk managers to include family members and other loved ones in the patient safety process. Based on her book "Safe and Sound in the Hospital," her program attempts to address some proven problems such as how patients tend to forget 80% of what a doctor tells them. The discharge process is another concern, she says, with research showing that many patients are sent home with incorrect or incomplete drug regimens and

instructions.

"We teach that it's OK to stop, take a beat, go through the checklist we provide, and make absolutely certain that the post-discharge care is complete and well thought out," Curtiss says.

The campaign's website at www.campaignzero.org offers a "quick course in patient safety" and numerous checklists the families can use to help keep the patient safe, along with other resources. For example, there are checklists on nine topics, including preventing falls and bedsores.

Curtiss urges risk managers to use the website for materials they pass on to family members, and to refer patients directly to the website for more information.

"It's also important to educate staff on how people are going to start walking in the door with checklists and they will be asking questions, and the nurses can't take it personally," Curtiss says. "The culture you want is one in which the staff expect family members to be vigilant and going through their own safety checklists, and we want it to be more noteworthy and unusual when the family members don't do that."

SOURCE

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Tight access to unit is key to preventing infant abductions

At press time, no infants had been abducted from healthcare providers in the United States in 2013, but there are steps you can take to ensure that disaster does not strike your facility, notes prevention expert **John Rabun**, ASCW, director of infant abduction response for the National Center for Missing and Exploited Children (NCMEC) in Alexandria, VA.

Rabun spent 28 years as executive vice president and CEO of NCMEC before semi-retiring in February 2012. Though the news of no abductions is good for this year, Rabun has observed that some hospitals need to improve their security practices. In particular, he tells *Healthcare Risk Management*, risk managers should confirm that their nurseries are using tight security.

Nurseries, both well-baby and neonatal intensive care, should be locked. Staff members should check the status of the locking system regularly, at least once on each shift. "Recently, there seem to be many cases wherein the badging system has been set to all facility staff rather than only to those staff with permission under policy to care for and transport newborns," Rabun explains.

Rabun says that in 2013, there have been "a number of penetrations into nurseries by women who were assessed as being potential abductors," although no infants were taken. Those incidents indicate that physical security of the nursery is a top priority for preventing abductions, he says.

> *"The number of assessed potential abductors from healthcare seems much higher than we ever suspected ..."*

"The number of assessed potential abductors from healthcare seems much higher than we ever suspected. There is no way to get precise numbers and no incidence study," Rabun says. "We do not know how many of these suspected individuals would never actually put their plan into final action, but that many are at least into the feigned pregnancy and surveying the hospital is very clear."

The more widespread use of recorded digital cameras is proving vital to the analysis of and reaction to these individuals and for the transmission of that information between area hospitals, Rabun says. That information indicates that potential abductors seem to make multiple attempts at multiple facilities before taking an infant, being caught, or giving up, he says. Rabun encourages risk managers to report any suspicious incidents quickly to the NCMEC so that he and his colleagues can look for patterns and trends of behavior and advise healthcare professionals and law enforcement.

"Many facilities are clearly, albeit gradually, reducing access points to mother and baby units and seeing good results in visitor control," Rabun says. "Diligence and frequent checks on the use of unique photo ID continues to be the mainstay for getting moms on the security team for their babies."

SOURCE

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Hospitals reduce serious falls 64% by sharing data, strategies

An 18-month patient safety effort by 21 hospitals in the Cincinnati, OH, region has reduced incidents of patient falls that result in injury in these hospitals by 64%, and one of the key reasons is that the hospitals did something that might have made risk managers gasp in recent years: They shared their own proprietary data about falls.

Before this effort began, the hospitals were working individually to reduce the risk of falls in their facilities. But the decision was made that progress could be made more quickly by working together, says **Steve Muething**, MD, vice president of patient safety at Cincinnati Children's Hospital Medical Center and chair of the Greater Cincinnati Health Council (GCHC) Harm Reduction Collaborative. Through the GCHC, a hospital membership organization, the 21 hospitals agreed to share incident data with one another for the first time and to use a formal improvement model developed by the Institute for Healthcare Improvement.

