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INSIDE

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Expect the unexpected: Create a policy for outcomes you don't expect

JCAHO now requires a policy on what and when to tell patients

Now is the time to decide what you will do when a patient has an unexpected outcome — and new information from the American Society for Healthcare Risk Management (ASHRM) might help with developing a policy.

Whatever resources you use, you have to move quickly. New patient safety standards that went into effect July 1 require hospitals to initiate specific efforts to prevent medical errors and to tell patients when they have been harmed during their treatment. **Dennis O'Leary**, MD, president of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), says the new rules from his organization represent a major milestone in the nation's continuing pursuit of improvements in patient safety.

"Health care executives, physicians, and nursing leaders must

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radically change their thinking about medical mistakes," O'Leary says. "We need to create a culture of safety in hospitals and other health care organizations in which errors are openly discussed and studied so that solutions can be found and put in place. These new standards are intended to do just that."

Geri Amori, PhD, ARM, FASHRM, president of Communicating HealthCare, a risk management consulting firm in Shelby, VT, also is president of ASHRM. She says she doesn't think most health care providers have policies in place for the disclosure of unanticipated outcomes.

"Most people are still formulating their policies," she says. "The Joint Commission doesn't require you to have written policies and procedures — just a stated policy on how you'll handle these unanticipated outcomes. It's not an entire program you have to develop, but you have to go beyond just thinking about it and put it on paper."

You should tell when patient is harmed

The new standards underscore the importance of strong organization leadership in building a culture of safety, O'Leary says. Such a culture should strongly encourage the internal reporting of medical errors and actively engage clinicians and other staff in the design of remedial steps to prevent future occurrences of these errors. He says the additional emphasis on effective communication, appropriate training and teamwork found in the standards' language draw heavily upon lessons learned in both the aviation and health care industries.

A second major focus of the new standards is on the prevention of medical errors through the prospective analysis and redesign of vulnerable patient care systems, such as the ordering, preparation, and dispensing of medications. Finally, the standards make clear the hospital's responsibility to tell a patient if he or she has been harmed by the care provided. O'Leary notes that JCAHO's accreditation process has long placed a high priority on patient safety.

"However, these standards will clearly raise the bar," he says. "When the new standards are implemented, over 50% of all of JCAHO's hospital standards will relate directly to patient safety."

The new standards are based both on JCAHO's own six-year experience in overseeing the management of sentinel (adverse) events in accredited organizations and on the opinions of a special panel that included patient safety experts as well as leaders from governments, hospitals, insurance companies, universities, and consumer advocacy groups. Broad field input was also solicited in finalizing the standards.

Don Nielsen, MD, president of the American Hospital Association (AHA), says the new standards echo AHA policy for its members — about 5,000 hospitals and health care systems nationwide — but AHA policy even goes further, advising hospitals to tell patients about mistakes that don't cause any harm.

ASHRM document can help

A new document from ASHRM can be a key resource for a risk manager developing a policy on unanticipated outcomes. "Perspective on Disclosure of Unanticipated Outcome Information" examines the ethical and legal context for withholding information from a patient, liability issues and some practical concerns about how to disclose information.

The full document is available free to ASHRM members on the group's web site at www.ashrm.org.

The ASHRM paper does not spell out exactly how providers should address unanticipated outcomes, but it explores some of the issues and provides a framework that risk managers can use to write their own policies. Amori says ASHRM didn't seek to answer all the questions but rather to give risk managers a base from which to reach their own conclusions.

"It seems like common sense that you should tell patients what happened to them, but it hasn't always been that way," she says. "We used to feel like it was our right to hide information and hope they never knew. We don't feel that way any more — or at least most of us don't. Some still feel that very strongly."

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- Sentinel events and 'never events'

Amori says the risk management profession has seen a shift in recent years toward more disclosure of unanticipated outcomes and other information, but the new Joint Commission standard is forcing people to get off the fence and take a stand, one way or the other.

"We're making formal the idea that we're all going to play by the same rules," she says. "The Joint Commission wants you to talk it out, state what you're going to do and put it in a formal document. Now it has to be based on good solid thinking, not just spur-of-the-moment decisions."

The Joint Commission Patient Safety Standards include RI.1.2.2, which states that "Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes."

