Healthcare RISK MANAGEMENT

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Hospitals threatened by theft of radiological material

Wanted for use in 'dirty bombs,' valuable material invites crime, violence

By **Greg Freeman**

The Government Accountability Office (GAO) recently issued a warning to hospitals about the risk of the theft of radiological materials, which could be used to make a dirty bomb. Experts caution that the presence of radiological materials in a hospital brings a significant obligation to provide security.

Experts caution that the presence of radiological materials in a hospital brings a significant obligation to provide security.

Nearly four out of five hospitals across the country have failed to put in place safeguards to secure radiological material that could be used in a dirty bomb, according to the report, which identifies more than 1,500 hospitals as having high-risk radiological sources. Only 321 of these medical facilities have set up security upgrades, according to the GAO review, which found some surprising lapses of security in 26 hospitals.

At one facility, a device containing potentially lethal radioactive cesium was stored behind a door with a combination lock. The combination was written on the door frame.

The National Nuclear Security Administration spent $105 million to complete security upgrades at 321 of more than 1,500 hospitals and medical facilities that were identified as having high-risk radiological sources, the report says. The upgrades include security cameras, iris scanners, motion detectors, and tamper alarms. *(See the story on p. 123 for more on the GAO report.)*

While it is not known that terrorists have stolen radiological material from hospitals, there have been suspected incidences of "probing" in which criminals seek to determine a hospital's security weaknesses. A series of incidents in 2005, in which people posed as inspectors from The Joint Commission to gain access, was attributed to terrorists planning attacks on hospitals, looking for radiological material, and assessing hospitals' capacity for emergency response. *(For more on those*

INSIDE

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incidents, see the story on p. 124.)

Hospitals' ability to protect radiological material is likely to vary greatly, says **Bryan Warren**, CHPA, senior manager for corporate security at Carolinas Healthcare System in Charlotte, NC, and president of the International Association for Healthcare Security and Safety in Glendale Heights, IL. Larger hospitals with a robust security program probably have policies and procedures in place that will at least make radiological theft difficult, he says. "But if the plant operations and maintenance people are handling security, they are likely not even aware of the issue, much less acting in a proactive way to protect this material," Warren says. "Unfortunately, being a smaller hospital does not mean you won't have radiological material."

Executive Summary

Hospitals must address the increasing threat posed by those who would steal radiological material for use in a "dirty bomb" terrorist attack. The presence of such material means the hospital is at risk of violence or a covert theft.

✦ The Government Accountability Office (GAO) recently issued a warning to hospitals about the risk of the theft of radiological materials. It said hospitals have been negligent.

✦ Extensive guidelines are available on how to prevent the theft of this material and protect the hospital.

✦ Past events suggest that terrorists have shown interest in obtaining radiological material from hospitals.

Help is available

Hospitals can improve their radiological security by working with the Global Threat Reduction Initiative (GTRI) in the federal Office of Defense Nuclear Nonproliferation, Warren says. GTRI helps identify, secure, remove, and/or facilitate the disposition of high risk vulnerable nuclear and radiological materials around the world that pose a threat to the United States and the international community. *(For information on contacting GTRI, see the resource at the end of this article.)*

"GTRI has been working with hospitals for a number of years to help protect any kind of radiological materials so that the bad guys can't get it and turn it into a dirty bomb," Warren says. "Once hospitals are aware of it, they can get a preliminary analysis of their infrastructure to see if they have enough radiological source material to pose a threat, and what they can get through this federally funded program to protect it."

Once a hospital requests assistance, GTRI sends a survey team to a site assessment concerning radiological materials, Warren explains. Most of the resources and assistance are provided at no charge to the hospital. The free aid can include surveillance equipment and other physical improvements to security.

"They also will train your staff and first responders from your local jurisdic-

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Editorial Questions

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

tion," Warren says. "They will pay for everything to send you to Oak Ridge, TN, for some very intensive training to mitigate the risk at your facility."

More than just high-grade at risk

The GAO report was not surprising to **Zachary Goldfarb**, EMT-P, CHSP, CHEP, CEM, principal with Incident Management Solutions, a company in Uniondale, NY, that helps hospitals and other organizations prepare for and respond to emergencies. Radiological material in hospitals has been a primary concern for homeland security professionals after the 2001 terrorist attacks, Goldfarb says. *(See the story below for more on improving radiological security.)*

Hospital risk managers should realize that terrorists might be interested not only in high-grade radiological material such as cobalt, Goldfarb says. That type of material is found in fewer facilities, but many hospitals have less radioactive substances that still could be a target, he says.

"For years we've been building scenarios that involve mixing low-level radioactive source material, like medical waste, with a bomb," Goldfarb says. "The real objective of a dirty bomb could be accomplished with low-level medical waste because if any radiation, even at a very low level, were detected after an explosion, it would be the first time for this country. It would create the intended effect of scaring the daylights out of many, many people."

"Unfortunately, being a smaller hospital does not mean you won't have radiological material."

SOURCES/ RESOURCES

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For more information on **Global Threat Reduction Initiative (GTRI)**, go to http://tinyurl.com/infoGTRI. To apply for assistance from GTRI, go to http://tinyurl.com/GTRIhelp. ✦

GAO finds serious faults with radiological security

The Government Accountability Office (GAO) visited 26 hospitals and other medical facilities to assess compliance with the Nuclear Regulatory Commission's (NRC) requirements for the protection of radiological material, and the report details many problems.

The NRC guidelines "do not consistently ensure the security of high-risk radiological sources" at the facilities visited, the report says. *(For information on accessing the report, see resource at end of this article.)* One reason for this problem is that the requirements are broadly written and don't prescribe specific measures that hospitals and medical facilities must take to secure medical equipment containing sealed sources, such as the use of cameras or alarms, according to the investigators. Rather, the requirements provide a general framework for what constitutes adequate security practices, which is implemented in various ways at different hospitals. Some of the medical equipment in the facilities visited was more vulnerable to potential tampering or theft than that of other facilities because some hospitals developed better security controls than others.

Some examples of poor security observed by the GAO investigators included:

• An irradiator, used for medical research and containing almost 2,000 curies of cesium-137, was stored on a wheeled pallet down the hall from, and accessible to, a loading dock at one facility.

• At a second facility, the combination to a locked door, which housed an irradiator containing 1,500 curies of cesium-137, was clearly written on the doorframe.

• At a third facility, an official told GAO that the number of people with unescorted access to the facility's radiological sources was estimated to be at least 500. In addition, some NRC and state inspectors said the training NRC requires is not sufficient.

As of March 2012, the National Nuclear Security Administration (NNSA) had spent $105 million to complete security upgrades at 321 of the 1,503 U.S. hospitals and medical facilities it identified as having high-risk radiological sources, according to the report. Of the 26 hospitals and medical facilities that GAO visited, 13 had volunteered for the NNSA security upgrades and had received security upgrades such as remote monitoring systems, surveillance cameras, enhanced security doors, iris scanners, motion detectors, and tamper alarms. Three others were in the process of receiving upgrades.

However, NNSA does not anticipate completing all such security upgrades until 2025, which leaves several facilities potentially vulnerable. In addition, the program's impact is

limited because, among other things, it is voluntary. To date, 14 facilities, including four in large urban areas, have declined to participate in the program.

Combined, those 14 facilities have medical equipment containing more than 41,000 curies of high-risk radiological material, the report says. Police department officials in a major city told the GAO that one hospital with a blood irradiator of about 1,700 curies has declined the NNSA upgrades due in part to cost concerns, even though the police department considers it to be a high-risk facility.

