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# Reducing patients' risk may lead hospitals to bow to pressure

*Looking for a way to reduce errors*

A new plan from Washington, DC-based The Leapfrog Group could force hospitals to adopt new measures to reduce medical errors or risk financial losses, and risk managers may find themselves leading the charge at their own institutions. The ultimate goal may be reducing risk to patients, but providers are likely to comply because of the pressure exerted by The Leapfrog Group.

The Leapfrog Group gained attention right after the release of the Institute of Medicine (IOM) report on medical errors. A consortium of major employers in the United States, the Leapfrog Group said then that it would exert strong pressure on health care providers to reduce medical errors by threatening to make health care purchasing decisions on error rates and efforts to reduce them. The threat was looming for months, but the group released what it termed a "forceful, market-based effort to improve patient safety across the nation." The group also released new research indicating that the approach could save up to 58,300 lives and prevent up to 522,000 medication errors each year.

The Leapfrog Group is a consortium of Fortune 500 companies and other large private and public health care purchasers. The Leapfrog Group's approximately 60 members provide health benefits to more than 20 million Americans; Leapfrog members and their employees spend more than $40 billion on health care annually. Under Leapfrog, employers have agreed to base their purchase of health care on principles encouraging more stringent patient safety

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## COMING IN FUTURE ISSUES

- Continuing liability risk from 'satanic cult' diagnoses
- Federal crackdown on nursing home quality
- Incentive programs for risk management
- Positioning risk management as a profit center
- Criminal penalties from medical care — growing problem?

measures. If a health care provider doesn't follow the Leapfrog guidelines, the member companies won't send any patients.

The group's plan includes three main requirements for providers: computerized physician order entry, evidence-based hospital referral, and intensive care unit (ICU) staffing by physicians trained in critical care medicine.

None of the ideas are new to risk managers, but the health care community may finally have to listen and start implementing them, says **R. Stephen Trosty**, JD, MA, director of risk management at Mutual Insurance Corp. of America in East Lansing, MI.

"Hospitals and other providers probably will have to pay attention," he says. "A lot of what they're saying are things that risk managers have recognized for a while makes perfectly good sense in reducing the potential for errors. This may create a new pressure that makes those ideas move forward."

### *The power of purchasing*

Citing the 1999 report by the IOM found that up to 98,000 Americans die every year from preventable medical errors made in hospitals, **Suzanne Delbanco**, PhD, executive director of The Leapfrog Group, says the member employers are trying to use their purchasing power to improve the country's health care system.

"Members of The Leapfrog Group have set out to reduce preventable medical errors by changing the way they purchase health care," Delbanco says. "By encouraging health care providers to adopt three proven safety measures, thousands of Americans can be protected from disability and death."

The plan is designed to force health care providers to take the necessary action to reduce medical errors immediately, says **Lewis Campbell**, chairman and CEO of Textron Inc. and chairman of The Leapfrog Group's Business Roundtable Health and Retirement Task Force. Campbell says the group expects health care providers to respond more quickly to the threat of financial losses than to any other motivation.

"The number of tragic deaths brought about by preventable medical errors is too striking for those of us in the business community to ignore," Campbell says. "Coming together with other employers through The Leapfrog Group, we feel confident in our ability to make a difference by harnessing and leveraging our health

care purchasing power. It's a straightforward business approach to tackling a complex problem, one that we must undertake to ensure our employees, retirees, and their families receive the highest quality and safest care available."

Trosty says the impact of the Leapfrog guidelines may come down to how much the member companies come through on their threats. If the employers refuse to send patients to any facility not complying with the guidelines, the impact could be substantial, he says.

"If The Leapfrog Group gets enough major businesses and employers to truly require and mandate this, that may result in sufficient buying power to get hospitals and other institutions to abide by these things," he says. "It depends on what kind of solidarity there is on the part of the businesses."

Other groups are moving in the same direction, Trosty says, and any success by The Leapfrog Group may lead the others to put more muscle behind the guidelines. Other business coalitions and regulatory groups, such as the Joint Commission on Accreditation of Healthcare Organizations, already are looking for ways to reduce medical errors, so The Leapfrog Group's action could be a bandwagon they will want to jump aboard.

"Ultimately, some of these things might be considered standards of practice, either because The Leapfrog Group has been successful in establishing that idea or because other groups lend their support," Trosty says. "I wouldn't be surprised if the Joint Commission gets on board and requires these things. I think they may become more than just suggestions from the business community."

## *Employers say they will use buying power*

The Leapfrog Group's plan was accompanied by research conducted by **John Birkmeyer**, MD, of Dartmouth Medical School in Hanover, NH. The research indicates that the group's three suggested improvements could save up to 58,300 lives per year, and prevent 522,000 medication errors, if implemented by all nonrural hospitals in the United States.

Computer physician order entry has been shown to reduce serious prescribing errors in hospitals by more than 50%, according to the group's research. Evidence-based hospital referral requires that patients needing certain complex medical procedures be referred to hospitals offering the best survival odds based on scientifically valid criteria — such as the number of times a hospital performs these procedures each year. The group's research indicates that a patient's risk of dying could be reduced by more than 30%. The group also claims that staffing ICUs with physicians who have credentials in critical care medicine has been shown to reduce the risk of patients dying in the ICU by more than 10%. **(See p. 4 for more on how the three initiatives will work.)**

Trosty says the three initiatives are solid ideas that have been proposed by risk managers for some time now. Whether each of them can be implemented quickly and effectively is another question, he says.

"Each thing that you do for reducing the potential for medical error is a positive thing," he says. "But I don't think there is any one thing that can be the answer to medical error reduction. A cost-benefit analysis might be necessary in some cases. With the intensive care units, for instance, specialists make sense intuitively but that doesn't mean you can't provide quality care without them."

There are still a number of questions to be answered regarding how to implement some of the ideas, Trosty says. Could it suffice to have a specialist supervisor on the ICU rather than all specialist physicians? For evidence-based referrals, how far do you carry that idea? For what procedures? What happens to a hospital that can't afford to comply with the guidelines? Do you shut down the hospital?

