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INSIDE

FEBRUARY 2002

VOL. 24, NO. 2 (pages 13-24)

Once more, with feeling: Wrong-site surgery is still an unsolved problem

Joint Commission is losing patience with major errors

Wrong-site surgery is the kind of medical error that for a long time seemed so egregious that there was no need to directly address it with prevention efforts. No more. The Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations has issued its second alert in three years about wrong-site surgery and risk managers are starting to see the problem as needing real attention.

The tone of the Joint Commission alerts has changed and may indicate a new way of looking at providers who commit wrong-site surgery. The first alert of three years ago sought to draw attention to the problem without beating up providers too much for the mistake.

But in the second alert, president **Dennis S. O'Leary**, MD, sounds more like a frustrated parent who can't believe he has to bring this up *again*.

"This concerned us because this is one of the few cases in which we have a second alert," he says. "The number of adverse events that we have reported to us each year is pretty much flat, about 400 cases a year. The number of wrong-site surgeries has gone up year after year."

In 1998 when the Joint Commission issued its first alert, there were 16 reports of wrong-site surgery. In 2001, there were 58. **(See p. 15 for more on the analysis of past events.)**

"That number has gotten higher each year, so we are becoming concerned about this," he says. "Health care experts are unanimous in their belief that these types of errors should never happen."

For risk managers, the financial cost of the mistakes will be a major concern. Aside from the media coverage and harm done to the patient, wrong-site surgery can cost a bundle. Physician Insurers Association of America in Rockville, MD, reports that 84% of wrong-site surgery claims against orthopedic surgeons and 68% against other physicians resulted in payment.

O'Leary says he does not think surgeons and risk managers are actively resisting the Joint Commission's pleas to act on this problem, but "I think we are dealing with a lack of sense of urgency around this."

The Joint Commission's most recent warning comes with support from the American College of Surgeons (ACS) and the American Academy of Orthopaedic Surgeons (AAOS). The three organizations jointly offer this advice for preventing wrong-site surgery:

- **Sign the operative site.**

Having the surgeon actually write on the operative site reduces the chance of operating elsewhere.

- **Orally verify the surgery.**

In the operating room just before starting the operation, each member of the surgical team should confirm that he or she has the correct patient, the correct surgical site and the correct procedure.

- **Take a "time out" in the operating room.**

This gives the surgical team one last chance to double-check among themselves about the impending procedure, check charts, and corroborate information with the patient.

Most of the advice for preventing wrong-site surgery involves improved communication and careful, repeated verification of the patient's identity, the planned procedure, and the exact surgical site. The AAOS recommends having the surgeon sign the operative site before surgery to confirm the proper site, but the idea has not been adopted widely enough for **S. Terry Canale**, MD, chief of staff and a member of the board of directors of the Campbell Clinic in Memphis, TN, and a past president of AAOS. Canale spearheads the AAOS campaign against wrong-site surgery. **(See p. 15 for more advice.)**

Risk managers should encourage surgeons to sign the surgical site at the time they visit with the patient before surgery, possibly the night before or first thing on the day of surgery, he suggests. Some surgeons have been doing that for several years now, but he says too many still think of it as being "overly cautious." The continuing problem shows that isn't true, he says. After two years of encouraging its members to sign surgical sites, a survey found that only 60% were doing so. Canale says that is disappointing, since AAOS members probably are more aware of the problem than other surgeons.

O'Leary put his weight behind the recommendation as well. In a news conference after the most recent warning about wrong-site surgery, he stated: "Organizations should require that the surgical site be marked."

So, considering how most health care providers view the the Joint Commission's advice, it's not just a recommendation anymore.

Watch for problem in outpatient surgery, too

Canale says he uses an indelible pen from the Devon Pen Co. that leaves a mark for about eight days, even after a surgical scrub. He cautions risk managers to address the problem in outpatient surgery just as diligently.

"As a matter of fact, 70% now of all orthopedic surgery is done in outpatient surgery centers, and most of the wrong-site surgeries occur in orthopedic surgery because we're dealing with two extremities."

Canale says risk managers must take action because if they don't, wrong-site surgery is bound to occur in their organization sooner or later. An orthopedic surgeon practicing for 25 years has a 25% chance of making the error, he says.

"That means, basically, one in every four orthopedic surgeons is going to make that mistake in his career," he says.

Donald Palmisano, MD, JD, a surgeon and secretary-treasurer of the American Medical Association, and a commissioner on the Joint Commission, also endorsed the warning and suggestions for improvement.

"When I operate on the patient, I always go in the room and make sure the patient can see me," he says. "I do it for two reasons. I want to make sure it's my patient and, second, I want the patient to have the comfort of knowing that I am there before they go to sleep."

Palmisano also encourages patients to get involved in the verification process. His wife recently had arthroscopic surgery by an orthopedic surgeon they trusted completely. But before she went into the operating room, Palmisano used a permanent marker to write: "This knee, Bob," and "Wrong side, Bob."

COMING IN FUTURE MONTHS

- Criminalization of medical errors
- Smallpox concerns alter disaster plans
- What to do when police come knocking
- Guidelines for releasing patient information
- HIPAA compliance: How do you know if you're ready?

"No one gets offended by that and everybody said, 'You know, this is a safe thing to do,'" Palmisano says. "We must look at systems. We must eliminate shame and blame."

Thomas Russell, MD, ACS executive director, cautions that one should not allow surgeons to delegate the signing too much. It's OK to have the patient do it, but the surgeon shouldn't put the task off on someone else, he says.

"Some surgeons delegate it to a resident and some may delegate it to a nurse," he says. "The problem there is the further you delegate it away from the person who is responsible — the surgeon — the more the problem is going to jump up at you. Maybe if the surgeon has a resident he or she can count on and really knows the guy, that's fine, but we really mean the surgeon should sign the site." ■

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Find links to other web sites that are essential references for risk managers. There also is a guide to upcoming conferences and events of interest to risk managers. Click on the User Login icon for instructions on accessing this site. ■

Streamline procedures to lower odds of big errors

The Institute for Healthcare Improvement, a Boston nonprofit offering advice on reducing medical errors, suggests that streamlining procedures can help prevent wrong-site surgery. This is some of the advice offered by the institute:

• **Reduce reliance on memory by designing processes with automatic prompts and less reliance on fallible processes.** Checklists, marking the operative limb, and double-checking by team members can prevent many wrong-site mistakes.

• **Simplify the system by reducing the number of steps and hand-offs in work processes.** Have the same personnel move the patient whenever possible. Always repeat the patient's name and surgical site aloud to the receiving person in front of the patient.

• **Standardize by limiting unneeded variety in drugs, equipment, supplies, rules, and processes of work.** Prescribing conventions and protocols for complex procedures can eliminate the opportunity for mistakes.

• **Use constraints and "forcing functions."** These tools prevent actions from occurring until certain conditions are met, helping to reduce reliance on memory and checklists.

• **If there is any deviation from procedure or doubt for any reason, build in a "stop process" so that the patient's proper identification is ensured before proceeding.** Train the team so that each member feels confident enough to raise concerns and other members understand they should never belittle or dismiss another team member's inquiry.

• **Use repetition, standard vocabularies, and insist on clear communication.** But allow judgment and critical thinking, rather than strictly adhering to rigid models.

• **Make sure any checklist or protocol can accommodate atypical scenarios such as emergency surgery and trauma.**

• **Design processes so that the safe channel is the one requiring the lowest energy.** Make doing the right things the easiest thing to do. When designing tasks and work systems, keep in mind issues of stress, workload, circadian rhythm, time pressure, limits to memory, and properties of human vigilance.

• **Decrease multiple entries of data because duplication increases the risk for errors.** ■

Errors: What we have is a failure to communicate

An analysis of the wrong-site surgery incidents reported to the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations indicates that shoddy communication is the main cause of most wrong-site surgery.

Wrong-site surgery is reported to the Joint Commission as a sentinel event. Of the 150 reports, 126 have root-cause analysis information. Forty-one percent were in orthopedic/podiatric surgery; 20% were in general surgery; 14% neurosurgery; 11% urologic surgery; and the remaining procedures were in dental/oral maxillofacial, cardiovascular-thoracic, ear-nose-throat, and ophthalmologic surgery.

Predictably, 67% involved surgery on the wrong body part or site. Thirteen percent involved surgery on the wrong patient, and 11% involved the wrong surgical procedure.