RESOURCE

The full Government Accountability Office (GAO) report is available online at http://tinyurl.com/GAOhospitalreport. ✦

Determine threat — Look for faults in policy and procedure

When protecting a hospital's possible targets, the first step is a threat assessment, says **Zachary Goldfarb**, EMT-P, CHSP, CHEP, CEM, principal with Incident Management Solutions, a company in Uniondale, NY, that helps hospitals and other organizations prepare for and respond to emergencies.

That step means determining what you are protecting your target from. Is it surreptitious theft by an employee or visitor? Is it an armed theft by one or two people? A full assault by terrorists? A quiet, nonviolent but skilled burglar?

The hospital's defense will depend on the perceived threat and the resources available, Goldfarb says. Keep in mind that a key part of any defense is the use of layers so that even if there is an armed attempt to reach radiological material, the criminals are slowed by having to get through multiple locked doors and other security. Those layers increase the likelihood that police can respond quickly enough to intervene, Goldfarb explains.

"A more likely scenario is that you have someone on the inside who takes away just a little bit of material at a time, over some period, until there is enough to pack some explosives around and have the desired effect," he says. "That is reason to take a good look at your screening processes and your surveillance procedures in this area, which may need to be much more extensive than in the rest of the hospital."

Any defensive measures and security procedures should be tested periodically with a "red team" effort, which means having one or more people try to access the controlled areas and obtain (or simulate obtaining) the radiological material. This step can be one of the best ways to find deficiencies, Goldfarb says. He refers to the hospital in the GAO report where a combination lock secured a sensitive area, but the combination was written on the doorframe.

"That's so overt, but people really do that kind of thing," he says. "You have to find those problems and ask yourself why they did it, rather than just saying, 'that's a crazy, willful violation.' Why did they do that workaround, and how can you improve the process so that they're not motivated to do that anymore?" ✦

Flashback: Fake Joint Commission surveyors tried to enter hospitals

In 2005, *Healthcare Risk Management* reported extensively on a series of suspicious visits to hospitals by people posing as surveyors from The Joint Commission. The impostors tried to gain access to the hospital and they asked probing questions about the location of radiological materials and the hospital's ability to respond to a major incident such as a dirty bomb detonation.

At the time, Joint Commission officials and security experts told *HRM* that terrorists might have been behind the multiple incidents. Obtaining radiological material was one likely goal, they said, and the impostors also might have been planning attacks on healthcare facilities.

The Joint Commission issued a warning to hospitals after receiving three reports in four months about such impostors. In all three cases, the impostors fled after being asked for proper identification. The law enforcement community also was concerned enough to issue special bulletins warning of the danger.

The impostors' methods suggested they were more than just petty criminals looking to steal laptops, drugs, or financial information, some security experts said. The average person doesn't even know about The Joint Commission or that surveyors could access the hospital, they said, so the impostors must have been sophisticated enough — and motivated enough — to have identified that

method through research.

There have been other suspicious incidents that could be related, says **Bryan Warren**, CHPA, senior manager for corporate security at Carolinas Healthcare System in Charlotte, NC, and president of the International Association for Healthcare Security and Safety in Glendale Heights, IL.

"A number of fire departments have reported thefts of coats and boots, items that could be used to impersonate a firefighter and possibly give someone access to places they could not otherwise enter," Warren says. "There has not been a pattern in healthcare lately, but that doesn't mean anyone should let their guard down." *(For the full story on the impostors and how they may have been probing hospitals for terror attacks, see* Healthcare Risk Management, *June 2005, pp. 61-67, and October 2005, pp. 113-114.)* ✦

Hospital shootings rare but purposeful, study finds

Shootings in U.S. hospitals typically generate widespread media publicity, but the likelihood of being shot in a hospital is less than the chance of getting struck by lightning, according to research at The Johns Hopkins University School of Medicine in Baltimore.

In a report published in the Annals of Emergency Medicine online and conducted by four researchers at Johns Hopkins, the investigators reviewed 11 years of data and identified some disturbing flashpoints. For one, almost 30% of U.S. hospital-based shootings occurred in emergency departments (EDs). Fifty percent of the ED incidents involved a police or security officer's firearm that was stolen to shoot victims or used by security to fire at an assailant.

The International Association for Healthcare Security & Safety (IAHSS) responded with criticism of the study, particularly aimed at what it says is too little focus on the use of trained and certified security professionals in hospitals. *(See p. 126 for more on the IAHSS criticism.)*

An in-depth review of the 154 hospital-based shootings, which resulted in 235 dead or injured, found that such shootings are difficult to prevent because most involved a "determined shooter," says **Gabe Kelen**, MD, the lead author of the report and the director of The Johns Hopkins Hospital Department of Emergency Medicine in Baltimore. Another key finding, Kelen says, was that most perpetrators had a personal association with victims. "Most of the events involved a determined shooter with a specific target," Kelen and the other authors write in the study.

Common motives for shootings were a grudge or revenge; suicide; and euthanizing an ill relative. The latter motives all appeared to be the case in the Sept.16, 2010, shooting at The Johns Hopkins Hospital in which an assailant shot a doctor and then killed his ill mother and himself. That incident was the impetus for the study, Kelen says.

In the study report, the Hopkins research team concludes that specialized training for law enforcement and security personnel, such as proper securing of firearms, might prove a more effective deterrent to future incidents than investment in expensive or intrusive technologies, such as magnetometers.

Such technologies might create a false sense of security, primarily because potential weapons get into hospitals by a variety of channels and because more than 40% of all the shootings studied occurred on hospital property outside of buildings, the authors note. Many security experts, the authors add, view metal detectors and similar measures as impractical solutions in hospitals because they typically have multiple public entrances and large numbers of visitors each day.

Although the study found shootings at hospitals to be infrequent, Kelen points out that no hospital is immune. Zero risk "is not achievable," the authors write. The IAHSS, however, says several key strategies were not discussed. Specifically, the group cites the need to seek out the guidance of a healthcare security expert during the decision-making process of a security program, such as when installing metal detectors or arming security officers is being considered.

Other recommendations put forth by the association touched upon the need for greater professionalism and training of security personnel, the value of due diligence and risk assessments for effective decision-making at the time of an incident, and the importance of liaison work with a hospital's local law enforcement community.

SOURCE

• **Gabe Kelen**, MD, Chair, Department of Emergency Medicine, The Johns Hopkins School of Medicine, Baltimore, MD. Telephone: (410) 955-3182. ✦

Executive Summary

A study by researchers at The Johns Hopkins University School of Medicine finds that hospital shootings are extremely rare. Many of the shootings involve grudges or euthanization of a patient.

- ✦ The emergency department is the scene of almost one-third of all hospital shootings.
- ✦ Half of the shootings involved a police or security officer's gun.
- ✦ Magnetometers might be an impractical solution in hospitals.

Depend on security professionals when planning

Hospitals should consult with a certified healthcare security expert in developing a program aimed at deterring shootings or other violence in the facility, says **Bryan Warren**, CHPA, president of the International Association for Healthcare Security & Safety (IAHSS) and senior manager for corporate security at Carolinas Healthcare System in Charlotte, NC.

There is more interest in security among healthcare providers due to recent high profile shootings in hospitals and other public places, Warren says. Organizations such as IAHSS can provide best practices and important protocols when a facility is developing its healthcare security plan, he says.

The recent report by **Gabe Kelen**, MD, director of the Department of Emergency Medicine at The Johns Hopkins Hospital in Baltimore, regarding hospital shootings is evidence of the increased focus on security, Warren says. The report should have recommended the use of security experts specifically trained for the healthcare arena, he says. Such a security expert can help carry out a risk assessment of a facility and can pinpoint specific details such as the demographics of the hospital location, economic condition, incidents occurring throughout the community, and proficiency of current security team, from which a plan can be further developed, Warren says.