This requirement does not necessarily mean that the patient must be told of every negative event, Amori says. In some cases, informing patients of unanticipated outcomes could harm their recovery, but Amori says those will be rare circumstances.

In most cases, the patient should be informed of any significant unanticipated outcomes and especially those that constitute an injury to the patient. Health care providers have been reluctant in past years to provide full accounting for fear of inviting a lawsuit, but Amori says that can no longer be a reason to keep information to yourself.

"It won't be easy," she says. "I'm not saying a few institutions won't take hits because of it, but it will be worth it because we're doing the right

It's not what you say, it's how you say it

Here are some tips for how to disclose unanticipated outcomes, such as injuries that occur during surgery:

• Be careful about who actually delivers the news.

People's personalities come into play when it's time to have a delicate conversation. **Geri Amori**, PhD, ARM, FASHRM, president of Communicating HealthCare, a risk management consulting firm in Shelby, VT, and president of the American Society for Healthcare Risk Management, says she once had two doctors consult her about how to deliver the bad news of a surgical injury.

"I talked to one first and then I talked to the other one about what happened," she says. "Then I said to the first one, 'Let her do the talking.' How you say it has an impact on how it's heard and the first guy just didn't come across very well."

Grena Porto, RN, ARM, DFASHRM, director of clinical risk management and loss prevention services at VHA Inc. in Berwyn, PA, and past president of ASHRM, agrees, adding that "there are some doctors you don't want to talk to a patient about an error even if they did it because they're just not good with people."

In those cases, she suggests choosing from a number of other people, such as the patient representative, a supervising physician, the risk manager, or even the hospital CEO.

• Be prepared for any reaction.

Things can get dicey if the health care provider thinks he or she is delivering news of an unanticipated but insignificant outcome and the patient reacts with anger. If the provider is not ready for that, he or she may react by dismissing the patient's concerns, which would only escalate the tension.

Remind doctors and staff to look at the issue from the patient's perspective. What seems minor to the clinician may not seem minor at all to the patient.

• The risk manager should not hover too much.

It may not be a good idea for the risk manager to always be present when unanticipated outcomes are disclosed. If the matter is not serious, the presence of the risk manager can lead the patient to fear that something is being held back or encourage the patient to think of legal remedies.

In other words, Porto says, the presence of the risk manager can look defensive and cause the patient to wonder what the hospital is scared of.

A better solution might be to have the risk manager informed of when and where disclosures are made, and then be available for immediate consult or to join in the meeting if necessary.

• Have an authority figure disclose significant unanticipated outcomes.

When you must tell the patient of a serious development, such as an accidental injury by a doctor or staff member, it might be best to have that news delivered by someone in authority instead of the person who actually made the mistake. This applies even to doctors, Porto says.

"If the mistake is severe enough, they may want to hear it from someone very high up. They need that sometimes," she says. "That conveys that the organization is taking this matter seriously and has sent someone who is authorized to do something about it." ■

thing." Amori points out that "unanticipated outcome" doesn't have to mean something negative, such as an injury to the patient. Some unanticipated outcomes could be positive, such as when a patient requires a less extensive surgical procedure than anticipated. The ASHRM document provides a discussion of just what constitutes an unanticipated outcome. **(For an excerpt from the ASHRM discussion, see box, below.)**

Grena Porto, RN, ARM, DFASHRM, director of clinical risk management and loss prevention services at VHA Inc. in Berwyn, PA, and past president of ASHRM, says the Joint Commission standard and the ASHRM document should help risk managers look at unanticipated outcomes from the patient's perspective. Porto also consults and speaks frequently on the issue of dealing with adverse events. She cautions that the patient's perception must be considered carefully when deciding what is and isn't "unanticipated."

"It's unanticipated in terms of the patient's own expectations," she says. "With an infection after surgery, the provider may say it's not an unanticipated outcome because we know a certain percentage will get infections. But we need to shift to what the patient thinks and remember that the health care system is there to serve the patient, not to serve our needs."

Porto says she hopes the Joint Commission standard will help risk managers do what they know is right. She hears from a lot of risk managers that they know they should disclose and that the risk of a lawsuit isn't increased, but a lot of institutions have an ingrained reluctance to reveal information to the patient.

She suggests that the health care provider must create an overall culture that supports the assumption that patients should know everything about their health care — a culture that allows people to report problems without fear. Disclosing unanticipated outcomes will be very difficult in an institution that is still blame-oriented, she says.