When the Joint Commission analyzed the factors contributing to the accidents, patterns emerged. Emergency cases accounted for 19%; and unusual physical characteristics, including morbid obesity or physical deformity, occurred in 16%. The operative teams faced unusual time pressures to start or complete the procedure in 13%, and unusual equipment or setup in the operating room in another 13%. The Joint Commission also reports the involvement of multiple surgeons can be factor, with 13% of the cases involving more than one surgeon. Multiple procedures being performed during a single surgical visit also were a risk, found in 10% of the cases.

The hospitals identified root causes as part of their analyses, with most reporting that the root cause was a breakdown in communication between surgical team members and the patient and family. Some also reported that marking of the surgical site was not required but would have helped. Other root causes were a lack of verification in the operating room, incomplete patient assessment, staffing issues, distraction, and availability of pertinent information in the operating room. ■

Found: 13-inch retractor was left inside a patient

Surgeons in Seattle accidentally left a 13-inch metal retractor inside a patient for a month, leading to a $97,000 settlement and a change in hospital procedures for counting instruments.

The hospital admitted that this was not the first time its surgeons lost large retractors inside patients.

The surgical team did not notice that the large retractor was still in the patient and did not notice that it was missing after the surgery. The patient complained of pain after the surgery, but his doctor kept telling him the pain was normal, even 30 days post-op. Finally, the man went to his own physician, who found the retractor on a CAT scan.

Eric Larson, MD, medical director at University of Washington Medical Center (UWMC), says the hospital accepts full responsibility for the error. Larson publicly apologized to the man and said the hospital has implemented procedures to reduce the likelihood of another such incident. The new procedures include counting retractors — something that previously was not done even though smaller instruments are counted routinely in operating rooms. The theory was that a 13-inch retractor would be noticed, so there was no need to count them.

"Our staff work diligently to count accurately and discover ways to improve our processes and aim for zero defects," Larson says. "Thus, we have dedicated additional resources to expedite a thorough review of all of our operating-room counting practices in order to re-engineer any related process or procedure that would further increase patient safety."

Four others since 1997

Larson says the hospital administration knows of four other "very similar errors" involving retained metal surgical instruments that have occurred at UWMC since 1997.

The issue came to light when 49-year-old Donald Church publicly revealed that he had settled his case for $97,000. He had undergone surgery in June 2000 to remove a tumor, his appendix, and part of his intestine. But when the hospital responded to Church's announcement, other cases were revealed. The most recent case of a lost retractor occurred in September 2001, Larson says.

"The patient had a complex abdominal surgery at our hospital in September," Larson reports. "A malleable retractor used in closing the incision was mistakenly left in her body. We removed the object in October. We have accepted responsibility for this error and apologized to the patient. As in the case of Mr. Church, the woman has made a full recovery from her cancer surgery and is doing well."

Larson says that although there are little published data on the subject the staff at UWMC are confident that such errors are uncommon. At UWMC, they represent one in approximately 12,000 cases per year — or less than .01% of all cases performed at UWMC since 1997.

Bioterrorism plans grow from variety of sources

As health care organizations race to develop a plan for treating patients exposed to bioterrorist agents, more resources are becoming available. Two of the most recent offerings are a comprehensive preparedness plan developed by the Stanford University Medical Center and a CD-ROM of bioterror information created by physicians for physicians.

A team of leading Stanford physicians, scientists, and medical staff members have developed a plan outlining ways to assess and treat victims of bioterrorism while limiting the potential spread of contamination. Stanford now is sharing the plan with hospitals, physicians, and public health agencies nationwide, reports **Philip A. Pizzo**, MD, dean of the Stanford University School of Medicine and former physician-in-chief of Children's Hospital in Boston and professor of pediatrics at Harvard Medical School.

"We initially focused our efforts on the local community but then realized our work could benefit the greater medical community," Pizzo says. "We all share in the same mission of protecting the health and safety of all Americans, and it is critical that we share information and work together on a unified front."

The Stanford plan

Soon after anthrax cases began surfacing on the East Coast, leaders at the Stanford University Medical Center appointed the Bioterrorism and Emergency Preparedness Planning Task Force to update the medical center's level of preparedness for dealing with potential cases of exposure to anthrax or other biological agents. The task force members represent all three entities of the medical center — Stanford Hospital & Clinics, Lucile Packard Children's Hospital, and the Stanford University School of Medicine — and come from a variety of fields, including infectious diseases, microbiology, critical care medicine, pediatrics, emergency medicine, and psychiatry. **Eric A. Weiss**, MD, co-chair of the task force, explains that the task force also includes representatives who deal with patient care, security, and logistical issues within the hospitals.

For the Stanford bioterrorism plan on-line, go to http:\ \bioterrorism.stanfordhospital.com.

"We are extremely fortunate to have some of the nation's top clinicians and researchers here at Stanford, and their expertise has been vital in helping us develop a plan for responding appropriately to anthrax cases and other incidents related to bioterrorism," Weiss says. "We know other hospitals are working on appropriate response plans as well, so by sharing our plan with them, we hope to free up their time to focus on other pressing issues."

He says the Stanford plan has two purposes — to ensure the health and proper treatment of the patient and to limit the potential exposure of medical staff and facilities. The Stanford plan is continually being modified and updated in accordance with frequent changes from the national Centers for Disease Control and Prevention and public health organizations, Weiss says. In addition, the task force continues working with law enforcement agencies and receiving input from medical centers throughout the country.

"The information about anthrax is changing rapidly," Weiss says. "The cases being treated on the East Coast vary from what has been reported in the medical literature and we have to adapt our understanding in light of these differences. We want to do everything possible to keep the information current."

Another source of information is available at the Bioterror Resource Center on the World Medical Leaders (WML) web site (www.wml.com). Access to the Bioterror Resource Center site will be restricted to physicians only. WML is sending a free CD-ROM to all hospital emergency rooms throughout the United States. It contains a lecture on emergency response to bioterrorist attacks titled "Bioterrorism for Physicians: A Practical Approach." The lecture focuses on a practical approach to recognition and management of biological terrorism.

Gerald Imber, MD, co-founder of World Medical Leaders, says bioterrorism has not been a subject of major interest in medical schools. The CD-ROM for emergency rooms is particularly important because it outlines how a hospital ER should respond to and be prepared for bioterrorism, he says. The lecture was presented by Paul Rega, MD, medical program director of the University of Findlay, senior medical officer of the Ohio-1 DMAT, and a recognized expert in the field. He also is the author of a definitive emergency manual on bioterror medicine.

"This is the most comprehensive site for information on bioterrorism in the world. It was

developed because doctors are not familiar with the symptoms and treatment of the diseases caused by biological warfare, and we need to be," Imber says.

WML was founded to create a physicians-only Internet site where doctors from around the world could learn from and interact with the most exceptional faculty of medical educators and thought leaders available. More than 140,000 physicians are currently members and more than 120 county and state medical societies and hospital groups, and the Department of Defense also are affiliated.

The bioterrorism CD-ROM is being sent to all emergency rooms, but physicians also can request a copy by going to the WML web site. ■

Doctors faces charges for Oxycontin 'scripts

An Indiana doctor who served as a paid spokesman for the manufacturer of Oxycontin, the powerful pain medication that has become a hot button because of its potential for abuse, has been arrested by federal authorities and charged with illegally prescribing the drug. In addition, the doctor is charged with defrauding Medicaid through the prescriptions.

According to a criminal complaint filed in federal court in the southern district of Indiana, Randolph W. Lievertz, MD, of Indianapolis, wrote more than $1 million worth of Oxycontin prescriptions in the past two years and submitted them to the state's Medicaid program for payment. Federal prosecutors allege that many of the drug prescriptions went to a crime ring that sold the tablets on the street, and that some prescriptions were so large that the patient would have had to use 31 pills in every 12-hour period. The manufacturer recommends one pill every 12 hours.

High volume of prescriptions drew attention

Susan W. Brooks, JD, the U.S. attorney in Indianapolis, says the doctor's high volume of Oxycontin prescriptions drew attention. Lievertz prescribed six times more Oxycontin than the next highest prescriber in the state, she says. The doctor faces a maximum sentence of 25 years in prison, a $250,000 fine, and up to three years of court supervision.

Oxycontin is made by Purdue Pharma of Stamford, CT. The narcotic is popular as a time-release medication for severe pain, but it also has become popular among drug abusers, who crush the tablets for a heroin-like high. ■

Hospital wins suit over surgeons and privilege

A New York surgeon must pay the legal fees and costs incurred by a hospital he sued when his medical privileges were suspended. The hospital's attorney says the victory is a major step forward for hospitals that long feared the legal repercussions from doctors unsatisfied with the revocation of privileges.