After completion of the due diligence phase, clear guidelines should be analyzed and implemented for specific issues such as whether to arm the security staff. Such guidelines would encompass questions such as what type of holster is being used for the firearm (providing a low or high level of weapon retention capability) and the make and model of the firearms being considered. *(See the story below for more on preparing for emergencies.)*

> *There is more interest in security among healthcare providers due to recent high profile shootings in hospitals and other public places.*

"These minor details need to be taken into account when considering whether to arm a security team because there are certain safety features of some handguns, for example, that may provide added protection to the security team, hospital staff, and patients in the event that the weapon falls into the wrong hands," Warren says. "Once these policies are in place, it is essential they become the framework around which hospital security officer training evolves."

Warren notes that the Johns Hopkins report did not speak to the training and professionalism of a security force, which he says is central to operating an effective security operation at any facility. According to Warren, it is critical that security and police staff have education and training on a routine basis, especially on firearms and weapons retention. "Unfortunately, this still does not exist in most facilities," he says. "There needs to be more emphasis on training for those responsible for healthcare security duties."

Workplace violence education and training for a hospital's clinical and ancillary staff also are necessary, Warren says.

"Better preparedness for an emergency event is crucial. Staff should be taught warning signs, who to call, when to call, and so on," Warren says. "Preparation is key to managing any crisis, and it should be an all-hazards approach." ✦

Good relations with local police essential to safety

In addition to the all the security precautions a hospital can take in anticipation of a shooting or other emergency, don't forget one important strategy: Get to know the local police.

"The most important thing is being prepared as much as possible for an emergency event, and part of that preparation is having a good relationship with your local law enforcement," says **Bryan Warren**, CHPA, senior manager for corporate security at Carolinas Healthcare System in Charlotte, NC, and president of the International Association for Healthcare Security and Safety in Glendale Heights, IL.

Partnering and pre-planning with local law enforcement is a critical element when it comes to emergency planning, Warren says. Establishing a personal familiarity between hospital and police will facilitate working in concert with local law enforcement on a routine basis and making sure everyone understands their roles and responsibilities in case of an emergency as well as what resources are available at the facility, he says. ✦

Hospital's kidney program suspended after botched transplant, investigation

The accidental disposal of a donor kidney has resulted in a hospital suspending its kidney donor program and a review of the hospital's compliance with regulations. The hospital also is facing bad publicity and the potential for malpractice lawsuits.

A nurse at the University of Toledo Medical Center accidentally disposed of a living donor's kidney during a transplant procedure, according to a report prepared by the Ohio health officials at the request of the Centers for Medicare and Medicaid Services (CMS). The nurse told investigators she did not realize the donor kidney was in chilled, protective slush that she removed from an operating room, took down a hall to a dirty utility room, and "flushed down a hopper," according to the report.

Errors such as this one usually point to a systemic problem within the hospital, explains **Karl J. Protil Jr.**, JD, equity shareholder with the law firm of Shulman Rogers Gandal Pordy Ecker in Potomac, MD. It would be a mistake to dismiss the incident as simply a failing by the individual nurse, he says. "This is like a never event, and those almost always can be traced to a series of events or a series of errors that came together to make this happen," Protil says. "This tells you that something within the hospital needs to be fixed so that this can't happen again." A great proportion of the malpractice cases that Protil handles involve a series of errors or omissions, he says. *(See the story on p. 128 for more information on the likelihood of a lawsuit in this case.)*

The nurse said she had been on a break when a surgeon told everyone the kidney had been put in the sterile, semi-frozen solution. *(The full report is available online at http://tinyurl.com/ohiokidneyreport.)*

Hospital administrative staff members interviewed by health investigators said they did not know how the nurse was able to take the 13-gallon bag of slush, meant to extend the kidney's viability, past several members of the medical staff without them noticing a problem, the report said. It said poor oversight and communication and insufficient policies were factors in the kidney's disposal, which prompted the voluntary, temporary suspension of the hospital's living-donor kidney transplant program and led to reviews by health officials and a consulting surgeon hired by the hospital. The hospital "failed to provide adequate supervision and communication resulting in a donor's kidney being carried out of the operating room, down a hall, into a dirty utility room, and flushed down a hopper," the report stated.

The hospital has since enacted clearer policies to clarify communication between nurses who fill in for one another and to make sure nothing is removed from an operating room until the patient has been moved from it, the report said.

The surveyors determined the hospital was not in compliance with CMS conditions of participation for transplant and surgical services. CMS issued a statement saying it will conduct a full review of the conditions of participation for the hospital. If found out of compliance, the hospital could be banned from Medicare and Medicaid participation.

Requests for comment were not answered by the hospital, which has not said what happened to the intended kidney recipient, the sister of the donor. The hospital issued a statement confirming that the intended recipient and her brother were released from the hospital.

Hospital officials apologized publicly and hired a Texas surgeon to evaluate their transplant procedures. The medical center suspended two nurses after the incident; one was later fired, and the other resigned, according to the hospital. A surgeon was stripped of his title as director of some surgical services, and a surgical services administrator that was put on paid leave has resumed work.

The hospital also notified 975 patients and potential organ donors and recipients that they might need to make other arrangements for services typically provided through the program under review.

SOURCE

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Executive Summary

An error during a directed donation kidney transplant at an Ohio hospital resulted in the kidney being mistakenly discarded with trash. The hospital suspended its living donor transplant program.

✦ A federal investigation revealed multiple deficiencies in the transplant program.
✦ The Centers for Medicare and Medicaid Services (CMS) has authorized a full review of the hospitals compliance with the Conditions of Participation.
✦ The hospital changed some policies and procedures after the incident.

Kidney mistake could lead to lawsuits, attorney says

The mistaken discarding of a donor kidney at the University of Toledo Medical Center in Ohio could lead to lawsuits but definitely should prompt the hospital to reassess the procedures that led to the mistake, says **Karl J. Protil Jr.**, JD, equity shareholder with the law firm of Shulman Rogers Gandal Pordy Ecker in Potomac, MD.

"They happen because the risk manager or someone else doesn't step in and stop these things from happening over and over again," Protil says. "They just become so commonplace that people mentally check the boxes and blow right by what should be a carefully considered safety step."

Protil wonders if the intended recipient will sue the hospital for losing the opportunity of a kidney transplant. "Kidneys aren't readily available. This patient now has lost the opportunity to have a kidney transplant, at least the best possible transplant option from a sibling," he says. "I don't think it's a stretch to see the patient suing the hospital and saying there was this once-in-a-lifetime opportunity for this optimal transplant, and you literally threw it away. I think the hospital can be liable for all the damages that flow from this."

The hospital also could lose significant revenue if publicity surrounding the case results in people deciding to have transplants elsewhere, Protil says. For that reason, he would advise the hospital to settle quickly and bring an end to the news coverage as soon as possible.

Protil recalls working with a hospital client that faced similarly bad publicity from an adverse event. The state's malpractice cap was $2 million, so the hospital quickly made an offer of $1.8 million to the patient.

"You tell the patient that you don't have to hire an attorney and pay an attorney's fee, and we also get a little break on the potential maximum payout," Protil says. "For some hospitals, it's the smarter thing to do. It takes care of the problem, it acknowledges the fact that you've made an egregious mistake, and you move on." ✦

$2.1M verdict handed down in peer review hearing case

Doctor contests hospital suspending privileges

A $2.1 million jury verdict against Los Angeles Metropolitan Medical Center for unfair privilege suspension of a doctor in a hospital peer review hearing is believed to be one of the largest jury awards in a peer review hearing case.

