Healthcare Risk Management™

30th year
30 Years of providing need-to-know news

AHC Media LLC

IN THIS ISSUE

Financial Disclosure: Author Greg Freeman, Editorial Group Head Russ Underwood, Managing Editor Karen Young, Nurse Planner Maureen Archambault, and *Legal Review & Commentary's* authors Blake Delaney and Jon T. Gatto report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Guest Columnist Joseph Grenny is co-founder of VitalSmarts.

JANUARY 2009
VOL. 31, NO. 1 • (pages 1-12)

Special Report: 30 Years of *Healthcare Risk Management*

Looking back: Much has changed, but goals and basic strategies hold steady

Healthcare Risk Management *celebrates 30 years*

As *Healthcare Risk Management* enters 2009, we celebrate 30 years of serving health care risk managers across the country. It has been an eventful three decades, with many changes in technology, philosophy, and strategies.

But the song remains the same. From the very first issue and continuing on year after year, *HRM* has highlighted the need for sound risk management principles, diligently applied no matter what current crisis had risk managers in a panic or what new technology offered a better solution. The first issue of *HRM* covered such topics as the need for good incident reports, the hidden costs of injuries, and how sloppy records could affect a jury's verdict — all topics that still should be of concern to any health care risk manager. **(See p. 4 for more on the first issue.)**

Leilani Kicklighter, RN, ARM, MBA, CPHRM, LHRM, a patient safety

EXECUTIVE SUMMARY

Healthcare Risk Management has been providing news and advice to risk managers in hospitals, health systems, and other health care settings for 30 years. Looking back on three decades in risk management, we find that many aspects of this business have evolved, but the fundamentals remain the same.

- Technology has had a significant impact on the field.
- Risk management always has depended on incident reporting, analysis, and risk-reduction strategies.
- There is more regulation than in past years, partly because the media make so much more information available.

and risk management consultant with The Kicklighter Group in Tamarac, FL, and a past president of the American Society for Healthcare Risk Management (ASHRM) in Chicago, says *HRM* was one of the first risk management-focused publications available to those in the health care field.

"As such, it has been invaluable to me as a risk manager over the years," she says. "This publication brought to us timely information and education about issues of national importance and other notable information along with commentary from and by our peers in a day before we had all the various textbooks and other publications now available."

These are some of the other headlines from the early years:

- "Computer system streamlines variance reporting for Iowa hospitals" — January 1980
- "Early physician intervention saves hospital's resources" — May 1980
- "Malpractice crisis similar to 1976 not possible, Mills says" — January 1981
- "Hospitals 'can't lose' with self-insurance, RM attorney says" — January 1982
- "Prevent patient suicides with early-identification strategy" — December 1982
- "Court-ordered guidelines regulate psychotropic drugs" — May 1983
- "Multiple explosions pinpoint hospital's disaster needs" — November 1983
- "Increased liability comes with reusing medical devices" – June 1984
- "Experts: Consider AIDS a handicap in employment matters" — April 1986
- "Temper ad claims to avoid suits from dissatisfied patients" — April 1987
- "Tougher COBRA fines may increase documentation" — April 1988
- "Will doctors declare war with RMs over National Data Bank?" — March 1989
- "The perennial challenge: Overcoming physician resistance" — September 1990
- "How can risk managers prove their effectiveness?" — December 1990
- "Court rulings yield new warnings against patient dumping" — October 1991
- "Separate anesthesia consent form can strengthen defense" — June 1992
- "Violence often enters a hospital through the ED" — May 1993
- "Hospitals share physician liability for misdiagnosed cancer claims" — August 1994
- "Unexpected avenues of sex harassment mean hospitals must be on alert" — December 1996
- "Telemedicine poses new, huge risks: Know what your docs are doing?" — November 1997

In recent years, *HRM* has covered those topics and more, including new and more complex regulatory requirements and the ever-changing legal rulings that affect malpractice prevention and defense. Patient safety has become a much bigger focus in recent years, and the technological innovations have greatly changed how risk managers do their jobs.

HRM has won a number awards over the years, including the prestigious Sigma Delta Chi Award for Excellence in Journalism, awarded by the Society of Professional Journalists, in both 2001 and

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

POSTMASTER: Send address changes to ***Healthcare Risk Management***®, P.O. Box 740059, Atlanta, GA 30374.

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), $495. 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.)

AHC Media LLC 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.

Editor: **Greg Freeman**, (770) 998-8455.
Associate Publisher **Russ Underwood** (404) 262-5521 (russ.underwood@ahcmedia.com).
Managing Editor: **Karen Young** (404) 262-5423 (karen.young@ahcmedia.com).
Senior Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Greg Freeman**, (770) 998-8455.