The policy also needs to include a great deal of input from the front line health care worker, she says.

"This is not something that can be handed down from on high by the CEO and just be implemented," she says. "It will take lots of preparation. They don't teach this in medical and nursing schools, so you're sending people out to do something they haven't done before. You can't do a half-hour lecture and assume they're good to go."

Porto says the training should involve role

'Unanticipated outcome' can include good news

What is an "unanticipated outcome?" This is an excerpt from "Perspective on Disclosure of Unanticipated Outcome Information," a resource document available from the American Society of Healthcare Risk Management:

"The Joint Commission [Joint Commission of Health Care Accreditation, JCAHO] intent provision provides some insight into what constitutes an unanticipated outcome. It is a result that 'differs significantly' from what was anticipated to be the result of a treatment or procedure. In theory, the JCAHO statement does not restrict the discussion to negative or bad outcomes. However, the placement of this patient safety standard and intent in the context of the patient safety provisions has left many with the belief that only 'negative' unanticipated outcomes merit disclosure. Additionally, it appears that the intent is to link the requirement for disclosure of unanticipated outcomes to those results that constitute a renewal sentinel event.

"Some health care organizations may set their policy on the topic to match that of the JCAHO. Others may take a more expansive view. Thus it is quite possible that 'positive' unanticipated outcomes might occur as a result of tests or treatment. For example, a pregnant woman who underwent ultrasound was told she was carrying twins. During delivery, it is learned that she was carrying triplets. All three are delivered quite healthy. This 'unanticipated' outcome is positive, not negative. Another illustration involves surgery. A patient is informed that surgery will necessitate an extensive resection of his bowel and will definitely involve a temporary colostomy.

"Upon examination of the affected area, the surgeon determines that the patient's condition is not as bad as thought preoperatively. Although a resection is done for the patient, it is far less extensive and no colostomy is performed. The outcome is unanticipated, but positive in terms of the impact on the patient's body, lifestyle, recuperation, and long-term prognosis."

The statement goes on to say that "ASHRM believes that patients are entitled to information on both types of outcomes and that the disclosure of this information is part of the communication process that forms the context for the caregiver-patient relationship." ■

playing and demonstrate a support system, such as peers that staff can turn to for advice and reassurance.

"Don't underestimate the value of being able to talk to a peer immediately, that day, to discuss their feelings and be reminded that disclosure to the patient is probably the right thing," she says.

Health care providers also may need to set up different mechanisms for how to disclose unanticipated outcomes that are minor and those that are severe. **(For more advice on how to talk to the patient, see box, p. 87.)**

There are different ways to formulate a policy, but Porto says the important thing is to think about it thoroughly and calmly, before the crisis happens.

"Whatever you do, don't just turn people loose without any training or resources and tell them to give information to patients," she says. "It'll be a disaster if you do." ■

Consent form blamed in fatality at Johns Hopkins

A young, healthy woman who died after taking part in a Baltimore-based Johns Hopkins University asthma study was not fully informed of the risks involved, according to a committee formed to investigate the death.

The committee filed a report with the federal government's Office of Human Research Protection, in which it concludes that the informed consent form signed by 24-year-old Ellen Roche and other healthy volunteers was "inadequate" and "should not have been approved" by the Institutional Review Board (IRB).

Louis Becker, MD, a Hopkins professor of medicine who led the university's internal review of the trial, said during a during a press briefing that the consent form should have made clear that hexamethonium, one of the drugs administered in the study, is not approved by the Food and Drug Administration (FDA) and is no longer in clinical use. The form also should have stated that hexamethonium delivered by inhalation, as it was in the study, "was only used experimentally, never clinically," and that serious adverse events or death were possible, he says.

The woman developed a cough after inhaling a gram of hexamethonium as part of the trial. Within a month, she died of progressive hypotension and multi-organ failure. The committee criticized the researchers and the IRB for other shortcomings, and it echoed a number of concerns raised by the FDA. The FDA cited Alkis Togias, MD, for what it says was a failure to disclose the woman's unexpected reaction.