The judge's decision is a first for New York, says attorney **Leonard M. Rosenberg**, a partner with the law firm of Garfunkel Wild in Great Neck. He tells *Healthcare Risk Management* that the court ordered a physician to reimburse the legal fees and costs of not only the hospital, but also several doctors he sued after they recommended suspending his medical privileges.

Rosenberg says the case involved a vascular surgeon, Nedunchczian Sithian, MD. Concerns were raised about his high incidence of morbidity and mortality, leading to a review of his competency by a panel of physicians. The peer physicians recommended that Sithian not be allowed to perform complex vascular procedures anymore, and the hospital took action.

That peer review process is federally protected, of course, but risk managers still get nervous about doctors who are so upset they threaten to sue. More often than not, the threat never comes to fruition, but in this case the surgeon challenged the suspension and filed an administrative complaint with the New York State Public Health Council. The council found no justification for his complaint and said the hospital's decision to suspend him was based on reasonable concerns for patient safety and the surgeon's character and competence. At the same time, the surgeon initiated a lawsuit against the hospital and several doctors involved in the peer review process.

"He did take that issue to court and the courts ruled against him, so that's the end of that matter," Rosenberg says. "But the hospital and the doctors were left holding the bag for a lot of associated legal expenses, and they didn't think they deserved to pay."

The defendants took the surgeon back to court and won. A New York Supreme Court recently ordered the surgeon to pay a total of $215,686 to Staten Island University Hospital to cover legal fees. Additionally, Sithian must pay legal costs of $23,236 to a surgeon from a different hospital who participated in the peer review. Rosenberg represented the hospital, its chief executive officer, members of its board, and some of its physicians. The ruling was made by Justice Joseph J. Maltese, in Richmond County, Staten Island. The doctor is appealing the decision.

The court ruling obtained by *HRM* indicates that the judge disallowed $40,347.50 in fees submitted by Rosenberg's law firm. A line-by-line review of the charges "shows instances of billing for the same work, numerous bills for review of prior work, and some billing items redacted so that the court cannot determine what they are for," the judge wrote. In response, the judge refused those charges and reduced the award for legal fees to $215,686.

Peer review is key

Risk managers should see the ruling as reason to stand their ground when threatened with lawsuits by spurned physicians — as long as a legitimate peer review process is used. The key to the ruling, Rosenberg says, is that the hospital followed proper procedures in denying the surgeon's medical privileges. Agreeing with a previous court ruling, the judge determined that the hospital and its peer reviewers had complied with the federal Health Care Quality Improvement Act, which provides review participants with immunity from liability for damages if its standards are met. The act specifically allows for awarding attorneys' fees if the court finds that the suit was brought unreasonably, frivolously, or in bad faith.

"The [act] was purposely designed to prevent the chilling effect which this type of lawsuit could have upon the participants in the peer-review process," the judge wrote. "The public is protected when there is a full and frank discussion of a physician's abilities. The purpose of this statute is to deter groundless suits against participants in medical peer review process. In bringing a frivolous lawsuit, the defendants are entitled to reasonable attorney fees and costs."

The judge went on to say that it was "bad faith" for Sithian to sue the hospital's medical executive committee and the doctor heading the peer review while the matter still was under consideration by the board of trustees. "Such a lawsuit sends a chilling effect to the board of trustees that any adverse action will result in personal litigation," the judge wrote. "Doctors who are sufficiently fearful of the threat of litigation will simply not do meaningful peer review. The result would be to continue the possibilities for abuse by bad doctors."

Risk managers should take heart in the ruling, Rosenberg says. Peer review can be an ugly, awkward process with an outcome that no one likes, but he says risk managers should not be overly fearful of legal action as long as proper procedure was followed. The court's ruling indicates that the legal system understands the review process will not be effective if the participants are intimidated by threats of retaliatory lawsuits.

"When the suit is without foundation, then individuals who have been embroiled in time-consuming, expensive, aggravating litigation that otherwise would have a chilling effect on the peer-review process can recover their expenses," Rosenberg says. "The message being sent by the court in awarding these damages is that they understand that meaningful peer review can't go forward unless the immunities and protections provided by law are enforced by the courts." ■

St. Paul discontinues malpractice insurance

In another display of how the market for malpractice insurance is in serious trouble, the St. Paul Companies recently announced that it would discontinue its malpractice insurance coverage. The action comes as many health care providers are facing huge premium increases and a dearth of coverage in some states.

St. Paul insures tens of thousands of physicians throughout the country, though the company does not release specific numbers. The St. Paul Companies discontinued its medical malpractice business as part of a restructuring intended to revitalize the company. The rest of the plan involves exiting certain reinsurance lines, exiting countries where the company is "not likely to achieve competitive scale," and staff reductions to reduce corporate overhead expenses.

Jay S. Fishman, chairman and CEO, says the actions are a response to major changes in the medical malpractice insurance market in recent months and years. Malpractice insurance premiums have

dramatically increased in the past, mostly because the insurers realized — too late for many of them — that they had significantly underpriced their products. Many insurers raised rates more than 30% in the past year, and industry analysts say the trend will continue and quite possibly get worse in 2002. **(For more on the premium increases and the mistakes that led to them, see *Healthcare Risk Management*, January 2002, p. 4.)**

Fishman says St. Paul will complete the process of exiting the medical malpractice business on a global basis through nonrenewal upon policy expiration, in accordance with regulatory requirements. The traditional property-casualty segment of the unit — property, workers compensation, and commercial auto insurance for health care professionals and facilities — will continue to be underwritten by the company's standard commercial underwriting operation.

Including the $600 million reserve increase, the company is forecasting that medical malpractice will generate a 2001 underwriting loss of approximately $940 million.

In addition, St. Paul's reinsurance operation, St. Paul Re, will narrow its product offerings and geographic presence. The reinsurance operation will focus on several core areas, including property catastrophe reinsurance, excess-of-loss casualty reinsurance, marine and traditional finite reinsurance, and significantly rationalize its reinsurance branch office structure.

The unit will no longer underwrite aviation reinsurance, bond and credit reinsurance, or offer financial risk and capital markets reinsurance products, and it will substantially reduce the North American business it underwrites in London. St. Paul is forecasting a 2001 underwriting loss for the reinsurance segment of approximately $230 million, excluding losses relating to the Sept. 11 terrorist attack.

AMA strongly reacts to St. Paul withdrawal

Medical leaders were taken by surprise by the St. Paul surrender and some are calling it a clear sign that the nation's judicial system is crippling both health care providers and their insurers. **Donald J. Palmisano**, MD, JD, secretary-treasurer of the American Medical Association (AMA), says the St. Paul announcement is "another piece of evidence that our tort reform system is broken and needs to be fixed."

At the AMA's December policy-making meeting in San Francisco, the AMA House of Delegates renewed its longstanding commitment to tort reform, calling it one of the AMA's top legislative priorities.

"The AMA has always held that patients who have been injured through negligence should be compensated fairly. Unfortunately, the current tort system has failed patients," Palmisano says. "The United States has created a liability lottery where select patients receive astronomical awards and many others suffer access-to-care problems because of it. We will never have true access to care for all unless the hemorrhaging costs of the current medical liability system are addressed."

Palmisano says the effect on physician practices is very real. The high cost of professional liability insurance forces physicians to close or limit their practices, he says. Some have stopped delivering babies and others are even going without professional liability insurance.

"The spiraling costs generated by our nation's dysfunctional liability system are borne by everyone," he says. "We need a system that ensures fair compensation and puts an end to the liability lottery."

Pennsylvania physicians are finding it particularly difficult to obtain medical malpractice insurance. More than any other specialty medical profession, orthopaedic surgeons are finding it is nearly impossible to buy commercial medical malpractice liability insurance, according to a recent survey conducted by Susquehanna Polling & Research Inc. The survey shows that nearly 40% of orthopaedic surgeons contacted had been notified that their medical malpractice liability insurance would be canceled or nonrenewed as of January 1, 2002.

Only 10 days before most policies would terminate, 31% of those surveyed said they had been unable to obtain new insurance coverage for 2002, according to Pennsylvania Orthopaedic Society (POS) president **Jeffrey A. Baum**, MD.

"For several years now, orthopedic surgeons have been faced with skyrocketing insurance premiums due to a tort system in this state that favors plaintiffs," Baum says. "Now we're seeing surgeons who may not be able to work in the emergency room or the operating room in January because they will not have insurance."