2005. The most recent Sigma Delta Chi award was for a groundbreaking report on how security experts believed that terrorists were behind a string of suspicious incidents in which people tried to gain access to secure areas of hospitals and asked questions about emergency response capabilities. Experts in hospital security and terrorism said the most likely explanation for those impostors' attempts to gain access is that they were collecting information for future attacks on health care facilities. **(For the full story on the impostors and how they may be probing hospitals for terror attacks, see *HRM*, June 2005, pp. 61-67.)**

Some change undeniable

As we look back on 30 years in health care risk management, Kicklighter says the field has changed significantly while staying much the same in many ways.

"Thirty years ago, there were no textbooks on risk management written by health care risk managers or by anyone else except those texts for the Associate in Risk Management (ARM) or the Charter Property and Casualty Underwriter [CPCU] designations," she says. "In those days, few — if any of us — knew what those designations were. There was no ASHRM and therefore no networking or knowing your peers to bounce ideas or issues or to benchmark against. It was only when ASHRM came on the scene did we as risk managers find out that we weren't alone and that significant and untoward events were not just happening in our facilities, but in our colleagues' facilities as well."

While many of the pioneering risk managers in the health care field were not responsible for the risk financing aspect of the management of risks, the insurance world, for the most part, did not have the partnership relationships with the facilities, much less with the risk managers in those days, Kicklighter says. Calling out to a broker for assistance was not always returned with a willingness to support and assist as there is today.

"However, the focus on risk management activities was, and still is today, on the prevention of injuries or situations that could lead to injuries to patients or visitors, for other assets, including employees," she says. "Data collection and analysis, for the most part, was done by hand and trusty secretaries. Risk managers who were on call 24 hours for early identification and to report a significant event carried a beeper, and we had to find a pay phone if we got a page while in the car or weren't in the office or at home."

Kicklighter recalls that working with those in senior administrative positions in many ways was easier and in some ways more difficult.

"In those early days, we were still getting reimbursed based on the percentage of Medicare patients who had incidents and claims, so there was an interest in our maximizing the accuracy and completeness of our capturing that data that seemed to give a different collaborative relationship in many ways," she says. "Today, there are organizations where the risk manager is recognized as a part of senior management and is a part of the C-Suite meetings and deliberations; while in others, risk management is a part of another division and reports up the chain through one or more levels and only focuses on incident reports and clinical risk management."

Having been in the field for 30 years, **Jane McCaffrey**, MHSA, DFASHRM, director of safety and risk management at Self Regional Healthcare in Greenwood, SC, and a past president of ASHRM, says the job looks quite different now. But at the same time, she says, it seems little has changed. It just depends on where you look.

"Risk management has more of a patient focus, with prevention being key," McCaffrey says. "But there are still those who focus on the financing and claims only. Now the C-Suite knows there is something called "patient safety"; and, in some cases, they associate it with risk management activities."

She offers these other examples of how health care risk management has changed over the years:

- Patients have finally realized that they have rights. "For most risk managers, this has been used to the benefit of patient safety, but there are still those who wish it weren't so," McCaffrey says.
- "We used to get paid even for the care after a patient was harmed while under our care. Now, we won't be and could be considered negligent."
- Paternalistic medical care is fading away and patients now are part of the team.
- Paper has given way to the electronic versions of documents.
- Protocols, guidelines, and best practices are now a fact of life and have contributed to improved and safer care.
- "Nonpunitive" approaches have become far too popular at the expense of accountability.
- There is more focus on process design and less on individuals.
- "We still lose dentures, have slips on wet floors or out of bed, give medication to the wrong patient or give them too much, nick organs, perform incorrect procedures, fail to respond to a deteriorating

First issue focused on incident reports, common mistakes

The October 1979 issue of *Healthcare Risk Management,* Vol. 1, No. 1, focused on a topic that would recur many times and continues to be a concern for risk managers. The first headline was "Incident reports: Five common failures and how to correct them."

"No matter what your hospital's bed size or budget, a comprehensive incident reporting system is essential to the success of a cost-cutting risk management program," the story began. "How do you avoid five common pitfalls that plague risk management professionals in the health field?

"Four nationally known experts with hospital experience agreed that accurate incident reporting can be realized in any hospital if certain guidelines are followed. Their advice focuses on specific ways to avoid the common failures to file reports, complete them correctly, route them to proper authorities, activate immediate correction, and plan long-range prevention strategies."

The story went on to explain that educating employees about the importance of incident reporting was one of the biggest hurdles.

"Getting hospital employees to fill out incident reports can be a stumbling block to a successful program in terms both of spotting the individual occurrence that can result in litigation and identifying trends that lead to prevention of similar events.

"Why are incident reports not filed? Some employees may fear the report will be used as a disciplinary tool on them or will be a mark against them in their record. Other employees — and some administrators — simply may not understand the importance of the incident report and the necessity for filing one on each incident." ■

condition, and so on," McCaffrey says. "But you know what? I believe we are having fewer incidents, know about a higher percentage of those that are happening, and are making a difference in preventing it from happening again."