The costs of implementing the guidelines must be considered carefully, he notes. Hospitals may have no choice but to comply if The Leapfrog Group's pressure proves formidable; yet there may be no way to recoup the costs of complying.

"This could put hospitals between a rock and a hard place," he says. "They may understand this is the way to go, but as reimbursement levels continue to decrease, will there be additional reimbursement recognizing the additional cost of providing this level of care? If hospitals agree to do this or are forced to do this, but compensation is not enough, hospitals can only afford to do this for so long before they go out of business."

To put some teeth into the initiatives, The Leapfrog Group member companies have all agreed to adhere to these four purchasing principles in buying health care for their enrollees:

- educating and informing enrollees about patient safety and the importance of comparing health care provider performance, with initial emphasis on the Leapfrog safety measures;

• recognizing and rewarding health care providers for major advances in protecting patients from preventable medical errors;

• holding health plans accountable for implementing the Leapfrog purchasing principles;

• building the support of benefits consultants and brokers to utilize and advocate for the Leapfrog purchasing principles with all of their clients.

Current members of the Leapfrog Group include such 900-lb gorillas as AT&T, BF Goodrich / Rosemount Aerospace, The Boeing Co., Coors Brewing Co., DaimlerChrysler Corp., Delta Airlines, The Dow Chemical Co., Eastman Kodak Co., Eli Lilly and Co., Ford Motor Co., General Electric Co., General Motors Corp., General Mills, Georgia-Pacific Corp., Honeywell, IBM, Schering-Plough Corp., SmithKline Beecham, United Parcel Service of America, and Xerox Corp. ■

## Guidelines could help save on bottom line

Risk managers could put The Leapfrog Group's guidelines to good use, says a risk manager familiar with the group's initiatives.

Since they are in line with initiatives that most risk managers would endorse to some degree, this could be a good time to push hospital administrators to do the right thing, says **R. Stephen Trosty**, JD, MA, director of risk management at Mutual Insurance Corp. of America in East Lansing, MI. If health care providers were reluctant to adopt measures to reduce errors because of the expense, the financial risk of not complying with The Leapfrog Guidelines could be enough to change their minds.

"If the potential to lose business is big enough, then I think hospitals may be left with no choice," he says. "These are things that risk managers have been advocating for a while, so now we can point to the risk of not doing it as well as the positive impact on claims reduction, expenses, and costs. Risk managers can help develop that side of the equation, to show that there is both a risk and a benefit."

The best strategy for risk managers is to "pay very close attention to what's being asked, and the implications for your employer," Trosty says.

In particular, he says risk managers should assess The Leapfrog Guidelines in these terms:

• Does our facility have any special problems that these improvements might address? Does our facility have a higher-than-average occurrence of prescription errors, for instance?

• Where is our organization already with regard to these improvements? Have we done anything at all to move in that direction or would we be starting at square one?

• What would we need to do to reach full compliance? How much would that cost?

• Who would we need to put on a team to develop these initiatives? ■

## Leapfrog Group outlines what is acceptable

The Leapfrog Group's research suggests that its health care initiatives could radically reduce medical errors in the United States if only health care providers would implement them expeditiously. And to encourage their implementation, the group has outlined exactly what it would consider acceptable action by providers.

To compile statistical measures on how effective the changes might be, the group used the same basic analysis strategy for each of the three safety standards. Researchers first estimated the population at risk — the number of patients who are currently receiving care in suboptimal conditions and thus stand to benefit from changes imposed by Leapfrog. To avoid access issues and other unintended consequences, The Leapfrog Group exempted hospitals in rural areas. Thus, the population at risk is restricted to patients in metropolitan areas.

Then the group estimated baseline risks (of medication errors or mortality) in hospitalized patients, and the potential risk reductions associated with each of the safety standards. This is a summary of the potential benefit from full implementation of the three initiatives and how The Leapfrog Group expects providers to comply:

• **Computer-based physician order entry (CPOE).**

The group estimates that implementation of CPOE in every nonrural hospital in the United States would avert approximately 522,000 serious medication errors each year. Because of the relatively few studies in this area, the analysis relied on two well-recognized trials from a single teaching hospital. The Leapfrog Group acknowledges

that some may question the validity of generalizing these data to other hospitals nationwide.

"However, we chose the most conservative estimate of CPOE effectiveness [55% medication error reduction rate] for our baseline analysis," the group reports. "Although a large proportion of serious medical errors is life-threatening, the number that result in fatalities cannot be determined precisely from the medical literature. Accordingly, we did not calculate the number of deaths potentially avoided by CPOE. However, if only 0.1% of such errors were fatal, over 500 deaths would be avoided every year. If the fatality rate were 1%, over 5,000 deaths would be avoided."

CPOE systems are electronic prescribing systems that intercept errors when they most commonly occur — at the time medications are ordered. With CPOE, physicians enter orders into a computer, rather than on paper. Orders are integrated with patient information, including laboratory and prescription data. The order is then automatically checked for potential errors or problems. The Leapfrog Group says the specific benefits of CPOE include prompts that warn against the possibility of drug interaction, allergy, or overdose; accurate, up-to-date information that helps physicians keep up with new drugs as they are introduced into the market; drug-specific information that eliminates confusion from drug names that sound alike; improved communication between physicians and pharmacies; reduced health care costs from improved efficiency.

In order to meet Leapfrog's CPOE standard, hospitals:

**1. Require physicians to enter medication orders via computer linked to prescribing error-prevention software.**

**2. Demonstrate that their CPOE system intercepted at least 50% of common serious prescribing errors, using a testing protocol specified by First Consulting Group and the Institute for Safe Medication Practices.**

**3. Require documented acknowledgment that the physician read the directives to any override.**

Despite the considerable benefits, The Leapfrog Group says fewer than 2% of U.S. hospitals have CPOE completely or partially available and require its use by physicians. The upfront cost of implementing CPOE is one major obstacle for hospitals. At Brigham and Women's Hospital in Boston, the cost of developing and implementing CPOE was approximately $1.9 million, with $500,000 maintenance costs per year since. Installation of even off-the-shelf CPOE packages requires a significant amount of customization for each hospital and can be very expensive. Finally, there may be cultural obstacles to CPOE implementation. For example, many physicians resist the idea of ordering prescriptions via computer instead of by hand.