The hospitals previously had shared some data for other collaborations, says **Dora Anim**, MPA, vice president of quality and data at the GCHC who helped lead the organization's Harm Reduction Collaborative. Still, this effort was different. "This was harm data. It was data around what happens to our patients while they're in a hospital," Anim says. "That is different for hospitals from sharing other types of information."

Muething points out that sharing data normally kept confidential will work only when senior hospital leaders endorse the effort. "When our senior leadership agreed not to compete on safety, agreeing to have a common measure and share our data and best practices, that set the stage for the nurses, the doctors, the risk managers, the quality improvement people to come together and know that it was not only OK to work together, but that senior leaders wanted them to work together," Muething says.

One important point for the collaboration was an agreement that data would be shared publicly only for the group, never for a single hospital, Anim says.

The hospitals set a goal of reducing by 50% the regional rate of patient falls that occur in hospitals and that result in moderate or severe injuries. They surpassed that goal by achieving a 64% reduction. In fact, an improvement was made in overall falls as well as falls resulting in injury.

Eighteen months ago, approximately 250 patients per month experienced a fall within the 21 participating hospitals in this region, and 11 patients per month had a fall that resulted in serious injury. The GCHC reports these current results:

- 48 fewer patients are falling per month (or two less patients per day).
- Seven fewer patients per month are experiencing a fall that results in a moderate or major injury.

"I think the impressive results of this initiative prove that true collaboration among healthcare leaders and clinicians can create meaningful transformation in patient safety and quality of care," Muething says. "Our goal is to continue to improve until we get to zero falls, but this is tremendous progress in a short amount of time."

The average hospital stay for patients who fall is 12.3 days longer, and injuries from falls lead to a 61% increase in patient care costs, Anim notes. "Our safety collaborative chose to work on reducing falls that result in injury because of the impact on patients and because they result in higher overall costs," Anim says.

Small tests of change were a key strategy for this work, Muething and Anim explain. A group of patient safety and clinical hospital representatives from the various hospitals convened each month. They alternated between learning sessions in which teams from the hospitals came together to plan changes and action periods in which the teams returned to their organizations and tested those changes in clinical settings.

Executive Summary

A group of 21 hospitals has reduced falls that result in injury by 64%, using a combination of strategies. The hospitals agreed to share data that typically is kept confidential.

- Senior hospital leaders signed on to the idea of competing hospitals working together.
- The hospitals used small tests of change and reported the results to each other.
- Participants included the human cost of falls in their calculations.

Some tests of change were proven effective, and some were not. For example, some hospitals piloted the use of a new toilet seat alarm in an attempt to reduce patient falls without great results. Regardless, hospitals shared findings with the entire group so all could learn. *(See the list below for more information on what changes were effective.)*

It was important for the collaboration participants to remember that their work had a human impact, rather than focusing exclusively on data, Muething says.

"We wanted to remind people every time we met that there were people behind these numbers and that reducing falls could have a major effect on people's lives," Muething says. "When we discussed an incident, we talked about the patients and how the falls affected them and their families after they came into our hospitals to get better. That was important to show the devastating effects a fall can impart on people, aside from the numbers and the costs."

SOURCES

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- **Steve Muething**, MD, Vice President of Patient Safety, Cincinnati Children's Hospital Medical Center. Telephone: (513) 636 -2068. Email: stephen.muething@cchmc.org. ✦

Strategies that Helped Hospitals Reduce Falls by 64%

- Hospitals change risk assessment procedures to include more patients or all patients rather than only high-risk patients.
- Increase the frequency of unit meetings where incidents of falls are evaluated. Some hospitals moved from monthly meetings to weekly.
- At some hospitals, a trial of different motion detectors, bed alarm systems, and bed positioning that could impact falls.
- Some hospitals implemented "purposeful rounding" – a proactive intervention in which nurses (or a combination of nurses and other healthcare workers) do bedside rounding on patients at regularly scheduled intervals – usually every hour. Hospitals used the rounding to assess the "4Ps" (pain, position, potty and proximity of personal items) which helps to minimize the instances of patients trying to get out of bed.
- Some hospitals experimented with post-fall team huddles after an incident to immediately assess the issues that led to a fall and put a solution in place to prevent further incidents.