Technology has had a significant influence on risk management in health care, including the flow of information, the advent of a computer on everyone's desk (and in a lot of pockets), the ability to analyze data faster and with more parameters, and the ease of maintaining or establishing contact through cell phones, Kicklighter says.

"The instant gratification, instant need satisfaction through the use of scanning, faxes, and e-mail can be stress-provoking, necessitating faster response and turnaround than in the past, but that often depends on which end of the request you are on," she says. "The job responsibilities have changed during the last 30 years as the risks and regulations have changed. The biomedical and medical technology aspects of patient care have changed significantly over these years changing the face of health care, and with that the risks have changed. The immediacy of the flow of information has changed our society and, as our society has changed, so has risk management."

Kicklighter also notes that risk managers work much more cooperatively with patients and their families than they used to.

"It used to be that if a patient or family was keeping a diary, we were on alert of a potential claim," she says. "Nowadays, we encourage our patients to keep notes, to have advocates, and to ask questions to be a partner in their care. Many patients consult their computers before seeing their physician for care and question their care more closely than in the past."

It seems as though the regulatory changes have grown significantly over these 30 years, Kicklighter says. She attributes part of that to the information explosion.

"The media can flash a significant court verdict or untoward outcome almost immediately worldwide within a very short time. It is more difficult to hide such negative stories; in turn, regulatory response is also almost immediate," Kicklighter explains. "Over these years, the issues have arisen that have been the bases for the laws and regulations that have created the need for compliance programs, reporting of untoward events and sentinel events with root-cause analyses along with the current focus and emphasis on patient safety and prevention of never events and errors in general."

Kicklighter also notes that risk financing and handling of claims has changed in many ways, with

SOURCES

For more information on the 30-year retrospective of *HRM,* contact:

- **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, LHRM, The Kicklighter Group, Tamarac, FL. Telephone: (954) 294-8821. E-mail: imlani@comcast.net.
- **Jane McCaffrey**, MHSA, DFASHRM**,** Director of Safety and Risk Management, Self Regional Healthcare, Greenwood, SC. Telephone: (864) 725-4111. E-mail:jmccaffrey@selfregional.org.

more self-insured organizations, creation of captives, and the roller-coasting hard-to-soft-to-hard markets. What once was a runaway verdict or significant settlement at $500,000 or $1 million is, while still a big hit, not so astounding in a day when we see payouts of more than $10 million in some parts of the country. Enterprise risk management, while new on the horizon, is beginning to see more attention, and more organizations are beginning to undertake the process to develop and implement this risk management program structure, she notes.

Despite all the changes, the basic concept of health care risk management has not changed so much over the decades, Kicklighter says.

"The basic philosophy or concept of risk management, protecting patients through prevention of errors, has always been the first goal of risk management," she says. "How we go about identifying, analyzing and treating/preventing those risks has changed due to the changes in the health care setting, regulations, advances in science and technology that have all influenced society in general. However, the theory of risk management is still the same: Prevention and, if that fails, early identification and early resolution." ■

Wyeth case could affect provider liability

The health care industry is awaiting a ruling from the U.S. Supreme Court in the case of *Wyeth v. Levine,* a case that could determine the future of drug labeling and potential liability for providers who don't follow those instructions to the letter.

The ruling is expected to determine whether manufacturers can rely on "pre-emption," meaning the Food and Drug Administration's approval of their label protects them from state court lawsuits alleging that the label was insufficient. If not, manufacturers could be subjected to endless lawsuits in each state. A ruling in favor of the plaintiff, some legal analysts say, also could lead to more precise instructions for drug use, and that would in turn create a tricky problem for providers: Either follow the instructions exactly, and rob your caregivers of the ability to practice medicine as they see best, or deviate from them and run the risk of huge liability. **(See p. 6 for background on the *Wyeth* case.)**

Peter Reichertz, JD, a partner in the Washington, DC, office of the law firm Sheppard Mullin, says the verdict could lead to more risk for the provider, if the end result is that plaintiffs have a harder time suing the manufacturer.

"It appears the court may find some limited degree of pre-emption, shielding manufacturers from liability if, for example, the manufacturer and FDA were aware of the risk, the manufacturer did not conceal it from FDA, and it is dealt with in labeling," he says. "That said, if the court finds any degree of pre-emption, I think it is all but certain that the new Democratic-controlled Congress will either pass legislation in advance of any decision to negate such a ruling or do so after the court rules."

They also could possibly deal with prior decisions relating to pre-emption found regarding use of medical devices, Reichertz says. There is an express pre-emption provision for devices, stemming from the *Riegel v. Medtronic* case. In *Riegel,* the Supreme Court determined that the federal authority of the FDA trumped state laws, blocking liability suits concerning allegedly defective medical device labels in state courts. If the FDA said the labeling of the device was correct, the court ruled, then it wasn't fair to have plaintiffs sue in state court and claim the labeling should have been bette. .Many in Congress feel that the *Riegel* decision went too far, so they may be eager to counter that ruling also.