• **Evidence-based hospital referral (EHR) — 2,581 lives saved in five high-risk procedures; 1,863 lives saved in high-risk deliveries.**

The Leapfrog Group says the greatest number of deaths would be prevented by evidence-based hospital referrals for coronary artery bypass graft surgery (1,486 deaths), followed by elective abdominal aortic aneurysm repair (464 deaths), and coronary angioplasty (345 deaths). Potential lives saved with esophagectomy and carotid endarterectomy were 168 and 118, respectively. The analysis estimates the benefits that could be achieved with full adherence to Leapfrog volume standards in all U.S. metropolitan hospitals. The other two Leapfrog safety initiatives — CPOE and IPS — involve all-or-none hospital interventions. Making these changes for Leapfrog employees implies their availability to all other patients at the same hospitals. In contrast, even if EHR could be increased for Leapfrog employees, there would be no mechanism for assuring the same change in referral pattern for other patients.

"For this reason, a very important contribution of the Leapfrog safety initiative may occur by simply increasing public awareness of the importance of volume for selected high-risk procedures," the group says.

For high risk neonatal intensive care, full implementation of EHR for high-risk deliveries would save 1,863 babies' lives each year in the United States, 1,369 lives for deliveries involving very low birth weight babies and 494 lives for deliveries involving babies with major congenital anomalies.

• **ICU physician staffing (IPS) — 53,850 lives saved.**

The Leapfrog Group maintains that IPS is so effective because such a large number of people die in ICUs each year (approximately one-half million). Thus, even small improvements in ICU mortality rates save many lives.

The group acknowledges that although work force issues have not been studied carefully, it is unlikely that there are currently enough board-certified intensivists to fully staff ICUs at all hospitals. And the group says that in hospitals with small units, meeting the Leapfrog daytime intensivist staffing standard may increase net cost per stay. "For these reasons, broad implementation of

intensivist model ICU staffing may require a mixture of increased fellowship training slots in critical care, consolidation of small ICUs, and advances in ICU telemedicine." ■

## A new survey says few pharmacy errors reported

Many pharmacy errors are not reported in a way that helps prevent the repeat of such errors in the future, according to the results of a recent survey by the Institute for Safe Medication Practices (ISMP).

The ISMP, a nonprofit group in Huntingdon Valley, PA, surveyed health care providers about how medical errors are detected and what is done with that information. The 417 responses indicate "it's clear that we need to pay greater attention to the processes involved and the environment in which these functions take place," the ISMP reports. The survey results were reported recently on the ISMP Web site at www.ismp.org.

The group found that spontaneous reports from staff are the most common method used to identify errors, with 97% reporting they use that method. Other methods of error detection, which the ISMP say may be more effective and productive, have not been widely adopted. For instance, the ISMP found that only 19% of respondents use a telephone hotline or other method to simplify error reporting. Sixty percent of the survey respondents said they reviewed medication records or patients' charts to uncover errors, but only 32% reviewed drug or laboratory triggers or markers that may signal an error.

The ISMP also found that only 17% used medical record external cause codes, or E codes, to identify adverse drug events.

"Although access to valuable error-related data may be easy to obtain, it may not actually be used to improve medication safety," the ISMP writes. "For example, more than a quarter of respondents (29%) said they had not collected and used information about pharmacy interventions to correct prescribing errors. As a result, about half of them said these intercepted errors are unlikely to be reported. More importantly, they are most likely to be repeated."

Providers also reported that only 40% of dispensing errors and 46% of transcription errors were likely to be reported, saying it is more likely for staff to report errors that actually reach the patient and cause harm. Even for that type of error, however, only 76% of respondents said they were fully confident that they would be reported in their facility.

"Potentially hazardous situations that could lead to an error were the least likely to be reported, which demonstrates how reactive, rather than proactive, healthcare continues to be today," the ISMP reports.

The survey results also suggest that providers are inconsistent in punishing and rewarding people. Respondents reported that nurses received more frequent and harsh punishment for serious errors, but nurses also were more frequently rewarded for reporting serious errors and provided with psychological counseling after an error. Physicians receive the least punishment for serious errors, according to the survey, but they rarely are rewarded for reporting an error or are provided with psychological counseling. ■

## Undertreatment of pain creates new risk

The undertreatment of pain is so common that it represents a huge new liability risk for hospitals and doctors, according to experts who predict that it won't be long before the health care community gets a wake-up call in the form of a major malpractice verdict.

Health care providers routinely neglect or intentionally refuse to treat severe pain, especially the pain of terminally ill patients, says **Kathryn Tucker**, JD, director of legal affairs with the Compassion in Dying Federation in Seattle. Not only is that undertreatment a cause for moral outrage, it also is reason for risk managers to consider the potential liability, Tucker says.

"Undertreatment of pain is epidemic," she says. "Patients don't get adequate pain care. Elderly patients are at particular risk, and that's a particular concern for risk managers because of the elder abuse statutes. That is a group known to be at risk for undertreatment and they have a legal remedy available to them that most groups don't."

Tucker spoke on the topic at the recent meeting of the American Society for Healthcare Risk Management in New Orleans. The problem of undertreatment is not new, she says, but the liability risk has grown from nearly nothing to potentially huge in just the past few years.

In one study, researchers found that 50% of all patients who died during hospitalization "experienced moderate or severe pain at least half of the time during their last three days of life."[1] Another study found that up to 40% of cancer patients in nursing homes are not appropriately treated for pain.[2] In addition, more than a quarter of those experiencing pain did not receive any pain medication, and 16% were given over-the-counter pain relievers like aspirin or acetaminophen for their pain.

One tragedy of the problem is that nearly all patients in severe pain can be treated successfully. Very few patients have medical conditions that make it impossible or excessively risky to relieve their pain, Tucker says.