The case involves anesthesiologist Georgia Bode, MD, who was suspended for the alleged improper return of a single ampule of Demerol, a charge that she denied. In fact, the judge instructed the jury that the hospital's actions were unjustified. Partners **Henry R. Fenton**, JD, and Abbie Maliniak, JD, of the law firm Fenton Nelson in Los Angeles, represented Bode in the matter.

The attorneys secured a $2.1 million jury verdict for Bode. For the 10 years it took to exhaust her administrative procedures, Bode steadfastly denied the charge, Fenton says. Prior to the commencement of the case, at the request of plaintiff's counsel, Judge Elizabeth Allen White, JD, instructed the jury that it already had been established that the hospital's actions against Bode based on the alleged improper return of the Demerol were unjustified.

Bode had an unblemished record since she began practicing in 1987. She gave up her staff membership at Centinela Hospital to come to L.A. Metro after the hospital replaced its entire anesthesiology department. The replacement followed incidents involving the mishandling of controlled narcotic substances, which caused an accreditation agency to award the hospital only a conditional accreditation.

After an incident in which an ampule of Demerol was unaccounted for, the hospital's surgery department held an emergency peer review meeting, where the hospital's chief of staff summarily suspended Bode's temporary privileges. In accordance with L.A. Metro bylaws and California statutory requirements, Bode followed

Executive Summary

A doctor has won a $2.1 million jury verdict after contesting a hospital's peer review action. The award is believed to be one of the largest for a case involving peer review.

- ✦ The hospital accused the anesthesiologist of mishandling a narcotic.
- ✦ The physician's record previously was unblemished.
- ✦ Association with the narcotics charge hindered the doctor's career for 10 years.

protocol to exhaust her hearing rights, as documentation and an eyewitness account verified that she did, in fact, return the ampule of Demerol, Fenton explains. This matter ultimately made its way to the California Court of Appeal and resulted in a published decision, Bode v. Los Angeles Metropolitan Medical Center.

After a five-day trial in the Los Angeles Superior Court, a unanimous jury decided that based on the behavior of L.A. Metro, Bode did indeed suffer past and future economic damages and past emotional damages. Fenton adds that while the size of the jury's verdict deserves a great deal of attention, what was truly at stake was the previously untarnished reputation of a doctor, who due to being associated with narcotics, has been unable to obtain medical staff membership and privileges at numerous hospitals.

"This is a victory for all physicians whose hospital privileges are unfairly limited, denied, or terminated," Fenton says. "Physicians who encounter the unfair termination or denial of hospital privileges must succeed in winning their case at the administrative hearing level before they can even get to the courts."

SOURCE

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Patient safety project reduces central line infections by 40%

A unique nationwide patient safety project funded by the Agency for Healthcare Research and Quality (AHRQ) reduced the rate of central line-associated bloodstream infections (CLABSIs) in intensive care units by 40%, according to the agency's preliminary findings of the largest national effort to combat CLABSIs to date.

The project used the Comprehensive Unit-based Safety Program (CUSP) to achieve its landmark results that include preventing more than 2,000 CLABSIs, saving more than 500 lives, and avoiding more than $34 million in healthcare costs.

The agency and project partners from the American Hospital Association (AHA) and Johns Hopkins Medicine discussed the findings recently at the AHRQ annual conference in Bethesda, MD, and introduced the CUSP toolkit that helped hospitals accomplish this marked reduction.

"CUSP shows us that with the right tools and resources, safety problems like these deadly infections can be prevented," said AHRQ Director **Carolyn M. Clancy**, MD. "This project gives us a framework for taking research to scale in practical ways that help frontline clinicians provide the safest care possible for their patients."

CLABSIs are one type of healthcare-associated infection (HAI). HAIs affect one in 20 patients in hospitals at any point in time.

The national project involved hospital teams at more than 1,100 adult intensive care units (ICUs) in 44 states over four years. Preliminary findings indicate that hospitals participating in this project reduced the rate of CLABSIs nationally from 1.903 infections per 1,000 central line days to 1.137 infections per 1,000 line days, an overall reduction of 40%.

The CUSP is a customizable program that helps hospital units address the foundation of how clinical teams care for patients. It combines clinical best practices with an understanding of the science of safety, improved safety culture, and an increased focus on teamwork.

Based on the experiences gained in this successful project, the CUSP toolkit helps doctors, nurses, and other members of the clinical team understand how to identify safety problems and gives them the tools to tackle these problems that threaten the safety of their patients. It includes teaching tools and resources to support implementation at the unit level.

The first broad-scale application of CUSP was in Michigan, under the leadership of the Michigan Health & Hospital Association, where it was used to significantly reduce CLABSIs in that state. Following that success, CUSP was expanded to 10 states and then nationally through an AHRQ contract to the Health Research & Educational Trust, the research arm of the American Hospital Association.

AHA President and CEO

Executive Summary

A project funded by the Agency for Healthcare Research and Quality (AHRQ) has reduced the rate of central-line associated bloodstream infections in intensive care units by 40%. The project is estimated to have saved more than 500 lives.

- ✦ Hospital-acquired infections affect one in 20 hospital patients.
- ✦ The reduction is estimated to save more than $34 million in healthcare costs.
- ✦ Teaching tools are available.

Richard J. Umbdenstock said, "This partnership between the federal government and hospitals provides clear evidence that we can protect patients from these deadly infections. Hospitals remain committed to curtailing CLABSIs and enhancing safety in all clinical settings. Tools such as CUSP go a long way toward accomplishing that goal."

CUSP was created by a team led by **Peter J. Pronovost**, MD, PhD, senior vice president for patient safety and quality at Johns Hopkins Medicine in Baltimore. "It is gratifying that this method has become such a powerful engine for improving the quality and safety of care nationwide," Pronovost said. "It is a really simple concept: Trust the wisdom of your frontline clinicians."

In addition, CUSP also builds on important work led by the Centers for Disease Control and Prevention and its evidence-based recommendations on treating infections.

RESOURCES

• Details about the Agency for Healthcare Research and Quality's (AHRQ's) national Comprehensive Unit-based Safety Program (CUSP) are available at http://www.ahrq.gov/cusptoolkit. ✦

IOM calls for more technology in healthcare

Technology hold the keys to addressing an increasingly complicated healthcare system plagued by inefficiency, high costs, and poor quality, the Institute of Medicine (IOM) said in a recent report.

In the report, "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America," an 18-member expert panel argues for a set of improvement strategies that panel members say will make information more accessible, engage patients and their families, and make care more equitable. Those changes, which the committee referred to as a roadmap, include increased adoption of health information technology, increased connectivity, use of new payment models, and a re-engineering of healthcare systems.

"Missed opportunities for better healthcare have real human and economic impacts," the committee said in the report. "If the care in every state were of the quality delivered by the highest-performing state, an estimated 75,000 fewer deaths would have occurred across the country in 2005. Current waste diverts resources from productive use, resulting in an estimated $750 billion loss in 2009."

The report comes more than a decade after the release of To Err is Human and Crossing the Quality Chasm, companion reports that sounded the alarm about preventable harm and poor performance. But poorly designed systems, lack of information at the point of care, and an entrenched culture have hindered large-scale improvement, the committee said.

"Available knowledge is too rarely applied to improve the care experience, and information generated by the care experience is too rarely gathered to improve the knowledge available," the report said. "The traditional systems for transmitting new knowledge — the ways clinicians are educated, deployed, rewarded, and updated — can no longer keep pace with scientific advances. If unaddressed, the current shortfalls in the performance of the nation's healthcare system will deepen on both quality and cost dimensions, challenging the well-being of Americans now and potentially far into the future."