But if the manufacturers find some protection from the courts and Congress doesn't find a way around that, the providers could be the ones left vulnerable.

"As to any finding of pre-emption and its effect on health care providers and institutions — if pre-emption is found and in the unlikely event that Congress doesn't change the law to negate any such decision — it could mean that plaintiffs would need to focus on the health care provider who administered or prescribed the product

EXECUTIVE SUMMARY

The U.S. Supreme Court is considering a landmark case involving liability related to a drug that caused serious injury to a patient. The ruling in the case could have an impact on how drugs are labeled and the provider's liability for not following the guidelines on the label exactly.

- The court is expected to rule soon.
- A ruling in favor of the drug maker could be good news for providers also.
- A ruling for the plaintiff could lead to more specific drug labeling and create more obligation for providers to comply with the label.

and/or the institution or setting it was administered or prescribed," Reichertz says. "In general, plaintiffs always sue both now as it is. In the *Wyeth v. Levine* case, the plaintiff had already obtained a judgment from the provider."

Karen Gibbs, JD, an attorney in the law firm of Crowell & Moring in Irvine, CA, also sees potential bad news for providers in the outcome of *Wyeth*. She notes that these types of cases often are brought as combination medical malpractice and product liability suits. Many defense attorneys consider *Wyeth* to be primarily a medical malpractice case, given the mistakes made in administration of Phenergan to the plaintiff, she says.

"A ruling against Wyeth thus is not likely to result in deflection of liability from hospitals or other providers," Gibbs says. "Hospitals are not likely to see any fewer allegations of malpractice based on the use of FDA-approved prescribed medications. On the other hand, if Wyeth prevails, a likely consequence may be an increase in malpractice lawsuits against and also an increase in the amount of damages demanded from hospitals, physicians, and other providers."

The former head counsel for the FDA tells *Healthcare Risk Management* that he is worried providers may take on more liability risk as a result of the *Wyeth* ruling. One question in *Wyeth* involves who was really responsible for Levine's injury and who should be responsible for compensating her, says **Sheldon Bradshaw**, JD, currently a partner in the food and drug practice at the law firm of Hunton & Williams in Washington, DC. Many observers say the case is simple malpractice and that the clinic and caregivers were the only ones who should have compensated her. Bradshaw believes Levine received $100,000 from the clinic, which was the cap on its insurance.

"Obviously that wasn't enough to compensate a professional musician who lost her arm, and the next step was Wyeth, which had much deeper pockets," he says. "A lot of people are worried that if the ruling determines that Wyeth wasn't responsible for putting more clear warnings on the product, that will completely transfer the liability and risk solely to the provider."

Bradshaw may not go that far himself. While he does see some potential for increased risk, he says some analysts may be overstating the threat.

"I don't think they will be held liable in cases where the drug maker would be held liable, just because of pre-emption, absent any evidence of malpractice," Bradshaw says. "But I do think there is good reason to review your insurance limits to make sure you are adequately protected. And you may want to make sure you have good protocols in place for the use of drugs that come with known risks, as was the case here."

Bradshaw speculates that the FDA did not insist on a label specifically warning against injecting Phenergan into an artery because that

Background: *Wyeth* case centers on labeling

The U.S. Supreme Court recently heard arguments in *Wyeth v. Levine*, and the ruling is expected to determine whether federal Food and Drug Administration approval of a drug warning label pre-empts product safety suits brought in state courts. The plaintiff is musician Diana Levine, who sued Wyeth after an injection of the nausea medication Phenergan, made by Wyeth, caused gangrene, which led to the amputation of one arm. The injury came when the drug was administered with a push IV injection rather than intramuscular, the method cited on the label as the preferred delivery method. Push IV was not listed as a preferred delivery method, but the label did not specifically prohibit that method either. During the push IV, the drug was accidentally injected into an artery, which led to the gangrene and the amputation.

Levine sued the physician, the physician assistant, the clinic, and Wyeth. All of the parties settled except Wyeth. In state court in Vermont, Levine argued that the Phenergan label was insufficient and should have warned about the known risk of gangrene from the push IV. A jury agreed with her and awarded $6 million.

Wyeth appealed, and the Vermont Supreme Court upheld the decision, so Wyeth appealed to the U.S. Supreme Court. The company argued that FDA approval of medication labels should preclude lawsuits in state courts related to the labels.

Wyeth says the risk of gangrene from push IV was known during the FDA approval process and that the FDA made no effort to have that method explicitly prohibited on the label. Since the FDA approval process is so intricate and demanding, Wyeth says, it isn't fair to hold the company liable for supposed deficiencies in a label that was approved by the FDA.