Recent paid advertising by 12 trauma centers in southeastern Pennsylvania warned that patients may be turned away beginning in January because so many surgeons were lacking insurance. Of the orthopaedic surgeons who reported that they were canceled or nonrenewed, 42% were from the five-county Philadelphia

region. Similarly, those who reported that they have not been able to replace their coverage, 39% are from the same five-county region. The poll, commissioned by the Pennsylvania Medical and Orthopaedic Societies, also surveyed physicians in neurosurgery, OB/GYN, plastic surgery, and cardiology.

Pennsylvania's doctors face some of the highest insurance rates in the country. In 1998, southeastern Pennsylvania awarded more money for medical liability cases than the entire state of California, Baum says. POS and other health care advocacy organizations are pushing for legislation to limit punitive damages and to create a cause of action for frivolous lawsuits. Additionally, they are asking for change in venue procedure as well as procedural and evidentiary rule changes in the judiciary.

Governor reaches out to help doctors

The governor of Pennsylvania was concerned enough to direct that emergency steps be taken to provide temporary relief from the high costs of medical malpractice insurance. Gov. **Mark Schweiker** announced the emergency steps in December 2001 and said the state would help providers get through the insurance crisis until comprehensive reform legislation can be passed early this year.

"While we continue to look at ways to overhaul what has become a financially burdensome system that threatens the quality of health care for Pennsylvanians, this temporary measure will provide some immediate relief to doctors in the short term," Schweiker said in announcing the emergency steps.

Schweiker directed the state's Medical Professional Liability Catastrophe (CAT) Fund director John Reed to delay collection of the surcharge for the calendar year 2002 from the Joint Underwriting Association (JUA) on behalf of those physicians it covers until June 30, 2002. The governor also asked Insurance Commissioner Diane Koken to require the JUA to delay the deadline for submission of the CAT Fund surcharge by physicians until April 30, 2002. JUA is the "insurer of last resort" for medical malpractice in Pennsylvania and generally covers those physicians who are unable to acquire private insurance coverage. As the insurer of last resort, JUA is obligated to insure all physicians who apply for coverage.

With private medical malpractice insurers refusing to write new policies and, in some cases, declining to renew existing ones, the number of physicians forced to obtain coverage through JUA could double in 2002, according to state predictions. ■

Pharmaceutical marketing practices face new scrutiny

By **Philip H. Lebowitz**, JD
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Philadelphia

Pharmaceutical manufacturers' drug pricing and marketing activities — and the response of health care providers to these promotions — are under closer federal scrutiny than ever. Risk managers, physicians, and other professionals should review their own policies and practices carefully to avoid running afoul of the ever-stricter standards regarding manufacturer inducements.

One case is particularly instructive of the risks involved. On Oct. 3, 2001, federal officials announced the largest health care fraud settlement in history — TAP Pharmaceutical Products Inc. agreed to pay $875 million to resolve criminal and civil charges based on fraudulent drug pricing and marketing conduct. The agreement came after a four-year investigation into TAP's marketing of Lupron, its drug used to treat prostate cancer and infertility. Two schemes drew the most attention. TAP provided free samples of Lupron to physicians who in turn sought Medicare reimbursement for administering the free sample. (While Medicare does not reimburse most prescription pharmaceuticals, Lupron is administered by the physician and is reimbursable.) Second, according to the government, TAP inflated the average wholesale price (AWP) of Lupron so that the physician's Medicare reimbursement, which was based on the AWP, not the average sales price, would be higher. The free samples and the reimbursement spread were alleged to induce physicians to prescribe Lupron over its competitor, Zoladex.

The government also charged five doctors with conspiring with the company to receive excessive Medicare reimbursements. Four of the five doctors

have pleaded guilty and are awaiting sentencing. The probe began when the medical director for pharmacy programs at Tufts Health Plan in Massachusetts alerted the U.S. Attorney's office in Boston that he had been offered a $65,000 "educational grant" to be used for any purpose, to switch the plan from Zoladex to Lupron, as well as the opportunity to be reimbursed by the government at a price higher than that paid to TAP. Ultimately, TAP also was charged with giving physicians trips to expensive golf and ski resorts, free consulting services, medical equipment, and forgiveness of debt.

Some observers have long perceived ethical issues in the symbiotic relationship between physicians and drug suppliers. In 1990, the American Medical Association's (AMA) Council on Ethical and Judicial Affairs created guidelines regarding gifts to physicians from industry. The guidelines were adopted by the AMA; however, by the late 1990s they were largely ignored by physicians and industry representatives. In 1999, an AMA task force recommended raising awareness of the guidelines among physicians. To fill this need, the AMA convened the Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry. The group includes more than 30 members representing physicians, corporations, medical associations, government, industry, and more.

Avoiding the appearance

The AMA initiative has been criticized for accepting funding and staff from pharmaceutical manufacturers and other industry sources. While this situation is not without irony, the issue is of prime importance to both the provider and the industry side. Not only does each hope to avoid the appearance of impropriety that may result from expensive gifts or cash payments to physicians, they also hope to avoid violating government regulations that would interpret a gift as a potential kickback.

The guidelines do not attempt to ban all exchanges of value between industry representatives and physicians. Manufacturers have a right to responsibly advertise and promote their products, most of which are of significant benefit to patients. The guidelines do, however, recognize that gift-giving can go too far, and seek to prohibit gifts that are unrelated to improving the physicians' understanding of their patients' conditions and cures. And while the guidelines are not binding, risk managers and providers could assume the guidelines cited in the enforcement or litigation areas as industry standards to be followed.

In 1994, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a Special Fraud Alert regarding the anti-kickback law's application to prescription drug marketing programs. OIG cited such conduct as payments by drug companies to pharmacies that converted a prescription from one brand to another, frequent-flier miles provided to physicians for completing a form showing that a new patient was placed on the company's drug, and a research grant program that rewarded physicians with substantial payments for minimal record-keeping tasks.

The OIG described as potentially improper gifts or payments 1) made to a person in a position to generate business for the paying party; 2) related to the volume of business generated; and 3) more than nominal in value or unrelated to any service other than the referral of a patient. The OIG threatened investigations of gifts of any kind in exchange for prescribing a particular product, and grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little effort.

Under some circumstances, remuneration to physicians can fall within one of the safe harbors published by HHS to protect permissible conduct that would technically violate the anti-kickback statute. Safe harbors for personal services and management contracts are sometimes appropriate if the manufacturer pays the physician for legitimate services that can be described in a written agreement, and if the compensation is unrelated to the volume or value of the manufacturer's product used by the physician. For a safe harbor to apply, all criteria for inclusion must be met.

Prescription drug marketing is once again near the top of OIG's agenda. In its 2002 Work Plan, the OIG specifies:

"We will evaluate the extent of gifts and payments to physicians from pharmaceutical companies. The pharmaceutical industry currently spends about $12 billion a year on marketing to physicians, and some of these gifts may present an inherent conflict of interest between the legitimate business goals of manufacturers and the ethical obligations of providers to prescribe drugs in the most rational way."

The OIG will examine any type of arrangement between a seller and a buyer or prescriber of pharmaceutical products to determine whether it contains overt or disguised incentive payments to prescribe a particular manufacturer's product. Risk

managers and physicians should review their current practices to see if they will withstand federal scrutiny.

(Philip H. Lebowitz is a partner in the law firm of Pepper Hamilton LLP, and chairman of the firm's health care services practice group.) ■

Group purchaser requires bar codes on medications

In an effort to reduce medical errors, Premier Inc. (Springfield, VA), which operates one of the nation's largest group-purchasing organizations serving hospitals, will require in its group contracts that covered medications and biological products have consistent product numbers and unit-of-use bar codes.

By requiring scannable bar codes for hospital pharmaceutical products similar to those used on grocery items, "medication errors in hospitals will be reduced with more assurance that patients get the right medicine at the right time in the right dosage," says **Howard E. Sanders**, a Premier executive responsible for group purchasing.

Sanders says the move also should reduce costs in the hospital supply process. Premier will implement the new requirement for product numbering and bar coding as current group contracts for existing pharmaceutical products expire, Sanders says. A leading alliance owned by not-for-profit health systems, Premier provides group-purchasing services for approximately 1,600 hospitals. Premier members purchase more than $14 billion a year in supplies and equipment through Premier group contracts, including over $6 billion a year in pharmacy products.

Premier has approximately 150 group contracts in place for pharmaceuticals, covering over 12,000 items. The Department of Health and Human Services earlier announced that it expects to propose a rule next year requiring the barcode labeling of hospital-administered medications and biological products.

"Premier's decision to move in advance of any regulation was made out of a commitment to patient safety," Sanders says. "We know this technology can save lives, and we won't wait to see if a regulation is approved to make sure it is available to our hospitals and the patients they care for."