Source: Greater Cincinnati Health Council (GCHC). ✦

Tuomey Healthcare guilty in $39 million false claims case

A federal jury in South Carolina has found that Tuomey Healthcare System, based in Sumter, violated the Stark Law and the False Claims Act (FCA) by submitting false claims for reimbursement to the United States to the tune of $39 million in damages.[1]

Interestingly, there was no allegation of overbilling. Instead, the violations concerned fair market value and non-compete provisions when contracting with physicians.

The case began in 2003 when several specialty physician groups in South Carolina informed Tuomey that they no longer would perform surgery at Tuomey's hospital and would instead conduct the surgical procedures in-office. To counter that potential loss in revenue, Tuomey made an agreement for the physicians to be part-time employees and required them to perform outpatient procedures at a Tuomey hospital. Each physician received an annual base salary, the amount determined by Tuomey's net cash collections for the outpatient procedures, as well as potential bonuses based on Tuomey's collections.

In addition, the agreements prohibited the physicians from competing with Tuomey during the term of the contract and for two years thereafter. One physician, however, did not agree to the terms and sued Tuomey as a whistleblower under the FCA, alleging that Tuomey paid doctors on average 31% above fees collected.

A 2010 jury found that Tuomey violated the Stark Law but not the FCA. On appeal, the Fourth Circuit found various errors and remanded the case back to the trial court. It noted that "if a hospital provides fixed compensation to a physician that is not based

solely on the value of the services the physician is expected to perform, but also takes into account additional revenue the hospital anticipates will result from the physician's referrals, that such compensation by necessity takes into account the volume or value of such referrals."

On retrial, the jury found that Tuomey violated the Stark Law and the FCA because Tuomey's contracts figured in anticipated referrals and the contracts were not consistent with fair market value. Even though there were no overbilling allegations, prosecutors said Tuomey violated the FCA by knowingly submitting Medicare claims for services that were rendered pursuant to a prohibited referral. Also, Tuomey knew that these arrangements resulted in false claims to the government, the jury said. Tuomey must pay $39 million in damages, and a court will determine later if the company must pay a penalty of up $357 million.

Reference

1. United States ex rel. Drakeford v. Tuomey Healthcare Sys., No. 3:05-2858-MBS (D.S.C. May 8, 2013). ✦

System said to reduce falls, transfers in elderly

A fall reduction system that encourages caregivers to respond early to warning signs has been proven to significantly reduce falls, according to the manufacturer.

EarlySense, based in Waltham, MA, announced the results of a multi-center clinical study demonstrating that the system helps medical teams at rehabilitation centers to reduce patient falls as well as the number of patients transferred back to the hospital.

The technology involves continuous patient monitoring in hospitals and rehabilitation homes by monitoring patients' heart rate, respiration, and movement without touching the patients. Eight hundred and thirty-three patient records at The Dorot Geriatric Center, a 374-bed facility in Netanya, Israel, and 773 records at the Hebrew Home at Riverdale, an 870-bed skilled nursing facility in Riverdale, NY, were collected and reviewed over six months. The transfer rate to the hospital decreased by 21% at Dorot, and the falls rate decreased by 38.5% at the Hebrew Home.

The contact-free sensing capabilities and immediate data transfer enable nurses to proactively provide personalized patient care and potentially prevent adverse events, the company says. Through continuous patient supervision, the system can help staff reduce the risk of patient falls and effectively work toward decreasing other adverse events, such as pressure ulcers.

The data was presented recently at the 2013 Annual Scientific Meeting of the American Geriatrics Society (AGS) by Hebrew Home medical director and study principal investigator **Zachary J. Palace**, MD.

"The system also alerted regarding early warning signs of patient deterioration, which enabled our medical team to proactively respond and literally save four lives," Palace adds ✦

'Catastrophic' malpractice payouts add little to healthcare's rising costs

Efforts to lower healthcare costs in the United States have focused at times on demands to reform the medical malpractice system, with some researchers asserting that large, headline-grabbing, and "frivolous" payouts are among the heaviest drains on healthcare resources. But a new review of malpractice claims by Johns Hopkins researchers suggests such assertions are wrong.