In addition, the FDA cited Togias for failing to seek the agency's approval prior to conducting the clinical trial, as well as changing the study protocol without permission from the IRB. Togias did not return a call seeking comment. ■

Landmark jury award for undertreating pain

In a case that observers say should be a red flag for risk managers, a California doctor has been ordered to pay $1.5 million because he undertreated a dying man's pain. The hospital's records, dutifully maintained in compliance with standards on pain management, proved to be the doctor's undoing because they showed that the man was in terrible pain and that the doctor must have known about it.

The case involved Wing Chin, MD, who treated an 85-year-old man at Eden Medical Center in northern California. The hospital staff assessed and charted the man's pain levels as required by the Joint Commission on Accreditation of Healthcare Organizations. Those records showed that he always reported that the pain was 7 to 10 on a 1-10 scale, with 10 being the "worst imaginable" pain.

Chin provided him with a 25 mg Demerol for pain. (The starting dose is typically 100 mg.) The doctor ordered further Demerol only as needed, rather than ordering a constant schedule that experts say is key to controlling severe pain. Chin did not provide any stronger pain relief.

Requests for pain relief went unheeded

Tucker says the nurses documented the pain and the family's repeated requests for pain relief but did not contact the doctor for a change in orders. The doctor's visits to the patient also did not result in any change.

The patient reported that his pain was a 10 on discharge. He died at home in terrible pain. His family claims that their pleas for pain relief were ignored.

Recent regulatory changes have upped the risk for providers when pain relief is inadequate, says **Kathryn Tucker**, JD, director of legal affairs with the Compassion in Dying Federation in Seattle. The Veterans Administration and the Joint Commission already require that pain be charted as a vital sign, which creates a record of pain management, for better or worse.

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

The California verdict was not the first warning. In an earlier case, a jury awarded $15 million, half of it punitive, from a nursing home where a patient had died in pain. The patient's family alleged that a physician had ordered morphine for the man's pain, but a nurse refused to administer it because she feared the patient would become addicted. She gave the man Tylenol instead.

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

In the California case, the family sued both the hospital and the physician, but the hospital settled out of court for an undisclosed sum of money. The jury's $1.5 million verdict probably will be reduced to $250,000 in compliance with state caps on jury awards.

The Alameda County Superior Court jury heard the case for a month, during which the doctor testified that he followed established protocols in prescribing pain medication. The jury deliberated four days and then voted nine to three against the doctor. (California law does not require a unanimous jury in such cases.)

James Geagan, JD, the lead attorney for the plaintiff, said, "Medical experts testified that there were numerous serious deviations from Standards of Conduct. They called Chin's conduct 'amazingly reckless' and 'inexcusable.'"

Geagan notes that the jury award could have been even higher. The jury could not reach a verdict on pain and suffering. Tucker also points out that the family sued the doctor for elder abuse rather than malpractice, because of provisions in California law. In an elder abuse case, the plaintiffs have to prove recklessness, a much higher standard than proving negligence, which would be required in medical malpractice.

"This case would have been easier to win in other states," Tucker points out. "This should be a real wakeup call. There is a serious risk to health care providers who won't provide proper pain relief." ■

Attempt to defy Jehovah's Witness strands a hospital

A hospital that agreed to perform a liver transplant on a Jehovah's Witness without using blood products was caught in the middle of a messy legal skirmish when the husband tried to circumvent the patient's wishes and her written declarations.

An attorney involved in the case cautions risk managers that similar circumstances could arise when clinicians get too emotionally involved in cases and try to thwart valid legal documents. In some situations, he says, such actions could leave hospitals vulnerable to serious charges of misconduct, to which juries would be unsympathetic.

Donald T. Ridley, JD, is the New York attorney who represented the Jehovah's Witness church elder who served as the durable power of attorney (DPA) agent for the patient, 34-year-old Maria Duran. She lived in Staten Island, NY, but sought treatment at the University of Pittsburgh Medical Center (UPMC) in 1997 because the hospital had a reputation for working well with Jehovah's Witness patients. Maria Duran was a devout Jehovah's Witness and would not accept any blood products, but her husband, Lionel Duran, was not and neither were her two teenage children.

Patient put wishes in writing

Ridley says Maria Duran made her wishes clear throughout her treatment at UPMC and her physicians understood that she would not accept any blood products. She executed a health care DPA form and appointed an elder from the local Jehovah's Witness congregation in Pittsburgh as her health care agent. Maria and Lionel Duran both lived with the church elder during their stay in Pittsburgh for the procedure.