Premier will make its support of unit-of-use bar coding clear to the companies that supply pharmaceuticals to its members, and it will urge those companies to become early adopters of this technology. Starting in 2003, when the bulk of current contracts expire for existing products, Premier will make implementation of unit-of-use bar coding a requirement of all new and renewed contracts. Sanders says Premier also expects to move toward requiring bar codes for medical devices and medical-surgical supplies in the future. No timetable has been set for group contracts in those areas, since their contracting periods vary.

"We understand that implementing unit-of-use bar coding will not be a simple task," Sanders says. "For companies that have not undertaken such approaches, implementation may necessitate process changes in both the clinical and manufacturing settings, perhaps even the retooling of internal and external information and manufacturing systems. Although some manufacturers and suppliers have

Healthcare Risk Management® (ISSN 0199-6312), including **HRM Legal Review & Commentary**™, is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Healthcare Risk Management**®, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $499. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $399 per year; 10 to 20 additional copies, $299 per year; for more than 20, call (800) 688-2421. 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 $83 each. (GST registration number R128870672.)

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concerns regarding such an investment, we believe the lives saved and ultimate supply chain savings clearly outweigh any initial investment."

Premier will work closely with its business partners to facilitate the bar code implementation, Sanders says, and it will also support streamlining of Food and Drug Administration approvals related to labeling changes.

In addition to improving safety and cutting costs, the use of bar coding would improve the ability of individual hospitals to track their data to improve the quality of patient care over time, according to **Bert Patterson**, vice president of the Premier Contracting Center of Excellence, and a clinical pharmacist. Many Premier member hospitals pool clinical, financial, and operational data in the alliance's databases, and hospitals compare performance indicators to identify areas for improvement. ■

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

Teen-ager dies after tonsillectomy: $9 million verdict in KY

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

News: To alleviate his apnea, a 17-year-old boy was admitted to a hospital for a tonsillectomy. The surgery was successful and morphine was administered to address his pain. The morphine complicated his apnea, leading to his death. Plaintiffs successfully claimed that the hospital failed to provide adequate post-surgical monitoring and treatment. The jury returned a $9 million verdict against the hospital and a defense verdict in favor of the named physicians.

Background: The 17-year-old patient was scheduled to undergo a tonsillectomy, or uvulopalatopharyngoplasty. The procedure was designed to partially relieve his apnea, which was aggravated by a tonsil that was too large. While the patient's obesity contributed to his condition, his otolaryngologist believed that removing the tonsil would mitigate the apnea. The enlarged tonsil interfered with the boy's ability to breathe and caused him to involuntarily stop breathing, mostly while he was asleep. The patient relied upon his snoring to awaken him, which it did many times during the night. But it also caused him to be drowsy during the daytime. The young man's doctor arranged to have the surgery performed at a local hospital, using the hospital's contract anesthesiologists.

The surgery was successful. In the recovery room, the anesthesia team administered morphine to treat the teen-ager's pain. However, the morphine had an adverse effect on the underlying apnea. While the patient generally depended upon his snoring to wake him when his breathing stopped, the morphine impeded that conditioned, natural response. Since the failure to wake-up could lead to an unhealthy buildup of carbon dioxide, it was necessary to keep the young man awake throughout the recovery process. Morphine has a half-life of approximately two to four hours, so the critical period for full postoperative recovery should have been about four to eight hours.

Over the next two hours, the young man continued to have oxygen and respiratory problems. A morphine-reversing drug, Narcon, was given to the patient to counter the adverse effects. Fifteen minutes after it was administered, the patient appeared to be improving, so the recovery room nurse transferred him from the recovery room to the regular unit. The half-life for Narcon is 20-40 minutes; the transfer took about 45 minutes.

When he arrived in the unit, his parents believed his condition was declining. A nurse assured them that all was well and suggested they go home. After they left, the unit nurses allowed the boy to sleep as the dangerous levels of carbon dioxide continued to rise. Though the Narcon had worn off and the morphine had not,

an additional dose of Narcon was not administered or ordered by the anesthesiologist.

In the meantime, a respiratory technician was called in to assist with the patient. Without doctor's orders — as was the hospital's protocol — he increased the amount of oxygen the patient was receiving. The patient's condition continued to deteriorate and the unit nurses contacted the otolaryngologist.

"If a nurse feels that any orders are inappropriate or in error, there are standards of practice that govern how to address the orders. Doctor's orders must be carried out unless canceled or discontinued. To not carry out orders given by a doctor is a deviation from accepted practice standards."

It is unclear exactly what information the nurses shared with the otolaryngologist who operated on the patient, but eventually the nurses and otolaryngologist all contacted a pulmonologist to consult on the case. The pulmonologist attempted to issue a variety of orders to treat the problem, including transferring the patient to an intensive-care unit (ICU) and ordering tests, including an X-ray and an arterial blood gas (ABG) to determine the level of oxygen and carbon dioxide in the patient's blood.

The specific facts were disputed, but apparently the orders were not followed. When the patient's monitoring devices indicated that there was an oxygen problem, the nurses administered more oxygen. The plaintiffs successfully contended at trial that the administration of additional oxygen contributed to the carbon dioxide problem and further obscured the fact that a potentially fatal problem was developing.

An hour later, the young man — who had not been transferred to an ICU bed — was in respiratory arrest. A code was called, and the patient was resuscitated. However, a serious hypoxic event had occurred in the interim and 26 hours later, the boy was dead.

The plaintiff parents brought suit against the otolaryngologist and anesthesiology team as well as the hospital. As to the otolaryngologist, the parents claimed that the physician failed to properly monitor their son postoperatively and failed to communicate preoperatively about the seriousness of the teen's apnea. The plaintiffs claimed that the anesthesiologist should not have administered morphine because the patient was not a good candidate for this drug in light of his apnea. The plaintiffs also claimed that once Narcon was given, someone should have realized it had a half-life of less that half of the morphine and that at least two doses should have been administered instead of one.

The plaintiffs further asserted that the hospital failed to keep the boy awake until the morphine completely wore off and the apnea complication had passed. Specifically, the plaintiffs claimed that a) the patient was prematurely moved from the recovery area, where there was 1-to-1 nurse coverage, to a floor where he could not be as closely watched; b) as alarms continued to sound indicating a problem, the nurses simply turned the alarms off or responded inappropriately; c) the parents were sent home with the admonition not to worry when they could have stayed and cared for their child; d) the nurses and respiratory technician practiced medicine unlawfully by administering oxygen without a medical order from either the attending physician or the pulmonologist; and finally; e) there were repeated delays in the nurses contacting the doctors and, when contacted, the nurses failed to properly advise the doctors about the patient's condition. The plaintiff claimed that the cumulative events were inexorably linked to the patient's respiratory distress and ultimate death.

Both the otolaryngologist and the anesthesia team denied negligence and pointed to the errors the hospital nurses made that led to the boy's death. The defendant physicians further claimed that had the nurses appropriately communicated with them, they would have responded differently.

The hospital said the nurses responded properly and in its defense raised factual disputes regarding the plaintiffs' characterization of the care provided. The errors in this case, the hospital contended, rested with the doctors who failed to provide the nurses with complete information regarding the severity of the apnea or to give the orders necessary to the treat the boy's condition and morphine-related complications. The hospital also claimed that the patient's pulmonary edema was the cause of the respiratory arrest. The plaintiff counterclaimed that up until just before the code was called the decedent could have been saved. The hospital admitted to erroneously turning up the oxygen but maintained that the technical mistake essentially had no effect on the

outcome of the case. The defendants also contended that the 17-year-old had a limited life expectancy because of his obesity and enlarged heart.

The plaintiffs countered that the patient's heart was enlarged, proportionate to his body type, and did not manifest any physical problems.

The jury awarded a verdict of $9 million against the hospital and a defense verdict in favor of the named physicians.

What this means to you: "One of the first things that jumps out at you in reading this case is the allegation that doctors gave orders to the nursing staff that were not followed," states **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, of the Kicklighter Group in Fort Lauderdale, FL. "If a nurse feels that any orders are inappropriate or in error, there are standards of practice that govern how to address the orders. Doctor's orders must be carried out unless canceled or discontinued. To not carry out orders given by a doctor is a deviation from accepted practice standards."

Should a nurse feel the orders given are not appropriate or are in error, Kicklighter recommends the following steps be taken as a matter of course:

- Speak to the ordering doctor.
- Speak to the pharmacist if the order involves a drug; the pharmacist can then speak with the doctor.
- If, after speaking with the doctor, there is no acceptable resolution, speak to the nursing supervisor on duty.
- If the supervisor agrees, it should be taken to the next step up the chain of command, to the department chief/chair and to the director of nursing.