In their review of malpractice payouts over $1 million, the researchers say those payments added up to roughly $1.4 billion a year, making up far less than 1% of national medical expenditures in the United States.

"The notion that frivolous claims are routinely resulting in $100 million payouts is not true," says study leader **Marty Makary**, MD, MPH, an associate professor of surgery and health policy at the Johns Hopkins University School of Medicine in Baltimore. "The real problem is that far too many tests and procedures are being performed in the name of defensive medicine, as physicians fear they could be sued if they don't order them. That costs upward of $60 billion a year. It is not the payouts that are bankrupting the system; it's the fear of them."

Called catastrophic claims, payouts over $1 million are more likely to occur when a patient who is killed or injured is under the age of 1; develops quadriplegia, brain damage, or the need for lifelong care as a result of the malpractice; or when the claim results from a problem related to anesthesia, the researchers found in a study published online in the *Journal for Healthcare Quality*.[1]

Makary and his colleagues reviewed nationwide medical malpractice claims using the National Practitioner Data Bank. They looked at data from 2004 to 2010, choosing a 2004 start date because that is when data regarding the age and gender of patients and severity of injury became available for the first time. The information includes only payments made on behalf of individual providers, not hospitals or other corporations, meaning the number of payouts may be underestimated by 20%, Makary says.

Over that period, 77,621 claims were paid, and catastrophic claims made up 7.9% (6,130 payouts). The seven-year nationwide total of catastrophic payouts was $9.8 billion, representing 36.2% of the $27 billion worth of total claims paid over that time period.

The most common allegations associated with a catastrophic payout were diagnosis-related (34.2%), obstetrics-related (21.8%), and surgery-related (17.8%) events. Errors in diagnosis showed twice the odds of a catastrophic payout compared with equipment- or product-related errors and were associated with a roughly $83,000 larger payment.

... real cost reductions, ... will come from reducing the overuse of diagnostic tests and procedures.

The age of the physician was unrelated to the likelihood of a claim, suggesting inexperience is not necessarily a factor. However, 37% of catastrophic payouts involved a physician with a previous claim in the database. The largest payout in the study was $31 million.

Makary says the data suggest that the focus of legal reform efforts should be on doctor protections aimed at reducing defensive medicine rather than the creation of malpractice caps. He says his findings argue for more research to determine what interventions might prevent the type of errors that result in catastrophic payouts, with the overall goal of improving patient safety and reducing costs at the same time.

But real cost reductions, he says, will come from reducing the overuse of diagnostic tests and procedures.

Reference

1. Bixenstine PJ, Shore AD, Mehtsun WT, et al. Catastrophic medical malpractice payouts in the United States. *J Healthcare Qual* 2013; Article first published online March 29, 2013. ✦

Noise in OR can compromise patient safety, study says

Ambient background noise — whether it is the sound of loud surgical equipment, talkative team members, or music — is a patient and surgical safety factor that can affect auditory processing among surgeons and the members of their team in the operating room (OR), according to a new study.[1]

The findings are the first to demonstrate that a surgeon's ability to understand spoken words in the OR is directly affected by noise in the environment, says study coauthor **Matthew Bush**, MD, assistant professor of surgery at the University of Kentucky Medical Center, Lexington. "To minimize errors of communication, it is essential that we consider very carefully the listening environment we are promoting in the OR," he says.

To assess the effects of ambient noise on communication in the OR, the researchers created a noise environment similar to that of an OR and tested 15 surgeons with one to 30 years of operating experience. The surgeons' ability to understand and repeat words was tested using the Speech In Noise Test-Revised (SPIN-R) under four listening conditions typical of OR environments. These conditions included quiet, filtered noise through a surgical mask, and background noise both with and without music. Subjects were tested in two situations: engaged in a specific surgical task and task free.