A free download of the full report is available at http://tinyurl.com/IOMtechreport. ✦

Supportive hospitals help nurses catch more mistakes

Nurses are more likely to catch medical errors in supportive hospitals, according to a recent study. The study, funded by the philanthropic Robert Wood Johnson Foundation, found that when nurses take steps to intervene in the medication process, they are more likely to catch would-be errors before they reach the patient.[1] On average, a U.S. hospital patient is subjected to at least one medication error per day, leading to more than 7,000 inpatient deaths every year, the report says.

Researchers looked at 82 medical-surgical units at 14 acute care hospitals. Nurses used intervention tactics, such as comparing the medication administration record and patient record at the beginning of a shift, determining the rationale for each ordered medication, asking doctors to rewrite orders if they used improper abbreviations, and ensuring that patients and families understood the medication regimen.

Reference

1. Flynn L, Liang Y, Dickson GL, et al. Nurses' practice environments, error interception practices, and inpatient medication errors. *J Nurs Scholarship* 2012; 44:180-186. ✦

COMING IN FUTURE MONTHS

✦ New system for patients to report errors

✦ Can EMTALA apply to inpatients?

✦ Crisis communication: Avoid the mistakes

✦ Hospital accused of hastening donor deaths

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe the legal, clinical, financial and managerial issues pertinent to risk management;
- explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
- identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

CNE INSTRUCTIONS

Nurses participate in this CNE program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ✦

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CNE QUESTIONS

1. **According to the report recently issued by the Government Accountability Office (GAO) about the risk of the theft of radiological materials, which of the following is true?**
   A. Nearly four out of five hospitals across the country have failed to put in place safeguards to secure radiological material that could be used in a dirty bomb.
   B. Nearly four out of five hospitals across the country have successfully improved their safeguards to secure radiological material that could be used in a dirty bomb.
   C. Nearly four out of five hospitals across the country have reported the loss of radiological material that could be used in a dirty bomb.
   D. Nearly four out of five hospitals across the country have reported that they have radiological material that could be used in a dirty bomb but do not think they are at risk of theft.

2. **According to Zachary Goldfarb, EMT-P, CHSP, CHEP, CEM, principal with Incident Management Solutions, what is the "more likely scenario" in which a hospital could be the source of radiological material used in a dirty bomb?**
   A. A burglar breaking into the hospital after normal business hours.
   B. An armed assault by one or two people.
   C. A full assault by numerous terrorists.
   D. Someone on the inside who takes away just a little bit of material at a time, over some period.

3. **According to the report on hospital shootings by researchers at the Johns Hopkins University School of Medicine, where do 30% of hospital shootings take place?**
   A. Obstetrics and delivery
   B. Emergency department
   C. Pediatrics
   D. Administration

4. **According to the state report on the accidental discarding of a donor kidney at the University of Toledo Medical Center, how did the mistake happen?**
   A. A surgeon put the kidney in the wrong container.
   B. A surgeon put the kidney in the correct container, but then a nurse changed the label on the container.
   C. A nurse discarded a bag of slush, not realizing that the kidney was inside.
   D. A technician removed the kidney while trying to change the slush in the bag.

HIPAA Regulatory Alert
Supplement to *Healthcare Risk Management* and *Hospital Access Management*

Meaningful use Stage 2 final rule released

Patient portals, behavior changes top list of challenges

An extra year to prepare to meet meaningful use requirements was welcome news with the release of the 2012 final rule for the Centers for Medicare and Medicaid Services (CMS) Electronic Health Record Incentive Program (meaningful use). Eligible hospital participants will report and attest to Stage 2 meaningful use criteria in FY2014, and eligible providers will report in calendar year 2014.

The additional year will give vendors time to develop certified electronic health records (EHRs) and give providers time to implement new software to meet the challenges of Stage 2. However, it's important that providers look beyond just meeting a list of requirements, says **Shane Pilcher**, FHIMSS, vice president of Stoltenberg Consulting, a healthcare information technology consulting firm in Bethel Park, PA.

"The purpose of Stage 2 meaningful use requirements is to stretch our capabilities," Pilcher says.

To effectively meet meaningful use requirements in a sustainable manner, organizations need to go beyond "checking boxes on a to-do list," he adds. "You need to see that you are working toward coordinated care."

The extra year to prepare to report will give organizations that started early an advantage as they have more time to fine-tune their applications and train staff. CMS is requiring participants only to report and attest to 90 days of meaningful use in 2014, which should allow time to upgrade and implement 2014 Certified EHR Technology. However, organizations that have not yet begun to prepare can't look at the extra year as more time to put off implementation of plans, says Pilcher. "If you are waiting, you are already behind schedule," he says.

Some of the changes between Stage 1 and Stage 2 are simple increases in the percentages of records required for compliance. For example, Stage 1 required 50% of patients admitted have demographic information collected as structured data, and Stage 2 requires 80%. *(See resource box at the end of the article for comparison charts and tip sheets from CMS.)* There are, however, some changes that will present challenges, says **Susan H. Patton**, a healthcare attorney at Butzel Long in Ann Arbor, MI.

Patient portals and access to information

"Stage 2 requires hospitals to provide patients with a portal to view online, download, and transmit information about their hospitals admissions within 36 hours of discharge," Patton points out.

"This runs contrary to hospital systems and culture that are accustomed to locking down patient information." Changing the mindset created by the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH) regulations will be a huge cultural challenge, she says.

In addition to the technical challenge to create a user-friendly, intuitive system that patients can use, hospitals also have to address the clinician component, says Pilcher. "This is more than an information technology issue," he says. "We have to make sure clinicians complete documentation in a timely

EXECUTIVE SUMMARY

In the 2012 final rule for the Centers for Medicare and Medicaid Services Electronic Health Record Incentive Program (meaningful use), the addition of one year to prepare for reporting and attestation requirements will enable organizations that are just now working on Stage 1 requirements time to implement electronic health records (EHR). Key challenges include:

- Cultural and behavior changes needed to provide patients with online access to medical information within 36 hours of discharge.
- Promotion of patient portals to create use of online service by at least 5% of patients.
- Cost and manpower needed to develop systems to comply with Stage 2.
- Current lack of broadband infrastructure in rural areas.

manner so the information is there for patients to access."

There are also clinical ramifications to providing access to information in a short timeframe, he adds. Clinicians need to pay attention to diagnostic or lab results that should be discussed with the patient to ensure proper interpretation of the results' meaning.

Staff and physician training should include a reminder for clinicians to invite patients to use the portal and to access their information, points out Patton. Stage 2 requires that 5% of patients actually access, view, or transmit information through the portal. This number is a reduction in the 10% that appeared in the proposed rule, but it will be a challenge to change patient behavior, Patton says.

"Hospitals need to take portal development very seriously, make it easy to use, and build in incentives for patients to access information," she says. *(See story at right for tips to make portals attractive to patients.)*

Lack of broadband networks

"Some rural and critical access hospitals will not be able to meet Stage 2 requirements," says Patton. "The Federal Communications Commission is in the process of creating broadband access to all areas of the United States, including rural areas. This is happening slowly, and many hospitals, patients, and healthcare professionals cannot make Stage 2 happen for lack of infrastructure."

Even rural or small hospitals in areas with broadband access will have trouble complying with Stage 2, says Patton.

"Compliance will be expensive, time-consuming, and require highly specialized information technology expertise," she says.

Hospitals that lack these resources can "buddy up" with other hospitals that can provide the support, Patton suggests. "This can be done through mergers and acquisitions, or through structural or contractual joint ventures, or vendor service contracts," she says.

If you are using vendors to bring the hospital into compliance with meaningful use requirements, be sure you plan long-term to sustain the program, Pilcher suggests. "Overseeing implementation is a full-time job for a large hospital or health system, and it will last three to four years," he says. Smaller hospitals that are relying upon vendors or consultants for implementation can use a combination of outside sources and staff to be sure employees gain the expertise needed to continue the program throughout the years.