A ruling in favor of the plaintiff, Wyeth told the court, would leave manufacturers in a no-win situation, forced to comply with the extensive FDA labeling process but still subject to state court verdicts when a plaintiff claims the label wasn't good enough. ■

SOURCES

For more information on the *Wyeth* case, contact:

- **Sheldon Bradshaw**, JD, Partner, Hunton & Williams, Washington, DC. Telephone: (202) 955-1575. E-mail: sbradshaw@hunton.com.
- **Karen Gibbs**, JD, Attorney, Crowell & Moring, Irvine, CA. Telephone: (949) 798-1329. E-mail: kgibbs@crowell.com.
- **Maureen Martin**, JD, Senior Fellow, Legal Affairs, The Heartland Institute, Chicago. Telephone: (920) 295-6032. E-mail: martin@heartland.org.
- **Timothy Ray**, JD, Partner, Neal, Gerber & Eisenberg, Chicago. Telephone: (312) 269-8456. E-mail: tray@ngelaw.com.
- **Peter Reichertz**, JD, Partner, Sheppard Mullin, Washington, DC. Telephone: (202) 772-5333. E-mail: preichertz@sheppardmullin.com.
- **Jill M. Wheaton**, JD, Attorney, Dykema, Ann Arbor, MI. Telephone: (734) 214-7629. E-mail: jwheaton@dykema.com.

obviously was bad clinical practice.

"You shouldn't have to put on the label 'don't inject directly into the spine, don't inject directly into the eye.' You could have a long laundry list of things that really amount to telling the provider not to practice bad medicine," he says.

Bradshaw expects the Supreme Court to rule in favor of Wyeth, but with a narrow pre-emption, providing protection to manufacturers only when there was no information about risks that the company could have provided to the FDA. There could be some shift in liability risks, he says, but the provider still is safe as long as there is no malpractice. There is no need to panic as long as you are taking adequate steps to ensure the proper administration of dangerous drugs and as long as you have adequate insurance.

"I think there are a lot of providers who haven't thought about the risk management principles in this area and aren't doing a good enough job of making sure they are followed," he says. "There could be a need to do some more training and updating of your protocols. You need to make sure your people are very carefully trained and monitored on these drug procedures."

Regardless of the outcome, *Wyeth* probably will prompt hospitals to increase training and review protocols for drugs with potentially serious side effects, says **Timothy Ray**, JD, a partner in the litigation practice group at the law firm of Neal Gerber in Chicago.

Ray cautions against risk managers taking too much comfort in a ruling that favors Wyeth. A Supreme Court ruling may tell manufacturers that they have some protection once the FDA approves the label, but that protection will not be unlimited for the provider.

"If you used the drug exactly as described on the label, followed all the instructions exactly and didn't do anything wrong, then I think the label provides an affirmative defense for any unforeseen injuries," he says. "But if you make any mistake in administering the drug, any errors in the actual providing of the drug to the patient, or if you use the drug in a way that is not prescribed on the label, then that defense is of no help to you."

A ruling against Wyeth could prompt manufacturers to revise drug labels to be much more explicit, says **Jill M. Wheaton**, JD, an attorney with the law firm of Dykema in Ann Arbor, MI. Levine was arguing in her case that the Phenergan label should have specifically prohibited push IV, so if that view is upheld, drug makers may protect themselves by making labels even longer than they already are and far more specific.

"This would really create a burden for the provider. It would tie the hands of doctors, who would either have to comply with these instructions or take on the risk of using the drug in the way they see fit," she says. "The labels currently give some deference to the treating physician, but drug manufacturers may be forced to change that." ■

Ruling against Wyeth could undermine FDA

A ruling in favor of the plaintiff could threaten the authority of the FDA by giving more power to state courts, says **Maureen Martin**, JD, senior fellow for legal affairs with The Heartland Institute in Chicago. She says the case could lead to a wholesale expansion of state regulation in other areas of law for any industry subject to intensive federal regulation. If that happens, the FDA will become ineffective, she predicts.

If the FDA's drug labeling authority has no value, the agency should be abolished, she says.

Martin notes that, while the Phenergan label did not explicitly prohibit push IV, it did make clear that the method carried serious risks. The FDA required the label to include four warnings telling providers to exercise "extreme care" in injections

with IVs. Gangrene would "likely" result if done improperly, the label says.

The label also warned health care providers to stop the injection immediately if the patient complained of pain, which the plaintiff did, Martin notes. And it warned dosages shouldn't exceed 25 mg.

"The plaintiff got twice that much. It sounds like the assistant didn't read the label at all," Martin says. "That's understandable. The label is two pages long."

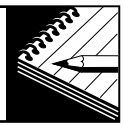
Martin says in closing arguments at the Vermont trial, the plaintiff's lawyer told the jury, "The FDA doesn't make the decision, you do."

"So what use is the FDA, if states can impose additional warning requirements?" she asks. "The Vermont Supreme Court found federal law imposed only minimum requirements and states are free to mandate stricter ones. If the plaintiff wins and each of the 50 states becomes free to impose drug safety laws in addition to federal laws, drug makers will have to monitor state law carefully and modify labels state-by-state. This is an unworkable system that would destroy any semblance of a national product market. It endangers drug marketing and new drug development, and therefore the public's health."