## Pain is widespread, largely ignored problem

More than 50 million Americans suffer from chronic pain, according to **Russell Portenoy**, MD, chairman of Beth Israel Medical Center's Pain Medicine and Palliative Care Department in New York City. The undertreatment of pain was confirmed recently by the Pain in America survey commissioned by Partners Against Pain, an educational resource for patients and professionals. More than half of all patients surveyed said they have experienced their pain for at least five years, and 52% said their current prescription medication is not completely, or not very, effective.

The underuse of opioids such as morphine and codeine is one reason for the undertreatment, Portenoy says. Physicians fear their patients becoming addicted or that the drugs will hasten death, and they also fear criticism from medical boards and regulatory agencies that may say they are handing out narcotics too freely.

"It is not uncommon for physicians to be investigated for prescribing controlled substances in amounts that regulators perceive as excessive," Tucker says. "Even if the physician's conduct meets relevant guidelines for pain management, the investigations may result in physician discipline, including suspension or revocation of prescribing authority and other limitations on medical practice."

Some of those fears may be justified, Tucker says. She urges state legislatures and federal agencies to revise rules that discourage doctors from providing adequate pain relief. The other fears regarding addiction and the hastening of death are based on false assumptions, Portenoy says. Even many people with histories of chemical dependency can have chronic pain addressed with drugs and maintain control of their use.

"When prescribed and used appropriately, opioid medications improve quality of life," Portenoy says. "If doctors and others better understood the complex issue of addiction, inappropriate fear of this outcome would not contribute to undertreatment with these drugs."

Undertreatment of pain also is caused by the reluctance of patients to discuss the problem with their doctors, and physicians' lack of skills in pain management. This is due in part to the fact that there is little training during medical school in either pain management or addiction medicine, Portenoy says. Tucker also notes that physicians should not hold back pain treatment out of fear of hastening a patient's death. Case law has established that, she says.

"Regardless of what you think of the right to die, patients have a right to adequate pain relief," Tucker says. "The highest court in the land has made that clear."

## Records create proof of undertreatment

Recent regulatory changes have upped the risk for providers when pain relief is inadequate. The Department of Veterans Affairs and the Joint Commission on Accreditation of Healthcare Organizations already require that pain be charted as a vital sign, so that creates a record of pain management for better or worse.

"Those directives from the government make it more likely that a patient will complain if pain care is inadequate," Tucker says. "And then if a lawyer comes on the scene and the substandard care can be proven, that could mean big trouble."

Some providers already have paid the price for the undertreatment of pain. In one case, a jury awarded $15 million, half of it punitive, from a nursing home where a patient had died in pain.[3] The patient's family alleged that a physician had ordered morphine for the man's pain, but a nurse refused to administer it because she feared the patient would become addicted; she gave the man Tylenol instead.

In other cases, families have been compensated for the emotional stress of watching loved ones suffer. The Oregon Board of Medicine has disciplined a doctor for failing to provide adequate pain relief, Tucker says.

A case currently in litigation involves a disturbing callousness toward the patient's pain, but Tucker says it unfortunately is not a rare situation.

In that case, an elderly man with cancer was admitted to the hospital and was provided with a 25 mg Demerol for pain. The starting dose is typically 100 mg. The doctor ordered further Demerol only as needed, rather than ordering a constant schedule that experts say is key to controlling severe pain.

Nurses charted the man's pain regularly, and he always reported that the pain was 7 to 10 on a 1-10 scale, with 10 being the "worst imaginable" pain. The doctor did not provide any stronger pain relief, and the patient reported that his pain was a 10 on discharge. He died at home in terrible pain, and his family claims that their pleas for pain relief were ignored. Tucker says the nurses documented the pain and the family's repeated requests for pain relief but did not contact the doctor for a change in orders. The doctor's visits to the patient also did not result in any change.

Tucker notes that the patient had refused chemotherapy, surgery, and radiation to treat his cancer. "That was entirely his right to refuse those treatment options, but the doctor still was obligated to provide pain relief," she says. "The doctor's pain control training was only his pharmaceutical class in medical school and one brown-bag lunch in 30 years."

The case has been pending for one year and the provider has made no settlement offer, Tucker says. The elder abuse provisions allow punitive damages and attorneys' fees, she says.

"There are no financial damages at play for this patient, but this is potentially a major case. Both the doctor and the hospital are defendants," Tucker says. "There will be more patient awareness and more tort action in egregious cases."

## Make providers aware of patient rights

The solution for the undertreatment of pain isn't simple, Tucker says, but risk managers should act now to alert their clinicians to the risk. Physicians and nurses should understand clearly that patients have a right — legally, not just morally or philosophically — to adequate pain control.

"Make sure your people understand that they have to provide pain relief just as much as they have to take actions to keep the patient alive and safe," Tucker says. "Pain isn't just something you take care of if you want to. The patient has a right to pain control, and if that is ignored, then somebody is going to pay a price. And it might be a very big price."

Other solutions involve regulatory reform. The American Society of Law Medicine and Ethics undertook an effort at reform recently by launching the Project on Legal Constraints on Access to Effective Pain Management. The project developed a model Pain Relief Act that creates a safe harbor to shelter physicians from both disciplinary and criminal action if the physician can "demonstrate by reference to an accepted guideline that his or her practice substantially complied with that guideline." The physician also must have kept appropriate records, written no false prescriptions, obeyed the Controlled Substances Act, and not diverted medications to personal use.

## Finding a safe harbor

Tucker says the safe harbor concept also is encompassed in state laws intended to ameliorate the problem. Known as Intractable Pain Treatment Acts, the existing state statutes generally provide shelter from disciplinary action but make no mention of criminal exposure. The Medical Board of California adopted a policy statement in 1994 that encourages aggressive pain care and then adopted another guideline that specifically identifies failure to adequately manage pain as "inappropriate prescribing." By making undertreatment of pain a type of inappropriate prescribing, the board expressly called it a form of professional misconduct subject to the full range of sanctions.

For the health care industry as a whole, Tucker says it make take a major lawsuit to get everyone's attention and force attention to the problem of undertreatment of pain. She notes that juries can relate well to the story of a loved one dying in terrible pain while medical professionals with the ability to stop it stand by and do nothing. The issue does not involve confusing medical issues, but pain is a topic that may disturb juries enough to prompt major awards.