A key to successful implementation of a meaningful use program is the buy-in of all employees, Pilcher says. "Don't position meaningful use as an information technology project," he says. Include clinicians as you evaluate tools and develop policies. "This is an organization-wide project that will improve patient care," he says.

Another important thing to keep in mind is that compliance with meaningful use requirements is a long-term strategy, not just a matter of completing specific tasks, says Pilcher.

"Don't stop at the requirements, look at them as a starting point," he suggests. "Meaningful use is not a sprint — it is a marathon."

RESOURCES/SOURCES

The Centers for Medicare and Medicaid Services provides comparison charts and tip sheets on the differences between Stage 1 and Stage 2 of meaningful use. To view and download the free documents, go to www.cms.gov. Select "Regulations and Guidance" from the top navigational bar, then under "Legislation," select "EHR Incentive Programs." On the left side of the page, choose "Stage 2." A list of documents as well as detailed timelines is displayed.

For more information about Stage 2 Meaningful Use, contact:

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• **Shane Pilcher**, FHIMSS, Vice President, Stoltenberg Consulting, 5815 Library Road, Bethel Park, PA 15102. Telephone: (412) 854-5688. Fax: (412) 854-5788. Email: spilcher@stoltenberg.com. ■

Encourage use of patient portals for compliance

Easy-to-use, valuable info will attract patient use

Meeting the Stage 2 meaningful use requirement that 5% of patients access their health information online to view, download, or transmit information requires more planning than just providing a patient portal, says **Shane Pilcher**, FHIMSS, vice president of Stoltenberg Consulting, a healthcare information technology consulting firm in Bethel Park, PA.

"This goes beyond a technology issue; it requires a change in behavior," he says. "To get people to change their behavior, you have to give them a reason to go online for health information."

The first step is to make sure you provide valuable, timely information, Pilcher suggests. He recommends that, in addition to viewing health information, a patient portal should enable a patient to do the following:

- schedule appointments;
- receive alerts to remind them of follow-up care;
- receive reminders about physicals or preventive

screenings that are due;

• use interactive tools to monitor health issues — for example, a tool that tracks weight loss and offers tips on ways to lose weight.

The key to making it easier for patients to contact you or learn about hospitals services is through your portal, says **Susan H. Patton,** a healthcare attorney at Butzel Long in Ann Arbor, MI. "If you offer instant messaging to departments or clinicians, you enable the patient to avoid looking through a telephone directory and calling, just to leave a voice message," Patton points out. "You can also offer links to health education or wellness classes offered by the hospital that can help patients better manage their health."

While training staff members to encourage patients to use the patient portal is important, consider offering a free service as an incentive to use the portal, suggests Patton. "A complimentary blood pressure screening or health seminar can be offered to people using the portal for the first time." If the portal is easy to access and the site is easy to maneuver, patients will be willing to use it in the future.

"I don't think most hospitals can create an effective patient portal internally," Patton says. "Hospital personnel have to unlearn and uncomplicate the language that is commonly used within a clinical setting and communicate in simple language that can be understood by patients of all educational levels."

Healthcare organizations that serve rural or low income populations also have to consider the lack of computer access for many of their patients, says Patton. "I've heard that hospitals are exploring a variety of ways to provide access for patients." Patton says that some hospitals are setting up computers in public locations such as libraries to provide access in the community.

"Hospitals need to approach the development of their portals in the same way banks and online retailers such as Amazon have," says Patton. "More people of all ages are using online services, but only if they make their lives easier, not more confusing." ■

Report offers guidance on security threats

Analysis of HHS breach data shows gaps

Business associate breaches represent the greatest threat to a healthcare organization's data security, according to a white paper produced by Miami-based accounting firm Kaufman, Rossin & Co.

An analysis of all of the breaches posted on the Health and Human Services website between Jan. 1, 2010, and Dec. 31, 2011, show that in 2010, 42 incidents occurred in which a covered entity's breach was due to a business associate. In 2011, 32 incidents related to business associates were reported. The report shows that one in five breaches occurred at a business associate's location. *(For more information about business associates and HITECH, see "Don't wait: Start reviewing BA agreements now,"* HIPAA Regulatory Alert*, November 2010, p. 1.)*

Some of the key numbers included in the report:

• 19.1 million — The total number of individuals affected by breaches of protected health information since reporting began in August 2009 through the end of 2011.

• 53% — Combined total of instances of theft.

• 9.7 million — Number of records compromised in the "other" category, which includes portables electronic devices, backup tapes, CDs, and X-ray films.

• Four — Florida's ranking, in 2010 and 2011, among states with the highest number of reported incidents. California was number one in 2011, and New York was number one in 2010.

• 71% — The percentage of computer breaches attributed to theft for 2010 and 2011.

Nearly twice as many individuals were affected by healthcare data breaches in 2011 versus 2010; however, fewer breaches were reported. The total number of unique covered entities involved in a breach also dropped in 2011 to 142 from 201 the year prior.

Changes in types of breaches for 2010 and 2011 were:

• theft: 53% of breaches in 2010, and 52% of breaches in 2011;

• unauthorized access: 19% of breaches in 2010, and 22% of breaches in 2011;

• loss: 16% of breaches in 2010, and 11% of breaches in 2011;

• hacking: 6% of breaches in 2010, and 6% of breaches in 2011;

• improper disposal: 6% of breaches in 2010, and 5% of breaches in 2011;

• unknown: 1% of breaches in 2010, and 3% of breaches in 2011.

Another part of the analysis looked at the compromised locations where data went missing. Laptops, paper, and "other" top the list. "Other" includes mobile devices such as tablets and smartphones.

Theft was the biggest threat to the safety of patients' health records. For breaches of information on laptops, 95% involved theft; for paper-based breaches, 26% involved theft. And for breaches of "other," which included mobile devices, 44% involved theft, and 42% involved loss.

The growing use of mobile devices by clinicians and staff members increases the risk of breaches due to theft, so report authors recommend strengthening

and enforcing policies requiring encryption as well as controlled access. *(For more information about protecting data on mobile devices, see "Beware of breach sources: Laptops and flash drives"* HIPAA Regulatory Alert, *May 2011, p. 1.)*

Despite the improvements in some categories, healthcare organizations still have a long way to go before patients' information is fully protected. The report identifies areas of vulnerability so healthcare organizations can focus risk assessments within their organization.

To download a copy of the full, free report go to www.kaufmanrossin.com. From the top navigational bar, select "White Papers." Scroll down to "HITECH Act three years later. Are health records safe?" ■

JOURNAL REVIEW

Who should own patient info to protect privacy?

Journal author examines patient ownership

Patient ownership of data included in electronic health records (EHR) offers little improvement over the protections provided by the Health Insurance Portability and Accountability Act (HIPAA), according to an article in the American Medical Association's *Journal of Ethics, Virtual Mentor*.[1]

As more healthcare organizations implement electronic health records and collect and store patient information in formats that can easily be transmitted and shared, the issue of the best way to protect privacy of information has been raised. Author Barbara Evans looks at the perceived benefits of patient ownership of data and the actual protections under HIPPAA. If patients owned their data, the same legal workarounds that infringe upon property rights — public health considerations and eminent domain — would apply to health information. While patients are concerned about the use of their information for research and development of services to improve patient care, patient ownership of information would provide no more protection than already provided by HIPAA.

REFERENCE

1. Evans B, Would patient ownership of health data improve confidentiality? *Virtual Mentor* 2012; 14(9): 724-732. ■

Resource available on health information law

Free service provides federal and state info

The George Washington University Hirsh Health Law and Policy Program in Washington, DC, has launched an online resource on federal and state laws governing access, use, release, and publication of health information.