The study showed a significant decrease in speech comprehension with the presence of background noise when the words

were unpredictable. In addition, the surgeons demonstrated considerably poorer speech comprehension in the presence of music compared with a quiet environment or one with OR noise present. However, the addition of music became a significant barrier to speech comprehension only when the surgeon was engaged in a task.

The researchers concluded that OR noise can cause a decrease in auditory processing, particularly in the presence of music. Furthermore, the ability to understand what is being said becomes even more difficult when the conversations carry critical information that is unpredictable.

Reference

1. Way TJ, Long A, Weihing J, et al. Effect of noise on auditory processing in the operating Room. *J Amer Coll Surg* 2013; 216:933-938. ✦

Four essentials are offered on the safety of opioids

Four essential steps can help providers improve safety for patients using opioids, according to advice offered by the Physician-Patient Alliance for Health & Safety (PPAHS), a Chicago-based advocacy group of physicians, nurses, respiratory therapists, healthcare organizations, and patient safety advocacy groups.

The four essentials help improve patient safety by making patients and their families a partner with their healthcare providers:

1. Ensure patients/families are provided information on proper use of the patient-controlled analgesia (PCA) pump, so they understand that the pump delivers a powerful narcotic and that only they should activate the pump.
2. Make sure patients/families understand why they must be monitored for safety reasons. Explain oximetry on the finger and a capnography cannula on the nose.
3. Educate patients and families about monitor readouts.
4. Explain why alarms sound and what to do when they sound.

Caregivers are encouraged to make patients and their families partners in patient safety, explains **Michael Wong**, founder and executive director of PPAHS. "Taking a brief moment to explain these four essentials will improve patient safety," he says. ✦

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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.

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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. **Which of the following is one of the tenets of the "Seven Pillars" approach?**
   a. Apologize and "make it right" by waiving hospital and doctors' fees.
   b. Withhold apologizing until a full root cause analysis has been performed.
   c. Apologize but do not offer a settlement unless a lawsuit is filed.
   d. Apologize only if a lawsuit is threatened.

2. **What does attorney Alvin Wolff Jr., JD, say is a common theme among the wrong-site surgery cases in which he represented the plaintiffs?**
   a. The physician proceeded despite being warned of the error.
   b. There was no time-out.
   c. One or more people in the surgical did not feel obligated to participate in the time-out.
   d. The wrong-site error could not have been avoided.

3. **According to says Kathryn Schulke, RN, principal with the consulting firm Booz Allen Hamilton, which of the following is a good rule for conducting a root cause analysis (RCA)?**
   a. Never include in your RCA team the people who were directly involved in the incident in question.
   b. Always focus on the problem, not the cause.
   c. Do not directly question those involved in the incident; rely on written summaries instead.
   d. If there is any question regarding the timeline, rely on personal statements by those involved and not the medical record.

4. **In the patient safety effort by 21 hospitals in the Cincinnati, OH, region that reduced incidents of patient falls that result in injury by 64%, what was cited as key reason for their success?**
   a. Strict confidentiality regarding fall data.
   b. Sharing fall data with competing hospitals.
   c. Setting a goal equal to the best results found at one hospital.
   d. Rolling out safety improvements all at once, throughout all hospitals at the same time.

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Hospital ordered to pay $7.4 million for severe brain injury after nurses' mistakes

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News: In March 2013, a jury awarded a multi-million dollar verdict to a young woman who suffered severe brain injuries after nurses failed to follow doctors' orders and mistreated her for an asthma-related condition.

Background: On Nov. 8, 2011, approximately four months after the plaintiff graduated from college, she was taken to the emergency department complaining of shortness of breath. The plaintiff had a lifelong history of asthma that was controlled through medication. On Nov. 8, despite taking her medications, the plaintiff's condition worsened.

Doctors in the emergency department initially treated the plaintiff for an exacerbation of her asthma. After she was stabilized, she was admitted to the hospital's telemetry unit for further evaluation and treatment. There, the plaintiff was placed on supplemental oxygen, and doctors ordered that she undergo cardiac monitoring as well as continuous monitoring of her oxygen saturation level.

... the plaintiff suffered a severe anoxic injury that left her in a vegetative state.