For a nurse to disregard doctor's orders is potential grounds for disciplinary action by not only the nurse's employer but also by the nurses' state board of nursing; and even if not included in the hospital's policies, the nurse may still have the professional obligation to take action and raise issues. However, most would advise having such policies and procedures in place and providing education on the issue.

To that end, "risk managers should review standing practices and policies and procedures regarding the process for addressing orders given by a doctor that are felt to be inappropriate by the nursing staff. The risk manager should make sure to emphasize how to handle such matters in written educational materials and inservice program presentations. In addition, risk managers should advise nursing and supervisory staff that they are available, 24/7, for consultation in such situations," adds Kicklighter.

Just as nurses should voice their concerns when they don't agree with doctor's orders, all members of the health care team should communicate with each other. Communication among health care providers is key to successful outcomes — even when the case seems minor or routine. Even the most mundane procedures can become untoward incidents if allied health professionals and physicians don't talk to each other and take things for granted.

"This case brings to the forefront an issue that faces health care workers every hour of every day, and that is COMMUNICATION between caregivers," Kicklighter asserts. "In this case, it is even more complicated because much of the communication scrutinized at trial was conducted by telephone, and there is no proof of what information was actually given by the nurses to the various doctors or what was received in return from the doctors to the nurses. This is always a ticklish situation, especially if the conversations are at night when one or other of the parties may not be at their most alert state. This is of such an important nature that some hospitals have actually set up devices to record such phone conversations. Not only does this provide clear information regarding what was transmitted by each party, it also serves as a quality improvement modality. In this case, such a system would have provided the information regarding what information the nurses gave the doctors, whether he or she asked questions to clarify the situation, and exactly what orders were given in response to the given information. Documentation in the medical record is a good backup, but again the doctor may say, as in this situation, that all the important information wasn't conveyed or that the physician's orders were not recorded. And, much to the facility's risk manager dismay, it seems that the doctors were believed in this instance given that the jury exonerated them."

Documentation can often make or break you once litigation is initiated, Kicklighter says. These questions occurred to her:

- **Was there extensive pre-surgical evaluation and documentation of the patient's apnea?** Specifically regarding his reliance on his snoring to awaken him from the apnea state.
- **Was the documentation in the postoperative**

orders regarding the need to keep the patient awake until he had fully recovered? And what was the definition of "fully recovered" in this situation?

"However in this case, regardless of where — if anywhere — the patient's underlying complication was documented, it seems that the health care providers had the opportunity to overcome any documentation deficiencies and appropriately care for the boy after the morphine was administered, but they failed to effectively communicate regarding his course of treatment following the incident," observes Kicklighter.

It would probably serve most risk managers well to review this case chronologically posing the following questions to be sure that the circumstances are not ripe for a similar scenario to occur in their organizations, Kicklighter says:

". . . It is probably not enough to simply have all of the right policies and procedures in place to dictate who should do what and when, if orders aren't followed and the communication culture and systems are faulty."

1. What is the process for identifying patients as "at risk" or "high risk" of surgical complications, as it seems this patient should have been labeled but was not.

2. If a patient is not initially deemed "at risk" at the time surgery is scheduled or initiated, did the facility have policies and procedures regarding the postoperative care of patients that become "at risk" — particularly as it relates to the care by the anesthesiology teams, which seems as though should have been done after the morphine was administered and adverse effects became known?

3. How long was the attending surgeon to remain on site post-surgery according to the hospital privileging rules? It seems he was no longer at the hospital when the orders to transfer the patient from the recovery room were executed. Subsequently, who determined when it was time for the patient to be moved. Namely, did a physician evaluate him? And, if not, then what criteria were used by whom to make that judgment call?

4. What are the hospital's rules regarding the length of time an anesthesiologist or other member of the anesthesia team is to remain with the patient postoperatively, and does this change if the patient is experiencing complications?

5. Where was the anesthesiologist during the apnea spells prior to the respiratory arrest? Were there policies and procedures in place to allow the nursing or respiratory techs to seek medical direction from an in-house physician if the attending physician is only available by phone, and what were the policies and procedures for documenting telephone conversations with the attending and consulting physicians not on site?

In addition to the issues of nursing practice standards, communication, and documentation, "since the anesthesiology group was on contract to this hospital, this case raises the very important risk exposure that may lurk in such contracts. Ideally, contracts with physician groups should provide that the group and each individual physician and other allied health professionals employed by the group carry a sufficient limit of professional liability insurance coverage and that there is a hold harmless agreement as well as an indemnity clause contained in the contract. In addition, the contract should clearly state that neither the group nor individuals who make up the group are agents of the hospital. The risk manager should be thoroughly knowledgeable as to the criteria in his or her respective state as to what constitutes an agent and work with the hospital's legal counsel and administration to assure that all loss prevention steps are taken to prevent any contractors from being held as an agent of the hospital whenever possible, adds Kicklighter.

"Lastly, organizations should re-examine their parental visitation policies and procedures based on the outcome of this case. Parents can be of great assistance to the nursing staff; and from the parents' view, they are often more comfortable remaining with their child, given the choice. As seen in this instance, not only might the parents' presence have saved their son's life, it more than likely factored into the jury's large verdict," adds Kicklighter.

"Bottom line, it is probably not enough to simply have all of the right policies and procedures in place to dictate who should do what and when if orders aren't followed and the communication culture and systems are faulty," concludes Kicklighter.

Reference

- *Dudley vs. Baptist East, et al*., Jefferson County (KY) Circuit Court, Case No. 97 C15760. ■

PATIENT SAFETY QUARTERLY™

PLANNING FOR NATURAL AND MAN-MADE DISASTERS

Look for specific hazards and then plan for problems

Like life insurance, a disaster preparedness plan is something you hope you never have to use. But in case you do, you'd better have a darn good one in place — especially if your worst-case scenario involves a nuclear accident.

At Lockheed Martin Energy Systems of Oak Ridge, TN, which manages energy-related facilities for the U.S. Department of Energy (D.O.E.), the disaster preparedness plan is characterized by a methodical, organized approach and attention to detail.

"Hazard and Consequence Assessment, as required by the D.O.E., is the foundation of the program," says **Joe Inman**, emergency manager, who oversees the plan. "It drives the type of response, the numbers of responders, and so forth."

Elements of the plan

Every response plan has the following four basic elements **(for an example of how each step works in a specific event, see chart, inserted in this issue.)**:

- **Planning:** understanding the potential problem;
- **Emergency preparedness:** putting in place the tools needed to ensure a proper immediate response;
- **Response:** being equipped and staffed with the capability to mitigate the emergency;
- **Recovery:** once the problem has been mitigated, making the transition back to normal operations.

"If you look at what we do, we basically have two missions," Inman explains. "First, we sit down and plan for those events we know could happen and walk through them in the calm of day, making sure everyone knows how to respond. Second, we put in place a framework that allows us to respond."

How the plan works

Inman explains how the four phases would play out in the event of a fire:

- **Planning:** Are there hazardous materials in the area? What are the evacuation routes? Determine where the assembly stations are, so you can make sure everyone gets out. If everyone doesn't get out, be ready to send responders (dressed in fireproof clothing) to look for them.
- **Preparedness:** Train your people, run them through a drill of the program, so if anything happens, they won't be experiencing it for the first time.
- **Response:** Make sure that not only internal people but also external people, such as fire departments or emergency brigades, are ready to respond.
- **Recovery:** If we lose a vital part of an administration building, such as computers, how can we recover?

During the employee orientation session, new employees are given general background information on what they need to do to protect their own health and safety, says **John Bolling**, energy systems emergency management program manager. This includes learning the different alarm sounds peculiar to specific situations. "They are also trained on how to report an emergency and to make sure help is summoned," he notes.

Anyone who comes on site unescorted must have this training, says Bolling. In addition, says Inman, "Each year they have facility-specific training." There is also an annual drill to ensure "evacuation accountability."

As with its health and safety program in general, the emergency response system at Lockheed Martin is based on smooth interdepartmental integration.

Each site is required to have its own medical program, he notes, "And we are required to define the interface between that medical plan and how the department interfaces with the emergency plan." For example, in a mass-casualty situation, occupational medicine professionals are mobilized as emergency responders.

However, Inman notes, some situations may call for more help than can be provided on-site. "We have memos of understanding with the surrounding community in case we exceed our capabilities — these include ambulance services [land and air], the fire department, the Red Cross, and the state of Tennessee."