"I think we're going to see more lawsuits, and it could be that we will see a case in which a provider is held liable for a huge sum of money," Tucker says. "Unfortunately, that may be what it takes to put an end to these egregious cases."

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3. *Estate of Henry James v. Hillhaven Corp.*, Sup. Ct. Div. 89CVS64, Hertford County, NC (1990). ■

# Maybe guests have come at a bad time

Two groups representing surgeons and operating room nurses have issued guidelines that discourage visitors in the operating room and suggest that patients give consent for any visitor. The guidelines could help risk managers tighten their policies on OR visitors by showing that the clinicians' own societies advocate a strong stance.

Risk managers have long sensed that surgeons are too lax about allowing visitors in the OR, usually salespeople who want to demonstrate a new device or others admitted for educational reasons. While many of those visits can be justified, some risk managers say hospitals run a risk by not obtaining consent from the patient and carefully policing all visitors.

The most recent development comes from the American College of Surgeons (ACS), which released a formal statement saying that any visitor should be allowed in the OR only under strict conditions.

The ACS says health care organizations should establish written policies defining requirements and procedures for manufacturers' representatives to be present in the OR, and restrictions to govern representatives' activities in the OR. The group also says the hospital should have a specific procedure for obtaining approval within the institution, and then a policy for orientation, training, and credentialing of the visitor.

But in the most significant guideline for risk managers, the ACS says "the patient should be notified of the presence and purpose of the representative in the OR and give written, informed consent." While risk managers and others have advocated consent from the patient, the ACS statement is a substantial step forward in reaching that goal, says **R. Stephen Trosty**, JD, MA, director of risk management at Mutual Insurance Corp. of America in East Lansing, MI. "There's already been a reason to get informed consent, but the ACS guidelines kick that up a bit. It's moving from just a good idea to something more."

Trosty says the increasing emphasis on the issue should prompt risk managers to seek more informed consent for OR visitors. Nearly every hospital allows such visitors at some time, according to ECRI, the nonprofit health research agency in Plymouth Meeting, PA. ECRI conducted a survey of 180 hospitals and found that 95% allow "outsiders" in the OR during surgery.[1] Of those that allow visitors, 86% have a policy in place to protect patients. More than three-quarters specify what the sales representative can and cannot do in the OR, and more than half require that the patient consent to the presence of visitors during the procedure.

More than half of the facilities surveyed by ECRI report that they require the patient's consent for visitors in the OR, but that consent is usually in the form of a general statement in the operative consent form, stating that the surgeon and facility may allow observers for professional reasons. That may be sufficient in most cases, though ECRI advises playing it safe and obtaining specific consent for visitors during the procedure.

Trosty agrees. Such a blanket consent may be sufficient in teaching hospitals, but not in any other case, he says. "If the visitor is not directly related to health care, like another physician or a medical student, it's probably best to get specific consent by name or at least by the person's function. If it's a salesperson, say so and explain why that person needs to be there. The blanket consent for visitors works sometimes, but I think the ACS is looking for something more."

### *Question appropriateness of visitors*

Trosty points out one complication. If the surgeon offers full disclosure that a salesperson will be in the OR, the patient is likely to ask why. And if the surgeon answers truthfully by saying, "This is the first time I've used this gadget, and the salesperson will be talking me through it," don't expect the patient to be pleased.

"That gets you into the whole question of what true informed consent is," he says. "If you aren't experienced with the item, maybe the patient should know that. It can get difficult, but I think the patient has a right to know."

The fact that the ACS has advised getting patient consent can be a powerful tool for risk managers, Trosty says. The ACS statement comes on the heels of a similar one by the Association of PeriOperating Registered Nurses (AORN); risk managers no longer have to seem like the bad guy when advocating stricter control. "In many cases, it is the surgeon or anesthesiologist who is bringing these people in, so these guidelines may give the risk manager some real ammunition to use with the surgeon resisting this type of consent," he says. "You can say, 'It's your own professional group that says you should do it.'"

Similarly, the AORN Position Statement on the Role of the Health Care Industry Representative in the Operating Room emphasizes that the presence of an industry representative must not compromise patient safety in any way. AORN advises making the patient aware of the visitor's presence, and says that "as the patient's advocate, the RN responsible for the patient's care during the procedure is accountable for maintaining the patient's safety, privacy, dignity, and confidentiality."

Trosty says the trend in past years is clear. The health care community is recognizing the risk to both patients and the institution from letting people in the OR too casually. With every new guideline that advocates a strict policy and patient consent, the risk grows greater for hospitals with a lax policy, he says. "With this enhanced focus on privacy, people should be asking why we're having those folks in there. Does the patient have the right to assume that only necessary medical professionals will be there in the OR? I think the answer is yes."

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## The quest begins to measure effectiveness

The American Society for Healthcare Risk Management (ASHRM) is initiating its Claims Data Gathering Project, a project intended to measure the effectiveness of hospital risk management activities and ultimately assist risk managers in identifying "better practices."

ASHRM's objectives for the project are to test the viability and effectiveness of standardized risk management definitions, capture information on events reported through internal vs. external notification and, eventually, identify performers that appear to be using better practices.

For the past few years, a national task force composed of health care risk managers and insurance company representatives has been designing a pilot study for collecting and analyzing nationwide risk management data. ASHRM leaders say the initiative is now ready to be tested by a group of hospitals across the country. The pilot project commenced Dec. 1, 2000, and runs for six months. The pilot will focus on the collection of data identifying how matters are reported to risk managers and the correlation between reporting mechanisms and asserted claims.

ASHRM is collaborating on this project with Vahe Kazandjian, PhD, president of the Center for Performance Sciences (CPS) and one of the leading health care researchers in the country. The Center, under Kazandjian's leadership, is renowned for the Maryland Hospital Association's Quality Indicator Project, currently the largest comparative data collection / sharing / benchmarking effort in the country. ASHRM has retained CPS to support the pilot project through the development of a computerized data collection application, accepting data and maintaining a database, and providing aggregate reporting and evaluation. ■

## Ergonomics rule flexes its muscle

Hospitals could see a significant increase in the costs of preventing physical strain and repetitive motion injuries if the federal ergonomics rule is not stopped by pending lawsuits, according to experts on all sides of the issue.