Martin says a Supreme Court ruling in favor of the plaintiff would lead to a surge in similar suits.

"State attorneys general are clearly salivating at the prospect of preserving and expanding their authority. Forty-seven of them filed a joint *amici* brief supporting the plaintiff," she says. "If the plaintiff wins, there are going to be 50 separate requirements for drug approvals, with the FDA as just the 51st. In that case, it should be abolished." ■

GUEST COLUMN



Use social influence to fight disruptive behavior

By **Joseph Grenny**
Consultant
VitalSmarts

With The Joint Commission's recent announcement that rude language and hostile behavior pose serious threats to patient safety and quality of care, risk managers are on high alert for disruptive behavior and searching for ways to combat it. And for good reason: The "Silence Kills" study, conducted by VitalSmarts and the American Association of Critical-Care Nurses, reveals that more than three-fourths of caregivers regularly work with doctors or nurses who are condescending, insulting, or rude.

But while these disruptive and disrespectful behaviors can be hurtful, what prompted The Joint Commission to address them as a condition of accreditation is the mounting evidence that these behaviors also are harmful. The Silence Kills study found that more than 20% of health care professionals have seen actual harm come to patients as a result of such behavior. **(For more on disruptive behavior and The Joint Commission's call to action, see *Healthcare Risk Management*, October 2008, p. 109, and November 2008, p. 125.)**

There are many ways that risk managers can combat disruptive behavior, but one of the most effective strategies also is one of the simplest: Get people to talk. Encourage them to have "crucial conversations" about disruptive behavior, so it can be stopped.

The Joint Commission has taken an important step by requiring hospitals to create a clear code of conduct demonstrating the unacceptability of disruptive behavior and laying the groundwork for holding caregivers accountable for their behavior. While this is an important element of influencing behavioral change, the research shows that there is something far more immediate and powerful individuals and leaders can do to drive change: They need to break the code of silence.

The most powerful force over human behavior is social influence. People will do almost anything to gain acceptance or avoid rejection. Unfortunately,

EXECUTIVE SUMMARY

Disruptive behavior can be countered by encouraging staff and physicians to speak up and discuss their concerns. Risk managers can lead the way by being vocal about having zero tolerance for disruptive behavior.

- Health care employees should directly confront disruptive staff and physicians.
- Administration must back up any sanctions handed down for disruption.
- Staff will not speak up unless upper management leads the way.

the vast majority of health care workers fail to exercise the enormous social influence they have in the face of disruptive behavior.

As a result, disruptive behavior has lingered for years awaiting social disapproval, yet receiving none.

If health care leaders want to not only secure the well-being of patients, but also increase employee retention and engagement, the most immediate and effective thing they can do is change this culture of silence. They need to substantially increase caregivers' skill and will to step up to crucial conversations immediately and directly when inappropriate behavior emerges.

Health care risk managers who want to engage social influence to eliminate disruptive behavior will have to break the code of silence in these four crucial conversations:

1. Administrations must go public about the pervasiveness of concerns. Most hospitals attempt to put a good face on disruptive behavior by dismissing it as a problem with "a few bad apples." The truth, according to the Silence Kills study, is that it happens every day in most hospitals. It is not just a few bad apples. In order to influence change, leaders need to begin by acknowledging the frequency of concerns.

2. Caregivers must directly confront disruptive behavior. Next, leaders need to invest substantially in increasing the will and skill of every employee to speak up when he or she sees problems. The focus needs to be not just on confronting disruptive behavior, but on speaking up when people see mistakes, incompetence, violations of safety standards, and more. The Silence Kills study identifies seven kinds of problems; fewer than one in 10 people address those problems effectively, which can lead to burnout, disengagement, errors, and worse.

3. Medical directors and nurse managers must respond appropriately to escalations. The research also shows that the problem is not just upward; it's sideways and downward. Nurses fail to speak up to their peers when they have concerns. Managers fail to confront direct reports. Medical directors give their underlings a "pass" rather than make waves. The silence is deafening in every direction — and lower-level employees will not feel the expectation to address concerns if their leaders don't lead the way.

4. Administration must back up sanctions when they occur. The most common reason people fail to speak up in hospitals is that they adopt the attitude of "It's not my job." The second most common reason is the belief that "Others won't back me up if I do." For example, nurse managers worry if they confront a disruptive doctor who brings a lot of money into a hospital, no one in administration will back them up. Administration must make it clear that if code-of-conduct violations occur, they will back up those who take appropriate action.

Risk managers must take a lead role in speaking out against disruptive behavior. Start the conversation. State clearly and loudly that disruptive, abusive, potentially harmful speech and behavior by physicians and staff will not be tolerated. Simply saying it out loud, and with authority, goes a long way toward changing the culture. As the saying goes, "Silence betokens consent."