The plan had to be exercised this spring, says Inman, during a tornado warning. Thankfully, there was no damage to the facility, he reports, but "the plan went quite well." ■

Systems Failure and Basic Staff Response

St. Joseph's Hospital, Savannah, GA

Computer systems	System down	MIS	Use backup manual/paper systems
Electrical power failure - Emergency generators work	Many lights are out. Only RED plug outlets work	Engineering	Ensure that life support systems are on emergency power (red outlets). Ventilate patients by hand as necessary. Complete cases in progress ASAP. Use flashlights
Electrical power failure - total	Failure of all electrical systems	Engineering and respiratory care services	Utilize flashlights and lanterns, hand ventilate patients, manually regulate IVs, don't start new cases
Elevators out of service	All vertical movement will have to be by stairwells	Engineering and all managers	Review fire and evacuation plans, establish services on first or second floor, use carry teams to move critical patients and equipment to other floor
Elevator stopped between floors	Elevator alarm bell sounding	Engineering and security	Keep verbal contact with personnel still in elevator and let them know help is on its way
Fire alarm system	No fire alarms or sprinklers	Engineering	Institute fire watch, minimize fire hazards, use phone or runners to report fire
Medical gases	Gas alarms, no O_2 or medical air or nitrous oxide (NO_2)	Engineering, material dispensing, and respiratory services	Hand ventilate patients; transfer patients if necessary, use portable O_2 and other gases, call for additional portable cylinders
Medical vacuum	No vacuum; vacuum systems fail and in alarm	Engineering, respiratory care, and sterile processing	Call central service for portable vacuum, obtain portable vacuum from crash cart, finish cases in progress, don't start new cases
Natural gas; failure or leak	Odor, no flames on burners, etc.	Engineering	Open windows to ventilate, turn off gas equipment, don't use any spark producing devices, electric motors, switches, etc.
Nurse call system	No patient contact	Engineering	Use bedside patient telephone if available; move patients; use bells, detail a rover to check patients
Sewer stoppage	Drains backing up	Engineering	Do not flush toilets, do not use water
Steam failure	No building heat, hot water, laundry, sterilizers inoperative, limited cooking	Engineering	Conserve sterile materials and all linens, provide extra blankets, prepare cold meals
Telephones	No phone service	Engineering and telecommunications	Use overhead paging, pay phones, bypass phones, use runners as needed
Water	Sinks and toilets inoperative	Engineering and sterile processing	Institute fire watch; conserve water; use bottled water for drinking; be sure to turn off water in sinks, use RED bags in toilet
Water non-potable	Tap water unsafe to drink	Engineering, dietary, and all managers	Place "Non-Potable Water - Do Not Drink" signs at all drinking fountains and wash basins
Ventilation	No ventilation; no heating or cooling	Engineering	Open windows (institute fire watch) or obtain blankets if needed, restrict use of odorous/ hazardous materials

BIOTERRORISM WATCH

Preparing for and responding to biological, chemical and nuclear disasters

Ease of access to deadly chemicals may be the greatest threat to hospital readiness

How close is your hospital to a railroad track?

Though biological agents have dominated recent terrorism discussions, ease of access to deadly chemicals may make them a greater threat to hospital readiness, experts emphasized recently at the University of Georgia in Athens.

"Eighty new chemicals a day are patented in America, and most of them will kill you," said **Jon W. Watson**, special agent in the FBI's joint task force on bioterrorism.

Watson joined other experts in a conference on preparing hospital clinicians for mass casualty situations. The underappreciated threat of chemical weapons was a recurrent theme throughout the Dec. 5, 2001 meeting.

"Most people do not realize that the chlorine — the substance we put in our swimming pools — will kill you," Watson said. "Yet tanker carloads of it are railed through the middle of Atlanta every day. A [munitions] charge placed on the side of that tanker would blow a hole in it, the chlorine would escape, form a flue, and move across the city."

A potent irritant to the eyes and skin, chlorine can cause severe pulmonary irritation that may result in death. Yet chlorine exposure is difficult to diagnose, and there is no specific antidote. **(See chemical agents, p. 3.)**

"That is not sexy; that's not going to make the news," Watson said. "We would much rather talk about Ebola and anthrax."

The chemical agent deployed by a terrorist could include an industrial hazardous material or a traditional militarized agent such as nerve gas.

While many nations still have stores of chemical weapons, in 1997, the United States and some 80 other countries signed a treaty banning their use. As a result of that legislation and prior actions, the United States is in the process of destroying its stocks of chemical weapons through incineration. One such storage site is the Noble Training Center in Anniston, AL.

"We are privileged to store 2,100 tons of sarin, mustard [gas], and VX derivation," said **John Hoyle**, MHA, LFACHE, director of the Noble Training Center and an employee of the U.S. Public Health Service.

A $1 billion incinerator has been built to destroy the chemical stocks, but people in the surrounding communities have expressed concern about the public health threat of the incineration process, he said at the conference.

"There is a lot of concern in the citizenry about those chemical weapons, but the Army has been storing and handling them for 50 years," Hoyle said. "I have toured the incinerator three times. I am very convinced they know exactly what they are doing."

However, while confident in the safety of the incineration program, he expressed concern about the amount of chemicals that are railed through that area and other parts of the country.

"I live but a mile from a train track, and we are the main route between Atlanta and Birmingham,"

This supplement was written by Gary Evans, editor of *Hospital Infection Control*. Telephone: (706) 742-2515. E-mail: gary.evans@ahcpub.com.

Triage, decontamination after chemical exposures

Have outdoor shower area ready

To increase preparedness for chemical exposures, clinicians at George Washington University in Washington, DC, have developed triage and decontamination plans that include the use of outdoor showers.[1] Some of the key points of the plan for dealing with chemically contaminated patients include:

✔ **Initial triage.**

Exposed and potentially exposed individuals should receive an initial brief triage, performed by medical personnel in personal protective equipment (PPE), before decontamination. They should then be directed to one of two areas, nonmedical decontamination or medical decontamination. The uninjured, those with minor injuries requiring no medical intervention during decontamination, and the majority of ambulatory patients will be assigned to nonmedical decontamination.

A brief sign-in process should record name and date of birth. (Full registration can occur after decontamination and should be consistent with the community patient tracking system.) A number on a log can be assigned to each patient, who would receive two identically numbered plastic bags and a nonpermeable wristband. Clothing would be placed into the larger clear, impervious bag. Valuables should be placed in the second, smaller bag.

✔ **Patient decontamination.**

It is recommended that the facility have partially fixed or preconstructed decontamination areas that can be activated immediately. This area should be designed to occupy little storage space and not disrupt routine operations while in use. The Israeli model, developed during the Gulf War, consists of showers permanently fixed to the ceiling structure of an open-air parking garage or the side of a building. The George Washington University Hospital model uses fire exit alleyways. Outdoor decontamination, however, must offer protection from inclement weather and have adequate lighting for night operations. Because clothing will be removed before decontamination, privacy must be protected to ensure compliance with full decontamination. The sexes should be separated, with a visual barrier between shower lines.

The water temperature must be adjustable. Excessively warm water should be avoided, as this may promote peripheral vasodilatation and toxin absorption. Stiff brushes or abrasives also should be avoided as they may enhance dermal absorption of the toxin and can produce skin lesions that may be mistaken for chemical injuries. Sponges and disposable towels are affordable and effective alternatives.

Decontamination can be accomplished by using a sequential copious warm water rinse, a hypoallergenic liquid soap wash, another warm water rinse, and then a final rinse after walking past other in-use showers. Promoting patient self-decontamination will significantly decrease the required number of health care workers. Of course, decontamination assistance for some patients in the nonmedical decontamination area and full passive decontamination in the medical decontamination area must still be available.

Decontamination facilities should contain multiple shower stations that are designed to allow patients to progress at various rates without compromising overall flow. Patients whose clinical condition deteriorates in the decontamination line can impede the progress of others. Plans must include means for sidetracking these patients into an area separate from the main decontamination sites, where treatment can be initiated.

Reference

1. Macintyre A, Christopher G, Eitzen E, et al. Weapons of mass destruction events with contaminated casualties. *JAMA* 2000; 283:242-249. ■

Hoyle said. “Chlorine cars, World War I warfare chemicals go through our town all of the time. [But] nobody worries about a rail-car accident, much less terrorism [involving] a rail car,” he added.