Health care workers have long been seen as a primary beneficiary of the rule because of the risk posed by lifting patients and other strains inherent in the business. Proponents of the rule say it prevents many injuries each year, but critics say it will create a terrific burden on health care employers. When the federal government finally released the long-debated ergonomics rule recently, it was promptly met by some of the harshest criticism ever levied against a new standard. A wide range of professionals, including some that rarely agree on anything, are calling the rule ill-conceived and hastily enacted.

To no one's surprise, the business community promptly filed a lawsuit challenging the ergonomics standards. Congress has repeatedly put up roadblocks to past efforts to issue the rule, but the U.S. Occupational Safety and Health Administration (OSHA) issued the rule in November despite stern warnings from Congress not to do so.

Many Congressional leaders oppose the rule so strongly that, in the past, they have threatened to withdraw essentially all funding for the federal

agency if the rule was issued.

Since the timing of the rule's issuance makes it virtually impossible for Congress to take any action to stop or delay the measure, the National Coalition on Ergonomics filed a petition for review in the Court of Appeals for the District of Columbia.

"For reasons only OSHA can explain, the agency has elected to ignore the will of the Congress and moved forward with its ill-conceived proposal," says **Ed Gilroy**, co-chairman of the National Coalition on Ergonomics.

Gilroy says the basis of the coalition's lawsuit is that medical science does not adequately support the need for the Labor Department's regulation; that the standard is too vague and incomprehensible; that the OSHA has produced a fatally flawed economic analysis; and that OSHA has committed serious procedural violations such as issuing an altered rule without a new round of public comments. The lawsuit represents various business groups including the National Association of Manufacturers and the National Federation of Independent Business.

The Society for Human Resource Management (SHRM) also filed a lawsuit in U.S. District Court in an effort to block implementation of the standard. SHRM filed formal comments in March arguing that the proposed rule placed unwarranted compliance burdens on employers, and had unrealistic goals that conflicted with the National Labor Relations Act, the Family and Medical Leave Act, the Americans with Disabilities Act, and state workers' compensation laws. SHRM also expressed concern that the regulations were based on inadequate science and would be much more costly than projected by the department.

"Despite minor changes in the final published




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standard, little has been done to eliminate our original concerns," says SHRM executive vice president and COO **Susan Meisinger**, SPHR. "It is unfortunate that the administration has taken this unprecedented course of action to rush such a complex standard through the regulatory process. It has left us with no option but to file suit."

The Department of Labor has claimed that the final standard was designed to reduce the number of musculoskeletal disorders (MSDs), or repetitive motion injuries, in the workplace. It requires all general industry employers to implement an ergonomics program when specific risk factors such as repetition, lifting, pushing, pulling, awkward postures, stress, or vibrations develop into an MSD or repetitive motion injury. It also calls for a 90% federally mandated wage replacement for employees removed from work due to an MSD and a 100% replacement for those workers placed on restricted or light-duty work. The department provides no guidance to employers in the regulations on how to rationalize this wage replacement requirement with state workers' compensation laws.

OSHA's ergonomics rule is 1,600 pages long. Businesses are expected to begin complying with the standards that OSHA says will prevent injuries and save businesses billions of dollars every year by Jan. 16, 2001.

The standard becomes effective Jan. 16, just days before President Clinton leaves office. Employers must begin implementing the ergonomics rule by educating employees and responding to injuries no later than Oct. 14. Employers will have four years to fully implement controls, such as purchasing mechanical lifts.

In a significant turnaround, the American College of Occupational and Environmental Medicine (ACOEM) immediately announced its opposition to the standard, citing the standard's lack of a sound medical foundation. While maintaining the need for a medically-based standard to protect the nation's workers, ACOEM becomes the only major medical association previously supporting the standard to withdraw support for the highly publicized OSHA standard, which is intended to reduce the number of MSDs in the nation's work force.

"We cannot support the final regulation as it is currently written," says ACOEM president **Robert Goldberg**, MD, FACOEM, and director of the ergonomics program and assistant clinical professor at the University of California, San Francisco. He expressed the college's fear that in its haste to publish the final standard, OSHA has put the standard in legal jeopardy by the agency's failure to address the shortcomings debated during hearings earlier in 2000. During those hearings, ACOEM submitted several recommendations to establish a firm medical basis for the diagnosis and treatment of musculoskeletal disorders.

"Fundamental to an effective standard is a process to verify the diagnosis of a musculoskeletal disorder and to determine that the injury or disorder is directly related to workplace duties," ACOEM explains in a statement opposing the standard. "Throughout the past two years of the rulemaking process, ACOEM has consistently urged OSHA to limit implementation of the standard only to work-related disorders for which credible scientific evidence exists. Yet, the final standard appears to require neither a medical diagnosis nor a causal assessment." ■

Healthcare Risk Management's
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# IV inserted to nerve results in radial nerve injury: $155,000 arbitration award

By **Mark K. Delegal**, Esq., and **Jan Gorrie**, Esq.
Pennington, Moore, Wilkinson, Bell & Dunbar, PA
Tallahassee, FL

**News:** A woman was admitted to a hospital for elective, outpatient surgery. Preoperatively, an intravenous line (IV) was placed in her wrist, hitting her radial nerve. The improperly placed IV resulted in reflex sympathetic disorder, which required subsequent surgeries, physical therapy, and nerve blocks. A binding arbitration award for $155,000 was granted to the patient.

**Background:** The 29-year-old divorced mother of two minor children, who worked as a mail carrier, was admitted to the hospital to have her nose reconstructed, which was elective, outpatient surgery. Preoperatively, an IV line was placed on her left wrist. The patient immediately complained of a burning, "shocky" feeling at the area of insertion with the burning sensation extending into her thumb and index finger. She cried and asked that the IV needle be removed, but the hospital staff nurse continued with the IV setup.