For 24 hours, the plaintiff remained stable and was treated every four hours. Following this treatment, however, nurses removed the plaintiff from supplemental oxygen. They then failed to monitor the oxygen saturation of her hemoglobin. After being removed from supplemental oxygen and breathing the room's ambient air for approximately seven hours, the plaintiff experienced a "cardiorespiratory event" that led to cardiac arrest. Emergency measures were taken, but the plaintiff suffered a severe anoxic injury that left her in a vegetative state.

On Nov. 21, 2011, the plaintiff, through her mother acting as guardian ad litem, filed a lawsuit against the hospital that treated her. The complaint alleged that the hospital failed to properly monitor the plaintiff's respiratory condition and that, had it done so, her cardiac arrest could have been avoided. Specifically, the plaintiff argued that although doctors had ordered continuous monitoring of the plaintiff's oxygen saturation level, nurses attending to the plaintiff failed to follow the order. The hospital countered that the plaintiff's cardiac arrest was the result of an unexpected allergic reaction to medication she was given that day. At trial, the plaintiff's nurses sought to avoid responsibility for not following the doctor's orders and attempted to justify their actions by appealing to independent authority and independent medical judgment.

After less than two days of

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. **Alvin Safran**, **Brandon M. Berkowski**, and **Jonathan D. Rubin**, co-authors, have no relevant relationships to disclose.

deliberation, jurors rejected the hospital and nurses' positions and found the hospital negligent in its care and treatment of the plaintiff. Following the incident, the plaintiff, who is 26 years old, requires lifelong around-the-clock care and has been resident in a neurocare facility that costs approximately $1,200 per day. Jurors initially awarded the plaintiff more than $3 million in pain and suffering and more than $15 million in economic damages for past and future medical expenses and loss of future earnings. The hospital was ordered to pay $7.4 million.

What this means to you: In this case it is important for us to focus on two risk management issues.

The first one is monitoring. In this case the litigation focused on telemetry monitoring, but it could have just as easily been other types of monitoring such as fetal monitoring as well. Monitoring difficulties can be the result of environmental issues or clinical issues. Monitoring systems by different manufacturers will likely have different recommended user instructions.

It is obviously important that all users understand exactly how the specific monitoring system works and what to do if it malfunctions. Failing to follow the manufacturer's recommendations for users can result in refusal to honor a warranty or refusal to defend, indemnify, and hold a user harmless. It is important from a risk management perspective that all contracts with manufacturers be carefully scrutinized particularly with respect to insurance and indemnification agreements.

Healthcare facilities must determine if they want to have dedicated technicians whose sole job is to vigilantly observe the monitoring system, e.g. "telemetry-techs." The setting of alarms becomes a crucial factor in a successful monitoring system. Many of us have heard the term "alarm fatigue." This situation happens when so many alarms go off that after a while staff members do not hear them or do not respond to them. It is also important to remember that although most of these systems can print hard copies of "strips," those strips are generally kept online for a limited time, typically 24-48 hours. Policies need to be in place prior to usage, as to the circumstances in which printouts of monitoring strips must be obtained. Consideration should be given to backup systems that can store strips for long periods of time so that the "strips" can be retained for as long as the medical record is retained.

It is not reasonable to think that an individual with a different scope of practice is able to intelligently question any decision that a physician makes.

One aspect of the defense strategy in this case brings up another risk management consideration I find particularly intriguing. I refer to the attempted defense on behalf of the nurse(s) by referring to their independent duty to exercise medical judgment. It is certainly important in a culture of safety that practitioners feel free to question clinical decisions of others even if they are not within the same level of the clinical hierarchy. That having been said, the independent duty concept is a doctrine that several well-known plaintiff attorneys in my home state, New York, try to use against nurses. I have never seen it used by defense counsel before. It is a controversial doctrine and must be executed very carefully. While it is true that all practitioners do have an independent duty to express their opinions when they disagree with orders, that independent duty to question must be restricted to within the scope of practice.