A reality in Tokyo

As with bioterrorism and anthrax, the threat of chemical attacks on citizens is no longer theoretical. While the use of chemicals is well documented in warfare, the incident that drove the terrorist threat home was the release of the nerve agent sarin in the subways of Tokyo in 1995. Twelve people were killed and 5,000 injured in the attack by the Aum Shinrykyo cult. It could have been worse. The group reportedly had little problem getting scientific assistance in developing the chemical, but never really came up an adequate delivery system.

(Continued on page 4)

Signs and Symptoms of Chemical Exposures

The following are among the major chemical agents that may be used by a terrorist. As a general rule, health care providers using appropriate personal protective equipment should remove the exposed person from the source immediately, and decontaminate by removing, bagging, and sealing the person's clothing. Flush the skin with water and then wash with soap. Take care to prevent secondary cases from contaminated clothing, ground, vegetation, or equipment.

NERVE AGENTS

- **Sarin (GB)** is a colorless, odorless liquid that mixes readily in water. Sarin can be ingested, inhaled, or absorbed through the skin. Depending on the dose, onset of clinical manifestations can vary from a few minutes to one hour, although most occur within minutes. Signs and symptoms include visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death. Treatment includes atropine, pralidoxime chloride, and diazepam.
- **Tabun (GA)** is a colorless-to-brownish liquid. Under average weather conditions, tabun can persist for one to two days. It is primarily released as an aerosol or vapor. Clinical signs and symptoms include visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death. Treatment includes atropine, pralidoxime chloride, and diazepam.
- **Soman** is a colorless and tasteless liquid that mixes readily with water. After release, it evaporates rapidly, dissipates, and eventually breaks down in the environment. Clinical manifestations include visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death. Treatment consists of decontamination; drugs such as atropine, pralidoxime chloride, and diazepam; ventilation to support respiratory function; and supportive care.
- **VX** is an amber-colored, oily liquid that will remain in the environment until it has been properly cleaned through decontamination methods. VX can enter the body through ingestion, inhalation, or through the eyes or skin. Health effects include constricted pupils, visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death. Diagnosis is based on history of exposure, clinical signs and symptoms, and confirmatory laboratory tests. Treatment includes atropine, pralidoxime chloride, and diazepam; ventilation to support respiratory function; and supportive care. Because of VX's persistent characteristics, take special care to prevent secondary cases from contaminated clothing, ground, vegetation, or equipment.

BLISTER AGENTS

- **Mustard (HD)** causes severe skin, lung, or eye damage. The health effects of exposure can be delayed up to 12 hours. Those exposed might notice the odor of mustard, which is similar to onion or garlic. Hours after exposure, the skin may appear red. Upper respiratory problems such as difficulty breathing, coughing, painful sinuses, or sore throat may occur. Over a period of hours, small blisters appear and gradually combine to form large blisters. Mustard exposure can be confirmed through a urine test. There is no antidote for mustard exposure.
- **Lewisite** is a blister agent that produces immediate effects. Its vapor causes burning or pain in the eyes, nose, and skin. Fresh air can increase the pain. Lewisite also may produce visible tissue damage within several minutes of contact. Later, severe damage to the skin, eyes, or airways may occur. Lewisite is diagnosed by recognizing its clinical manifestations (immediate pain or irritation of skin and mucous membranes). Other signs and symptoms that may occur later are skin flushing, blisters on the skin, and eye and airway damage. Treatment consists of decontamination, the use of the antidote British Anti-Lewisite (BAL), and supportive care.

PULMONARY AGENTS

- **Phosgene (CG)** has the odor of newly mowed hay. This highly toxic substance immediately irritates the eyes, nose, and skin. It also produces tissue damage within several minutes of contact. Phosgene exposure is diagnosed by recognizing the signs and symptoms (eye and airway irritation, difficulty breathing, chest tightness, and delayed pulmonary edema). There is no specific antidote for phosgene. Decontaminating all exposed areas is the most effective means of decreasing tissue damage.
- **Cyanide** is a colorless liquid that prevents cells from using oxygen, which results in death. Inhalation is the primary mode of exposure. Cyanide in moderate amounts may produce headache, nausea, dizziness, weakness, or anxiety. A large amount of cyanide will produce loss of consciousness within seconds, and death may occur within minutes. Cyanide exposure is diagnosed by the clinical signs and symptoms suggestive of inadequate oxygen. Successful treatment for acute cyanide poisoning depends upon rapid treatment with oxygen and the use of antidotes (amyl nitrite, sodium thiosulfate, and sodium nitrite).
- **Chlorine** is a greenish-yellow gas with an irritating odor. It is a potent irritant to the eyes and skin. Exposure also causes severe pulmonary irritation that may result in death. Chlorine exposure is difficult to diagnose. There is no specific antidote. Remove from the source and provide fresh air. If eyes or skin were exposed, rinse them with plenty of water. Provide oxygen if there is shortness of breath or difficulty in breathing.

Source: Centers for Disease Control and Prevention, Atlanta.

"[Terrorists don't] have to hire a bunch of PhDs and spend millions to try and create some sarin — not when you've got rail cars full of the stuff going through our towns everyday," Hoyle warned.

Lessons learned from the Tokyo sarin attack include the fact that a significant number of exposed individuals may find their own means of transportation to the health care facility after a chemical attack.

"The vast majority of casualties in any disaster will get to your hospital without the benefit of EMS," Hoyle said. "They simply don't wait around for EMS to organize, set up a triage, casualty collecting points, and all that."

In addition, "worried well" patients who have experienced very little or no exposure will go to a hospital. Many may still require decontamination because it may be difficult to rule out exposure. Any real symptoms of a chemical agent will occur in conjunction with anxiety and confusion. All the while, residual chemical agents on those exposed may pose a risk of secondary spread to workers, as evidenced by pesticide patients presenting at emergency rooms.

Indeed, three health care workers — one who was subsequently hospitalized for nine days — fell ill after a patient who had ingested pesticide came into an emergency room in a South Georgia hospital in 2000. As a result of the case, the Centers for Disease Control and Prevention (CDC) recommended staff take personal protection measures beyond standard infection control precautions. Depending on the extent of the contamination, health care workers caring for chemically contaminated patients should use level C protection (i.e., full face mask and powered / nonpowered canister / cartridge filtration respirator) or level B protection (i.e., supplied air respirator or self-contained breathing apparatus). The type of canister / cartridge should be appropriate to the agent. If the agent cannot be identified, use an organic vapor / HEPA filter, the CDC recommended.

Self-reliance a must

Other practical considerations are the availability of heavier gloves, because thin latex medical gloves are of little protection against many chemicals. In addition to the need for surface decontamination of patients, body fluids also must be contained to prevent skin and inhalation exposure. To limit spread of the contaminant, the emergency room's ventilation exhaust should be directed away from the hospital's main ventilation system. A less-expensive alternative is to set up an outdoor shower decontamination area. **(See related story, p. 2.)**

Such preparations may be critical because local officials will be too busy at the scene of exposure to assist hospitals with incoming patients, Hoyle warned. "Hazmat people will not show up at the hospital emergency room and decontaminate patients for you, because they are still going to be in the area of the exposure. You have to think self-containment. You're going to have to direct your own traffic and decon your own patients."

Moreover, it is actually a regulatory requirement that hospitals are prepared to deal with chemically contaminated patients, added **Henry Siegelson,** MD, FACEP, a consultant with Disaster Planning Intentional Inc. in Atlanta. The Occupational Safety and Health Administration (OSHA) requires such preparation as part of its regulations on hazardous wastes, he told conference attendees. "[OSHA] rules require employers — including hospital CEOs — to plan for Hazmat if they expect their employees to handle an emergency involving chemicals," he said.

In complying with OSHA, the preparedness plan will also meet requirements of the Joint Commission on Accreditation of Healthcare Facilities, Siegelson added. Despite the risk of accreditation problems or OSHA fines, the response to the regulations has been historically lackluster, he said. "Prior to Sept. 11, some people said, '[OK] fine me. I don't care.'" he said. "Really, I ran in into that all over the country. Before [the 11th] we were called to train hospitals by safety committees, nurses, security professionals. Now we are being called by hospital CEOs."

In general, the OSHA requirements include that all employees — including affiliated personnel, physicians, and nurses — who may be involved in chemical emergency response must be familiar with the plan. By the same token, facilities must plan for emergency treatment of noncontaminated patients, he noted.

"What are you going to do if someone comes in with a heart attack or a broken hip while you are dealing with this decon event?" Siegelson asked.

Reference

1. Centers for Disease Control and Prevention. Nosocomial poisoning associated with emergency department treatment of organophosphate toxicity — Georgia, 2000. *MMWR* 2001; 49:1,156-1,158. ■