The pervasive and risky problems with disruptive behavior in hospitals today will not be eradicated by codes of conduct — although these are a worthwhile step in the right direction. The real change will occur when we substantially increase skills in conversation — especially the emotionally and politically risky conversations we so consistently avoid. When this vast potential of social pressure is finally tapped, our hospitals will become healthier for patients and caregivers alike.

(Editor's note: Joseph Grenny is the co-author of the books Influencer, Crucial Conversations, *and* Crucial Confrontations. *He is a co-founder of VitalSmarts, a consulting group in Provo, UT, that offers advice on the role crucial conversations play in medical errors, employee retention, and patient satisfaction. For more information, go to www.vitalsmarts.com.)* ■

Defensive medicine carries hefty price tag, study finds

A first-of-its-kind survey of physicians by the Massachusetts Medical Society on the practice of "defensive medicine" — tests, procedures, referrals, hospitalizations, or prescriptions ordered by physicians out of fear of being sued — has shown that the practice is widespread and adds billions of dollars to the cost of health care in that state alone.

The physicians' group says such defensive practices, conservatively estimated to cost a minimum of $1.4 billion per year in Massachusetts, also reduce access to care and may be unsafe for patients.

The "Investigation of Defensive Medicine in Massachusetts" is the first study of its kind to specifically quantify defensive practices across a wide spectrum and among a number of specialties. The study also is the first of its kind to link

EXECUTIVE SUMMARY

Defensive medicine is widespread and costs billions of dollars a year, according to a new study. The practice also threatens patient safety by overburdening the health care system.

- A great majority of physicians report practicing defensive medicine.
- About a quarter of all tests and procedures were defensive.
- Actual costs are probably even higher than reported in the study results.

such data directly with Medicare cost data. The survey queried physicians in eight specialties between November 2007 and April 2008: anesthesiology, emergency medicine, family medicine, internal medicine, general surgery, neurosurgery, orthopedics, and obstetrics/gynecology.

The study also is believed to be one of the largest of its kind, with nearly 900 physicians completing the survey, says researcher **Manish K. Sethi**, MD, of the Department of Orthopedic Surgery of Massachusetts General Hospital and a member of the Medical Society's Board of Trustees and its Committee on Professional Liability. The other researcher was **Robert H. Aseltine Jr.**, PhD, of the Institute for Public Health Research at the University of Connecticut Health Center in Farmington.

"This survey clearly shows that the fear of medical liability is a serious burden on health care," Sethi says. "The fear of being sued is driving physicians to defensive medicine and dramatically increasing health care costs. This poses a critical issue, as soaring costs are the biggest threat to the success of Massachusetts health reform efforts."

Sethi says while the survey specifically addressed Massachusetts, he would expect similar results nationwide. Physicians were asked about their use of seven tests and procedures: plain film X-rays, CT scans, magnetic resonance imaging (MRIs), ultrasounds, laboratory testing, specialty referrals, and consultations, and hospital admissions. The results were self-reported by the physicians responding to the survey.

The results showed that 83% of the physicians surveyed reported practicing defensive medicine and that an average of 18% to 28% of tests, procedures, referrals, and consultations, and 13% of hospitalizations were ordered for defensive reasons.

Sethi and Aseltine estimated the costs of the tests to be $281 million for the eight specialties surveyed, based on Medicare reimbursements rates in Massachusetts for 2005-2006. In addition, the cost of unnecessary hospital admissions was estimated to be $1.1 billion, for a combined total estimate of nearly $1.4 billion. The authors point out, however, that the dollar estimates do not include tests and diagnostic procedures ordered by physicians in other specialties, observation admissions to hospitals, specialty referrals and consultations, or unnecessary prescriptions. The eight specialties represented in the survey account for only 46% of the physicians in the state.

Because of those excluded elements and the fact that less that half of the state's doctors were represented in the survey, the researchers said the actual cost of defensive medicine in Massachusetts is significantly higher than the survey quantified.

Aseltine notes that defensive medicine may come in various forms, including the ordering of medically unnecessary laboratory or radiologic tests, prescriptions, specialist referrals, invasive procedures, and hospital admissions. Also included would be the avoidance of high-risk procedures or even the avoidance of high-risk patients, he says.

Alan Woodward, MD, vice chair of the Medical Society's Committee on Professional Liability and a past president of the organization, says physicians practice defensive medicine because they don't trust the medical liability system.

"This survey should provide a strong impetus for legislative, business, and health care industry initiatives promoting fundamental liability reform," he says. "Reducing defensive medicine in Massachusetts could dramatically reduce costs and at the same time improve patient safety, access to care, and quality of care."

Woodward added that defensive medicine is not only costly, but it also reduces patient access to care and may be unsafe for patients. Because of the malpractice environment, many specialists have closed their practices, stopped performing high-risk procedures, or reduced their care of high-risk patients. As a result, many smaller communities have little or no access to medical specialists, he says.