Any departmental or administrative policy with verbiage that places an independent duty to question decisions of physicians on the nurses should be clarified with the words "within their scope of practice." It is not reasonable to think that an individual with a different scope of practice is able to intelligently question any decision that a physician makes. Sometimes a plaintiff's attorney will try to make this argument so they can reach the hospital's "deep pocket" by bringing a nurse into the litigation. In such instances, the defense counsel should require the plaintiff to specify exactly in which decision(s) the nurse failed to exercise independent judgment. If that decision falls outside the nurse's scope of practice, the allegation of failure to exercise independent judgment should be vigorously opposed.

In order to exert their independent duty to question decisions, it is important that all practitioners know their "chain of command" when they believe that their concerns are not being given proper consideration.

This case presents an opportunity for us to examine some of our policies and procedures pertaining to the monitoring of patients as well as strategies for optimizing defense.

Reference

Case No. MC023074, California Superior Court, Los Angeles County (2013). ✦

Ruptured aneurysm results in multi-million dollar verdict and much legal wrangling over pain and suffering

News: After two trials, a man who suffered a debilitating stroke as a result of an undiagnosed aneurysm was awarded, along with his wife, a total of $17.8 million for pain and suffering and other categories of damages. In April 2013, an appellate court ruled that the challenged award would stand, less $9.6 million, and that a new trial was necessary solely on the issue of the amount the defendants should have to pay for pain and suffering.

Background: In April 2013, an appellate court ruled that a large verdict against two doctors and a hospital would stand, but that the amount awarded to the husband and wife plaintiffs for pain and suffering must be determined at a new trial solely on that issue. The winding path that led to the appellate court's ruling began on July 18, 1998, when the plaintiff husband began suffering from a severe headache accompanied by vomiting and sensitivity to light. Over the next three weeks, he was treated by several doctors, two of whom were defendants in the lawsuit, and he underwent a CT scan at the defendant hospital. The CT scan was read and interpreted by an independent facility that contracted with the hospital to provide that service. No written report of the CT scan was generated, and the results, apparently showing no abnormalities, were orally reported to the plaintiff and his doctors. Fifteen days later, an undiagnosed aneurysm ruptured in a blood vessel near the plaintiff's brain, which caused a severe stroke that left him permanently disabled.

At trial, the plaintiff's counsel argued that the plaintiff's two treating physicians and the hospital were directly liable for failing to diagnose the plaintiff's aneurysm. Compelling evidence suggested that the independent facility had failed to properly interpret the plaintiff's CT scan. The facility was not a defendant in the lawsuit, however. Fearing that they could not demonstrate the hospital's vicarious liability for the facility at trial, the plaintiffs' counsel de-emphasized the role played by the facility and tried instead to steer the jury toward finding the hospital directly liable.

The strategy was successful. After trial, jurors assigned 6% of the liability to the doctors, 75% to the hospital, and 19% to the independent facility, for which the hospital was found to be vicariously liable. They awarded damages totaling $5.1 million. The plaintiff's counsel argued that the award was too small, and the court agreed and ordered a new trial unless the defendants agreed to pay $17.4 million. The defendants rejected the court's additur and prepared for a second trial. Because the purpose of the second trial was only to determine damages, however, the court precluded the defendants from arguing that their negligence was not the sole cause of the plaintiffs' injuries.

Compelling evidence suggested that the independent facility had failed to properly interpret the plaintiff's CT scan.

This step is significant because the plaintiff sustained injuries related to his aneurysm that were unpreventable and not necessarily attributable to the negligence of the treating hospital and doctors. For example, the plaintiff's groin became seriously infected as a result of an angiogram that he underwent while being treated. At the second trial, the plaintiff's wife offered graphic testimony about the course of this infection and the pain and suffering it caused. The defendants were precluded from demonstrating that this angiogram would have been necessary to treat the aneurysm itself, even if it had been properly diagnosed; therefore, they were prevented from showing that they were not necessarily liable for the pain and suffering attributable to it. After the second trial, jurors awarded the plaintiffs $17.8 million. Of that amount, $9.6 million was for pain and suffering.