Following surgery, the patient was groggy, but in the postoperative suite she noticed that the IV line had been moved to her right arm. Her medical record gave no indication when or why the IV line had been moved, nor did it mention that she complained about pain at the IV site. After recuperating, she was driven home by her brother, who later testified that she complained of severe pain in her left arm during the ride.

She continued to complain to her parents of severe pain and sensitivity in her left arm. Ten days later, still in pain, she was referred to a hand surgery specialist who diagnosed her as with reflex sympathetic dystrophy, which was the result of the radial nerve having been hit by the initial IV needle used in surgery.

At first, the injury was conservatively treated with medication and light therapy. Failing to achieve any measure of relief, the hand surgeon began to administer nerve blocks. When this, too, proved unsuccessful at alleviating her pain, the hand specialist performed surgery to remove a piece of the superficial radial nerve by burying it the muscle of the patient's left forearm. When the piece of nerve at the original IV site was examined by the hospital pathologist, he found a focus of traumatic nervoma presumably caused by the needle hitting the nerve. Following the initial nerve-shift-burial surgery, a second nervoma formed at the site where the top portion of the nerve was buried in the arm. This led to secondary pain syndrome in the left forearm, which was also diagnosed as reflex sympathetic dystrophy.

The hand surgeon sought a second opinion from a neurosurgeon, who confirmed the diagnosis. He also prescribed medication and physical therapy. Subsequent treatment involved extensive physical and occupational therapy, eight separate nerve block procedures, and two additional surgeries.

The plaintiff claimed that this was a classic "res ipsa loquitur case," which translates as "the thing

speaks for itself." Practically speaking, it means the burden of proof that the defendant was not negligent falls upon the defendant because the injury was caused by the instrumentality of the defendant (the IV needle), the IV needle was under the singular control of the staff nurse, and it was an injury that does not ordinarily occur absent negligence.

In this instance, the IV needle impaled the superficial branch of the radial nerve, resulting in reflex sympathetic dystrophy. A plaintiff's medical expert testified that her radial nerve was not in an anatomically abnormal position, and so the defendant could not argue that the nerve was hit because it was in an unusual place. As the sole provider for her two children, the plaintiff was reluctant to quit her full-time work as a mail carrier and file for disability. However, she misses eight weeks of work and had to wear a protective splint for an extended period of time in order to protect the area of hypersensitivity.

In its defense, the hospital argued that when an IV line is started, there is an inherent risk of hitting a nerve, and that this is a known risk. Alternatively, the hospital maintained that the incident never occurred because the medical records did not indicate that the patient had complained of any pain in the IV insertion area on the day of surgery. However, there was debate about the medical records being accurate and precise. The defendant argued that the injury was greatly exaggerated, and that subsequent treatment and surgeries were only a means to bolster her claim of negligence.

Ultimately, the claim was settled through arbitration for $155,000.

**What this means to you:** It appears that the patient was neither listened to nor heard.

"Had the patient's complaints been more closely evaluated, perhaps the untoward outcome could have been avoided. This incident emphasizes the need for communication, which includes listening and hearing, as well as the need for good, thorough documentation," notes **Leilani Kicklighter**, assistant administrator, safety and risk management, North Broward Hospital District, Fort Lauderdale, FL.

"Specifically recommended is the institution of a required educational program for newly hired staff who are authorized to insert IVs and documented evidence of successful completion of the program in the individual personnel files. And not simply an IV program, but one that is compliant with acceptable standards. Once such educational programs are provided, there should be a system in place to annually evaluate the continued competency of each staff member authorized to insert IVs, which should include monitoring of IV-related incidents. Placing IVs entails more than practicing on fruit. As indicated by this case, the insertion of IV lines is a learned skill," Kicklighter says.

"As for the documentation on the care provided to this patient, there seems to be very little. The adage of 'If you did not write it down, it did not happen' comes to mind. Health care practitioners must be sensitive to the fact that patients' thresholds for pain are highly variable, and if you believe that the patient is ultrasensitive, document it. Further, it is very difficult to defend a case when you are unable to demonstrate what care was provided through the medical record," notes Kicklighter.

*Elvia Cortez-Burgueno v. Kaiser Foundation Hospitals*, Los Angeles County (CA) Superior Court, Case No. ■

# Improper IV leads to amputation

**News:** A woman came to a Texas emergency room (ER) with an accelerated heart rate. An IV line to her right hand was placed into an artery rather than vein. Though the patient complained of discomfort, the IV remained improperly placed for long enough to cut off the arterial blood flow to her hand, ultimately resulting in the loss of her thumb and index finger. Prior to trial, the case was settled for an undisclosed amount.

**Background:** When the 56-year-old woman came to the emergency room for evaluation and treatment of a rapid heartbeat, ER personnel determined that she was suffering from supra ventricular tachycardia, and started her on Adenocard. The Adenocard was administered through an IV catheter placed in the patient's left wrist near the base of her thumb. The IV site used was the treating nurse's position of first choice for placing all IV's regardless of the medication being administered.

Following the initial administration of the Adenocard, the patient complained of a burning sensation where the IV catheter had been placed

and moved distally into her hand. Despite her complaints, emergency room personnel continued to use the IV catheter to administer additional intravenous medications, including another dose of Adenocard, as well as Nubain and Phenergan.

The nurse who inserted the IV used a tourniquet. However, it appears that she never palpated the site to determine if the vessel was a vein or artery, and it seems as though the nurse had placed the patient's IV catheter into the dorsal branch of the radial artery instead of a vein. Later that day, the patient was discharged with pain medications for her hand.

By the next morning her thumb and index finger had turned black and blue. She returned to the same emergency room. In her evaluation, the ER nurse noted that it appeared as though the woman had dyed her two fingers. An ER physician sent her home without further treatment.

The following day, her condition had not changed and she went to another hospital's emergency room. The hospital was larger and operated a trauma center. The ER nurse suspected that medications had been improperly administered. Both Nubain and particularly Phenergan are known to cause pain, severe chemical irritation, and significant spasm of distal arterial vessels, which can result in gangrene. The patient had developed gangrene in her thumb and index finger, which necessitated amputation of those two digits.