The survey found that 38% of responding physicians reported they reduced the number of high-risk services they performed, with orthopedic surgeons (55%), obstetrician/gynecologists (54%), and general surgeons (48%) reporting the highest frequencies. Additionally, 28% of physicians in the sample reported reducing the number of high-risk patients they saw, with obstetrician/gynecologists (44%) and

the surgical specialties (37%-42%) much more likely to reduce their number of high-risk patients.

Woodward notes that safety issues can arise from defensive medicine procedures. For instance, patients exposed to unnecessary imaging tests face the risks of radiation exposure and possible severe allergic reactions to contrast dye.

"In addition, many surgical procedures like cesarean sections have increased as a result of liability concerns," he says.

(Editor's note: For the full results of the report on the Investigation of Defensive Medicine in Massachusetts, go to www.massmed.org/defensivemedicine.) ■

Health system cuts med errors by 29%

The implementation of an online order entry system at the University of Michigan Health System in Ann Arbor has produced a 29% reduction in medication errors while at the same time cutting by 40% the time between ordering and administering urgent medications.

The health system took nearly three years to implement the computerized physician order entry (CPOE) system, but the benefits became obvious right away, says **Robert Kelch**, MD, executive vice president for Medical Affairs and CEO of the U-M Health System. The system, known as U-M CareLink, required training for thousands of faculty and staff members, Kelch says. "We have used information technology to make our patients' care better and safer, and our workflow more efficient," he says. "This is a major enhancement to our already advanced medical information capabilities."

Since June 2007, nearly 5,300 staff, including nurses and respiratory therapists, physicians, techs/ancillary staff, clerks, and administrative staff were trained. More than 1,966 desktops, laptops and requisition printers were deployed, Kelch says.

The system was first implemented in the Women's Hospital, including the Department of Obstetrics and Gynecology, in October 2006. It was implemented at the Neonatal Intensive Care Unit in February 2007 and C. S. Mott Children's Hospital in June 2007.

Douglas L. Strong, MBA, CEO of University of Michigan Hospitals and Health Centers, says the benefits have not come easily. Implementing such a system was a daunting task because of the size of the health system, which has 913 inpatient beds, he says.

"This has been a massive undertaking in the U-M Health System," Strong says. "Every day, tens of thousands of orders are written, carried out, and documented in our three hospitals and major hospital-based treatment areas. In just a few years, we have successfully moved all of those handwritten orders online. The results in the key areas where we have already implemented UM-CareLink have been impressive."

Using the CPOE system, clinicians can order tests, procedures, medications, and nutrition services online, from almost computer in the hospital, eliminating the need for paper forms. It also lets them get instant access to patient allergies, potential drug interactions and other information, enabling patient safety at the highest levels. The system allows providers to order patient medication electronically and tracks patient handoffs between caregivers and departments, minimizing risks associated with multiple providers caring for one patient.

In addition to improving safety by alerting caregivers to allergies and potential errors, the system also is more efficient than the traditional method of handwriting orders, Kelch says. "It reduces the time it takes to get medication from the hospital pharmacy to the patient's bedside," he says. ■

CE objectives

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

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

COMING IN FUTURE MONTHS

- Special report on air ambulances
- Proving your worth to management
- EMTALA mistakes you can avoid
- Self insurance — when it makes sense

CNE Questions

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

1. According to Leilani Kicklighter, RN, ARM, MBA, CPHRM, LHRM, what is one significant change in risk management over the past 30 years?
A. Risk managers work much more cooperatively with patients and their families than they used to.
B. Risk managers work much less cooperatively with patients and their families than they used to.
C. Liability risks from malpractice have greatly increased, but only in rural areas.
D. Liability risks from malpractice have greatly decreased, but only in urban areas.

2. According to Jane McCaffrey, MHSA, DFASHRM, which of the following is true regarding risk management over the past 30 years?
A. Patients have finally realized they have rights, and risk managers are universally pleased and using that knowledge to improve patient safety.
B. Patients have finally realized they have rights, and some risk managers are using that knowledge to improve patient safety while others are not as pleased.
C. Patients have not improved their understanding of their rights.
D. Patients have lowered expectations to a more reasonable level in terms of their rights.

3. According to Peter Reichertz, JD, what would be one effect of the *Wyeth v. Levine* verdict?
A. The verdict could lead to more risk for the provider, if the end result is that plaintiffs have a harder time suing the manufacturer.
B. There is no way the verdict could lead to more risk for the provider.
C. Any verdict will end up increasing the risk for the provider.
D. Any verdict will end up shifting more risk to the manufacturer.

4. Which of the following is true regarding *Wyeth v. Levine?*
A. The original plaintiff sued only the drug manufacturer.
B. The original plaintiff sued only the clinic.
C. The original plaintiff sued only the physician and assistant.
D. The original plaintiff sued the drug manufacturer, the clinic, the physician, and the assistant.

Answers: 1. A; 2. B; 3. A; 4. D.