The defendants appealed and were granted a third trial, solely to determine how much they must pay for pain and suffering. They still were liable for the $8.2 million portion of the award attributed to other categories of damages at the second trial, but they were permitted to demonstrate that their negligence was not the sole cause of all of the plaintiffs' pain and suffering.

What this means to you: The first risk management issue that this case brings to mind is the hospital's arrangement with an independent facility to read the CT scan. Many hospitals have arrangements with other entities to read radiological studies, often at times of the day when there are no radiologists available at the hospital. The most unusual factor in this particular case is that there was no written report generated. This lack of a report means that the hospital relied on something other than a final report of a CT scan. The results apparently were verbally reported by the independent facility to the ordering physician. Consequentially, there

is no official report of the radiological study in the medical record. This type of arrangement opens the door to several communication issues. The first obvious communication issue is the possibility that person reciting the verbal report might mean something different from that which the person receiving the verbal report interprets. Any subsequent written reports would have no official report to compare the findings, so the practice of having previous reports available for comparison is not an option. This practice is contrary to the recommendations of the American College of Radiologists. *(For those recommendations, go to http://bit.ly/11tuTK7.)*

Another possibility is a claim by the person receiving the verbal report that the results were never communicated. The likelihood of having a dispute arise in court between the physician who ordered the test and the radiologist issuing the verbal report exists in such an arrangement. The subsequent finger pointing that would ensue would bring bad news to both parties and is a plaintiff attorney's dream come true.

Another variation of an official report, all too common, is commonly called a "curbside reading." This usually occurs when a wet reading is needed immediately and it would not be practical to wait for the final report. It can take place in less-than-optimal circumstances, and it is difficult to document properly.

In the case at hand, the verdict is being appealed, but the appeal is limited to the monetary award for pain and suffering. This type of appeal brings up several related risk management and claims management considerations. A somewhat rare option in defending a case is to concede liability. This option may be exercised when it is believed that the evidence against the defense is overwhelming and the defense believes it would be inflammatory to go over all of the departures in detail in front of the jury. Simply, the defense believes the case is indefensible.

The danger in using this type of strategy is that the defense would be barred from presenting any mitigating circumstances involving the treatment of the patient. A plaintiff's attorney might try to sneak in some of the departures by claiming it is impossible to describe the pain and suffering without describing the treatment.

Mediation will work only if both sides are sincerely serious about wanting to settle the case without going to trial.

Sometimes when the argument is reduced to monetary damage, mediation might present a viable option toward settling a case. Mediation will work only if both sides are sincerely serious about wanting to settle the case without going to trial. Mediations have some limitations built into them. Neither side wants to delve too deeply into the facts, as they both realize that should the mediation fail, they will have revealed their trial strategies. Clearly economists (or other financial experts) will play an important role in arriving at the value of economic damages.

Another strategy in settling monetary disputes could be the implementation of a structured settlement. In that case, the plaintiff agrees to forego a lump sum payment and instead agrees to receive a periodic payment for an agreed-upon duration of time. The periodic payment is created through the purchase of one or several annuities which in turn guarantee a specific amount of future payments. This type of arrangement guarantees a larger payment but it is spread out over a period of time. Structured settlements also generally provide beneficial tax consequences for the beneficiary. These are some of the considerations that might be evaluated when managing a defense limited to monetary loss.

Reference

New York Court of Appeals, 2013 WL 1294518, 2013 N.Y. Slip Op. 02164. ✦

Primer offers strategies to prevent medication errors

A growing evidence base supports specific strategies to prevent adverse drug events, according to a patient safety primer posted online on the Patient Safety Network (PSNet) for the Agency for Healthcare Research and Quality (AHRQ).

The primer outlines strategies providers can use at each stage of the medication use pathway — prescribing, transcribing, dispensing, and administration — to prevent adverse drug events. These strategies range from computerized provider order entry (CPOE) and clinical decision support to minimizing nurse disruption and providing better patient education and medication labeling. The primer also identifies known risk factors for adverse drug events, including health literacy, patient characteristics, high alert medications, and transitions in care.

To access the full patient safety primer, titled "Medication Errors," go to http://1.usa.gov/13zIDaC. ✦

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