The plaintiff patient alleged negligence on the part of the emergency room personnel with respect to the initial placement of the IV catheter and more particularly the treating physicians' and nurses' failure to move the catheter after the patient repeatedly complained of pain at the site and distal radiating pain. The plaintiff also maintained that the hospital was negligent in simply discharging her with pain medications for her sore hand without first seeking an appropriate consultation to diagnose and treat the condition.

The defendant physicians, hospital, and hospital personnel denied that the injury was caused by administering Nubain or Phenergan, claiming instead that the loss of blood flow was caused by an unrelated blood clot or embolus. Under that scenario, the defendant physicians felt that they were not negligent in failing to diagnose that event or failing to undertake treatment for that condition.

Prior to trial, the case was settled with all defendants for a confidential amount. The second ER physician, though he was named in the case, did not have to pay anything based on testimony that while he failed to diagnose the condition, it was not reversible, and therefore his oversight did not cause additional harm.

**What this means to you:** "While those of us who work in health care recognize how busy an emergency department care be and are aware of the dynamics of that department, we must not forget that we are dealing with people, each with unique pain thresholds. Again, it seems that the patient's self-reported pain was ignored. Listening to and evaluating what the patient has to say is important and should not be dismissed," says **Leilani Kicklighter**, assistant administrator, safety and risk management, North Broward Hospital District, Fort Lauderdale, FL.

Once again, the facts of this case lead to the need for proactive and, hopefully, preventive education and training.

"Specifically, the differentiation between a vein and an artery, the effect that certain medications have on the blood vessels, and how that impacts the decision of where to place an IV, as well as a review of the anatomy of the sites most usually selected to be used for IV insertion, are all essential components of an IV education course. For instance, in this case it may have been better to have placed the line at her elbow given the medications being administered," adds Kicklighter.

In addition to reviewing the role the nursing staff played in this case, the actions or inactions on the part of the emergency department physicians should be examined.

"Presumably, the continuing hand pain was brought to the attention of and evaluated by the emergency department physician prior to discharge on the day of the first admission. In view of the description of the fingers upon the return visit to the emergency department, it raises the question of the adequacy of not only the physical evaluation at triage but that of the physician. If the nurse determined and documented that there was a compromise to circulation or pulse it would seem that the situation would be more emergent.

"The nursing staff would have an obligation to question the treating physician as to the lack of treatment in the face of such apparent obvious compromise. If the response from the physician was not receptive, the nurse would have had an obligation to contact both the nursing supervisor and hospital risk management. In any event, an

incident report should have been made out by the triage nurse who initially recognized the state of the fingers just 24 hours after discharge from the emergency department. The fact that the patient went to another emergency department the following day with a potentially emergent condition that had not been evaluated and stabilized is a potential EMTALA violation. This is another reason for an incident report to risk management." notes Kicklighter.

Another note on the emergency physicians is whether they were hospital employees or contract providers.

"If the emergency department physicians were contract providers, the risk manager should revisit the agreement to evaluate quality of care clauses, verify that the emergency department consent language reflects the contractual relationship, and make sure that there are signs in various locations throughout the emergency department that indicate the contractual relationship. In addition, the 'track record' of the two physicians involved in this patient's care should be examined in light of incident," Kicklighter says.

*Zelma Shannon v. Martin G. Guerroero, MD, Carmelito Arkangel, Jr., MD; Judy White, RN; and Methodist Healthcare System of San Antonio, Ltd.; d/b/a San Antonio Community Hospital*, Bexar County (TX) District Court, Case No. 98-CI-14760. ■

# Infant's IV results in $300,000 GA verdict

**News:** A 6-week-old infant was admitted to the hospital with severe dehydration. He was placed on IV fluids and received a blood transfusion through the same line. After his mother complained of the child's unmerited crying, the line was finally checked. As it turned out, IV fluids had infiltrated the child's muscle and hand. This resulted in permanent muscle damage and scarring. A Georgia jury returned a verdict of $300,000 in favor of the patient and his mother.

**Background:** The infant was taken to the emergency room and admitted to the hospital for severe dehydration. Throughout the night, he received fluids intravenously. Approximately 16 hours after admission, he was given a blood transfusion through the same line. One hour later, his mother called for the nurse because her son was crying for no apparent reason. The nurse removed the tape surrounding the IV line and discovered that the IV fluids had infiltrated the tissue in the child's hand. The infiltration resulted in permanent damage to the child's left hand and wrist.

The plaintiffs alleged that the hospital staff had improperly placed and monitored the child's IV line. The defendant hospital countered that the line was properly monitored and that when the IV pump alarm sounded staff responded appropriately.

The jury awarded the plaintiffs $300,000.

**What this means to you:** "Pediatric patients pose a different issue in that, depending on their age, children can't tell us where or how it hurts, and so practitioners must rely on the parents to assist in making those determinations," says **Leilani Kicklighter**, assistant administrator, safety and risk management, North Broward Hospital District, Fort Lauderdale, FL. "Parents' assessments may be critical in providing care to pediatric patients. The amount of infiltrated fluid in a child's tissues that can potentially cause a slough or other significant damage compared to an adult is much less. Also, the reaction to a chemical irritation from the medications in a pediatric patient might be more pronounced due to the tenderness of the child's skin and tissue. In all aspects of pediatric IV therapy, these concepts must be kept in the forefront of the mind of the patient care staff and should be components of an IV educational program where pediatric patients are involved.

"In each of these cases, the patients [or parents] attempted to communicate their discomfort to the attending practitioners, and each time they were ignored. Each of the patients tried to warn the providers that something was wrong, but they were dismissed. Not enough can be said for the need to adequately train and educate health care providers regarding IV placement, monitoring, and medications and documentation of what they are doing. However, some errors can be mitigated through simply listening and hearing what your patients are saying," concludes Kicklighter.

*Safaris and Tash Lewis v. Phoebe Putnam Memorial Hospital,* Dougherty County (GA) Superior Court, Case No. 97-S.V.-417. ■