The website, HealthInfoLaw.org, offers information on laws and regulations such as the Health Insurance Portability and Accountability (HIPAA) Act's Privacy Rule, the Health Information Technology for Economic and Clinical Health Act (HITECH) Act, and the Patient Protection and Affordable Care Act. It will include information on health information aspects of state health insurance exchanges as it becomes available. ■

Entertaining game enhances staff training

New way to present privacy and security info

Tedious" and "boring" are often the kindest adjectives used by healthcare employees to describe privacy and security training required in every organization. However, a new, free training program offered by the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology can make some of the training more enjoyable.

"Cybersecure: Your Medical Practice" simulates a game environment to provide insights into privacy and security issues by having the employee play a game in which they face scenarios they might encounter in their physician practice, a small clinic, or even departments within a hospital. As the game is played, the employee learns about proper procedures as questions are asked and feedback given. Scenarios include game characters asking if they can take their laptop home to work on billing; if records can be loaded onto a personal USB drive; and how to send patient information to a physician at a conference, without sharing passwords.

While the game is not intended to replace comprehensive privacy and security training, it does provide a no-cost solution for periodic refresher courses. To access the training module, go to www.healthit.gov. Select "Providers and Professionals." Under "Privacy and Security," select "Privacy and Security Training Games." ■

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Jury slaps hospital with $103 million verdict for premature delivery of now brain-damaged child

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News: On Aug. 24, 2012, a jury awarded the family of a 17-year-old girl with cerebral palsy upward of $100 million in damages and found that the birth hospital's negligence in caring for her pregnant mother caused premature birth and permanent brain injuries. According to the lawsuit, the hospital's staff failed to recognize that the mother was experiencing contractions and thus failed to prevent a pre-term delivery. As a result, one of the twin girls delivered suffered a brain injury, which caused cerebral palsy and other permanent neurological disorders.

Background: On Jan. 14, 1995, a woman pregnant with twins suffered a premature membrane rupture only 24 weeks into gestation and was taken to a local hospital for immediate care. Though not in active labor upon her admission, the woman began experiencing mild contractions shortly thereafter, and she was given intravenous magnesium sulfate (MgSO4) to halt the contractions.

The jury deliberated for three days and ultimately found the hospital vicariously liable for the actions of its employees.

A fetal-maternal medicine specialist was called in to examine the fetal ultrasound, and he diagnosed Twin A (the plaintiff) as having a partial premature rupture of the amniotic membrane, good fetal movement, and a normal anatomy. He recommended reserving caesarean section for obstetrical indications, and the woman was transferred to the antepartum maternity floor. Bed rest was ordered.

The woman remained stable through Jan. 17, but on the morning of the 18th, she had a second onset of early contractions. MgSO4 again was administered, and the contractions again subsided. However, the woman complained of intensifying abdominal pain and at 2:50 a.m. on Jan. 22, she was rushed to the labor and delivery unit. Her cervix quickly dilated from 6 to 10 cm, and the hospital's obstetrical-gynecological resident was called to deliver the twins. The infants were born three months early, and each weighed less than 2 pounds. Twin B was delivered without issue. As a result of the premature delivery, Twin A now suffers from cerebral palsy, spastic quadriplegia, grade I intraventricular hemorrhage, periventricular leukomalacia, hyperbilirubinemia, hyaline membrane disease, anemia, and cytomegalovirus disease.

At trial, plaintiff's expert stated that the hospital departed from an accepted standard of medical care by allowing the pregnant woman out of bed and for failing to keep her in a recumbent position. His testimony attributed the premature birth to the woman's level of activity dur-

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ing her hospitalization. The expert then cited the pre-term birth as the cause of the infant plaintiff's current medical conditions, along with the compression-decompression syndrome that occurred during delivery as a result of the doctors' failure to perform an episiotomy or caesarean section. Moreover, the woman's husband testified that on the night of the premature delivery, the hospital staff ignored his wife's complaints of abdominal pain and gave her only an allergy and anti-itch medication and forced the husband to go home.

The jury deliberated for three days and ultimately found the hospital vicariously liable for the actions of its employees. The family was awarded $103 million for pain and suffering, lost wages, and future medical expenses. Two individual doctors were named as defendants to the action, but ultimately they were not found to be liable.

What this means to you: This case, with its subsequent substantial verdict for the plaintiff, presents several interesting risk management considerations for healthcare providers. Allegations of failure to recognize and treat premature labor; failure to provide appropriate obstetrical assessment, diagnosis, and intervention within the prevailing standard of care; and failure to prevent premature birth are but a few of the risk concerns presented in this case. The situation of possible premature birth of twins automatically increases the risk of negative outcomes for the mother and the neonates, as well as increasing the potential for litigation for all parties involved in the process of caring for high-risk patients such as those identified in this case.

It is interesting to note the hospital proceeded with the risk of trial, often not the choice in what is frequently considered a "bad baby case," a case in which the plaintiff has suffered lifelong birth-related injuries due to alleged medical negligence. Perhaps mediation had been attempted over the years and failed, which left no option for the defense other than a jury trial. Therein, however, lies yet another risk for healthcare providers: the double whammy of a sympathetic witness combined with a sympathetic jury. Imagine introducing to the jury an attractive 17-year-old female who enters the courtroom in a wheelchair, cognitive issues evident, with plaintiff's expert witnesses assuring the jury that this situation is how this young woman will spend the rest of her life, all due to obstetrical care delivered outside of the prevailing standards 17 years prior. Presenting a plaintiff who invokes compassion, empathy, and/or sympathy increases the risk for the defense of a favorable verdict for the plaintiff.

It was indicated magnesium sulfate (MgSO4) was administered to the patient on two occasions in an attempt to retard premature labor. Orders for complete bed rest (constant recumbent position) versus bed rest with bathroom privileges (increase in physical activity) was a point of argument related to the standard of care. Assessment of the patient for signs and symptoms of premature labor was critical, particularly as the patient voiced complaints of intensifying abdominal pain. A risk reduction consideration here is the importance of accurate and appropriately descriptive documentation, medical record entries that clearly paint the picture of the care that was delivered to the patient. Thorough documentation of the assessment, monitoring, interventions, and treatment of patients can make or break a case for the defendants or the plaintiffs.

Another risk reduction consideration is that of effective and caring communication. Establishing a positive relationship with patients serves to keep lines of communication open. In this case, the patient and her spouse believed the patient's complaint of intensifying abdominal pain was being ignored. Care providers taking time to reassure the patient, sharing with her and her spouse the interventions that were being done and the rationale for the same might have aided in reducing the potential for patient and family anger and frustration, which often leads to thoughts of litigation. The perception of "forcing" the patient's husband to go home might have been averted had calm and soothing explanations and reassurance been provided at the time.

The plaintiff award was based in part on the failure to prevent premature birth. Of curiosity in the jury verdict is the fact that while Twin A suffered permanent congenital injuries due to the premature birth as a result of medical negligence, Twin B, obviously also born prematurely, did not. Understandable, based on plaintiff's arguments and witnesses, is the jury's finding of pain and suffering, future medical expenses, and lost wages for Twin A. At the same time, it raises the question of why Twin A suffered birth-related injuries and Twin B did not, if indeed the premature birth was a critical factor? This, in turn, raises the question of the root cause of Twin A's injuries. Premature birth? Medical negligence? Partial rupture of Twin A's membrane? Different care providers? Same hospital, same policies, and same procedures. Why then, the difference of a negative outcome for one and not the other? What were the mitigating factors in Twin A's birth versus Twin B's birth? Risk reduction strategies in this case include performance of a root cause analysis immediately following the birth event, peer review evaluation of the clinical record, and hospital policy and procedure review.

Two physicians initially cited as defendants in this case ultimately were not held culpable. The finding

of liability on the part of the hospital only, vicariously responsible and accountable for its employees and their actions, indicates the evidence presented in this case was not sufficient to support proof of appropriate care or interventions rendered. Risk management and risk reduction strategies are key in ensuring the safety and well-being of healthcare recipients in all healthcare settings.

Reference

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Hospital medication errors causes drug reaction that is nearly lethal — $121 million verdict awarded

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News: When seeking treatment for seizures, a woman wound up permanently disabled by an extreme and potentially fatal allergic reaction to prescribed medications. In a malpractice action brought on her behalf by her mother, three hospitals were found guilty of mismanaging the woman's medications, failing to properly respond to her symptoms, and failing to provide the treatment necessary to prevent permanent damage. The $121 million verdict allocated 90% of the liability between two city hospitals, 5% to a third hospital, 4% to one of its neurologists, and 1% to the plaintiff. The plaintiffs' award was reduced to $119.8 million per the fault apportionment.

Background: A 37-year-old mother of two suffered permanent brain damage, skin lesions, cerebral thrombosis, and burns to 80% of her body while seeking treatment for seizures in 2004. The woman, now incapacitated, was treated by several hospitals and prescribed Dilantin and Carbotatrol for her condition. Yet an extreme allergic reaction to the anti-seizure medications led to the development of Stevens-Johnson Syndrome, a rare and severe systemic disorder affecting the skin and mucous membranes. It often begins with flu-like symptoms, followed by a painful rash that spreads and blisters, eventually causing the top layer of skin to die and separate from the body. Once 30% of the body surface area is affected, the condition is referred to as toxic epidermal necrolysis. Both conditions can be fatal, with a mortality rate of 15% in Stevens-Johnson Syndrome patients and up to 40% for those with toxic epidermal necrolysis.

Most Stevens-Johnson Syndrome lawsuits are brought as products liability actions against the pharmaceutical companies who manufacture the medications. However, a growing number of lawsuits are being filed as malpractice claims against healthcare providers for failing to recognize and adequately treat Stevens-Johnson Syndrome at its onset. This was precisely the argument raised by plaintiff on behalf of her daughter at trial. More specifically, plaintiff alleged that the hospitals were negligent in their failure to properly prescribe medications, monitor the effects of said medications, and recognize that the woman's swollen face, eyes, and throat were symptomatic of an allergic response to the anti-seizure medication.

According to the trial, the woman returned to the emergency department when her swelling began, but she was discharged without seeing a neurologist and without instructions to discontinue the medication. Days later she visited a second emergency department where she was diagnosed with Stevens-Johnson Syndrome. Unfortunately, the woman's condition continued to worsen until she was again transferred to a third facility and treated with intravenous immunoglobulin, which reportedly stopped the progress of her skin lesions. The woman then began to show signs of respiratory distress, and unsuccessful attempts to oxygenate her resulted in cardiac arrest, coma, and permanent anoxic brain damage. Now 45 years old, she is unable to care for herself and requires full-time nursing care.

After a seven-week trial, the jury awarded the plaintiff $121 million in damages, which the defense described as excessive. Although the woman earned less than $40,000 a year prior to her hospitalization, the jury awarded her $10 million in lost earnings. Similarly, the jury award of $5 million for past medical expenses far exceeds the plaintiff's actual total costs, $583,000 since 2004. As for fault apportionment, the jury allocated 90% of the liability between two city hospitals, 5% to a third hospital, 4% to one of its neurologists, and 1% to the plaintiff. The plaintiffs' award was reduced to $119.8 million per the fault apportionment.

What this means to you: The jury verdict in this matter is surprisingly substantial. It is no surprise, however, that the defense considered the total plaintiff award to be excessive. It is difficult to understand, for example, how $5 million dollars is compensatory for actual incurred expenses of $583,000. Lost wages of $40,000 per year for a 37-year-old who might have continued to work for 30 additional years, with allowance for reasonable salary increases, would not begin to approach a lost wages sum equal to $10 million dollars. Full-time nursing care for 30-40 years presents a rational explanation for a several million dollar award in combination with salary loss and medical expenses; the extent of the award in this case makes a statement and appears to be punitive in nature.

As previously stated, there are risks associated with a jury trial, primarily from the well-disposed witness (plaintiff) and understanding jury aspect. This case, involving a young mother of two who incurs permanent brain damage and incapacity due to adverse and allergic responses to medication administration while under clinical care, has the potential to kindle an enormous sense of loss, injustice, and empathy in any juror.

A patient's right to expect safe and appropriate medication management when seeking medical care and treatment is supported through The Joint Commission standards, Medicare regulatory requirements, patient rights and responsibilities acts, and state agencies for healthcare administration, to name a few. While no one can consistently predict or prevent an allergic reaction in a patient to a medication, there is a duty to assess, monitor, and provide immediate intervention as needed to control and minimize negative outcomes when an allergic response is recognized. Knowledge of a patient's clinical and medication history, including previous modes of treatment and response to same, is one of the strategies used to reduce risk to the patient and the provider. The old adage, "start low and go slow" has been an effective means of administering a medication that is new to a patient. This approach allows for adequate monitoring and intervention time in the event the patient is observed to be experiencing a less-than-desirable effect from the medication. This approach also minimizes the amount of medication received by the patient in the event a reaction to the medication appears.

It is also the responsibility of the patient to report any untoward responses or concerns related to medication and its use to their healthcare provider, whether it is their primary care physician, community clinic, or emergency department personnel. It is also the responsibility of the patient to seek medical assistance and to comply with care instructions as provided by their healthcare team members.

In this case, a severe allergic reaction leading to the development of Stevens-Johnson syndrome left a 37-year-old woman permanently incapacitated and disabled. Not only did she experience the discomfort of a systemic reaction, skin lesions, painful rash, and blisters, but the failure to adequately treat her extreme response to anti-seizure medications led to cardiac arrest, coma, and anoxia, leaving her with permanent brain damage. In recognizing the patient's right to safe medication administration and the life-threatening, permanently negative outcome for this woman, the jury's award seems less excessive and perhaps rightfully punitive in assessing most of the liability to the hospitals and a physician. At the same time, the jury, in its appropriation of 1% liability to the patient, clearly understood and expressed its recognition of patient responsibility in this matter.

It is interesting to observe the medico-legal move to ultimately hold practitioners who prescribe medications responsible for monitoring and treating undesirable responses to the medications they prescribe instead of accounting liability to the pharmaceutical firms that manufacture the medications. Pharmaceutical companies are, without doubt, responsible to research and develop safe and well-tested products under the supervision of the Food and Drug Administration and their own risk management practices and protocols. The drug manufacturers, however, do not prescribe or administer the drug to patients, nor are they responsible to observe, monitor, and immediately respond to adverse reactions in patients. The medical team is front and center when it comes to medication administration and patient assessment.

Another risk issue is that of multiple practitioners treating and prescribing for the same patient, often without the knowledge or review of previous treatment modalities by other practitioners. The practice of medicine today has become highly specialized, losing in the specialization process the overall broad-spectrum knowledge of the individual patient the general practitioners (family doctors) of the past had enjoyed.

Whatever information, documentation, or evidence of care was presented at trial by the defense, it was obviously not sufficient in disproving the allegation of medical mismanagement and malpractice. The duty to care was established, the breach of that duty was clear, as evidenced by the patient's permanent injuries and loss of function, and irrevocable harm occurred. The jury award might be viewed as a wake-up call to healthcare providers that the patient's right to safe and appropriate care will not be compromised.

Reference

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