The DPA form explicitly stated that Maria Duran would accept no blood of any type, not even her own stored blood, and it went on to say that "Family, relatives, or friends may disagree with my religious beliefs and with my wishes

expressed herein. However their agreement is legally and ethically irrelevant because it is my subjective choice that controls. Any such disagreement should in no way be construed as creating ambiguity or doubt about the strength or substance of my wishes." The hospital did not challenge the DPA and agreed to treat her under those conditions.

When an organ became available, Maria Duran underwent the transplant surgery at UPMC. Her body rejected the organ, but she never regained consciousness from the procedure. Her doctors went to her appointed DPA agent for permission to perform a second transplant. He consented and a second liver was transplanted a week later. Her body rejected the second transplant and she remained unconscious.

Maria Duran's doctors determined that she was in urgent need of transfusions, but did not ask the DPA agent for permission. Instead, the husband went to court to seek an emergency order appointing him guardian over his wife, which would usurp the DPA. Ridley says it is unclear how the husband came to take the legal action, but he suspects the hospital staff and physicians helped him.

"The staff knew the DPA was there. They had consulted him already and he was around the whole time," Ridley says. "He told me he overheard a hospital employee tell the husband they could help him get around the DPA. It seems to me the hospital was working with the husband and some other family members who wanted to get around the DPA and have him appointed guardian."

Court appoints husband as legal guardian

The risk manager at UPMC did not return Healthcare Risk Management's calls seeking comment. Ridley says the hospital denied orchestrating the court action. Hospital representatives said in court that UPMC was a third party waiting for instructions. But he says he suspects the hospital suggested the legal maneuver and put the husband in touch with a local attorney.

The DPA was in the hospital for long stretches and well known to the treating staff, but Ridley says he was never notified of the court hearing. The court accepted the husband's argument that an emergency order was necessary to save his wife's life and appointed him emergency legal guardian. He authorized the blood transfusions and Maria Duran received several over three weeks.

She died without ever regaining consciousness.

Despite her death, the DPA agent filed suit to appeal the lower court's decision granting the husband legal guardianship. The Superior Court of Pennsylvania unanimously reversed the lower court's order.[1] In its opinion, the court agreed that "the trial court violated Maria Duran's common law and constitutional rights when it appointed an emergency guardian to consent to a blood transfusion on [her] behalf . . . in spite of her religious beliefs and prior directives." The Superior Court went on to say, "when a patient has executed a DPA and named a personal representative, that choice is given paramount importance. Maria was not in need of a guardian. When the very situation contemplated by Maria's DPA arose, the court should have given effect to Maria's unequivocal directions. . . . The appointment of Lionel Duran as guardian for the express purpose of consenting to a blood transfusion contradicted Maria's clear and unequivocal directions. To hold differently would devitalize personal health care directives and devalue the common law right to personal autonomy."

Results could be worse for hospital next time

Ridley is sympathetic to the husband and the hospital staff who wanted to help Maria Duran live, but he says the Superior Court was adamant that the DPA was valid and should have stood. The hospital should have educated its staff better about working with a DPA and the difficulty of adhering to it once the patient is unconscious and in peril.

"From an ethical standpoint, it was almost unconscionable what was going on here," Ridley says. "I don't doubt they were trying to help the patient, but this shouldn't have happened. There were two lawyers and three judges who thought this was just a fine thing to do, but that is simplistic thinking, a domineering way of thinking to say that they can override her religious beliefs."

In this case, Ridley says it does not appear the hospital is vulnerable to any legal or civil consequences for ignoring the DPA. Even if Maria Duran had survived and was angry that she received blood transfusions, she probably would not have a case for battery against UPMC because it was operating under a valid court order when it provided the blood, he says. But he still suggests that hospitals are taking a huge risk by circumventing a legal document they don't like.

"It would be a novel claim, but I think it could

be a breach of fiduciary duty if you could show that the hospital actively encouraged or supported this kind of thing," he says. "You could say they went against their word when they agreed to provide care under these conditions. I'm not sure any provider would want this kind of messy story in front of a jury or in the public eye. When the DPA is so clear, I don't think there would be much sympathy for the provider, no matter how good their intentions. I could see a jury getting upset."

Conversely, Ridley says he thinks the hospital would not be exposed to liability if it followed a properly executed, valid DPA and the patient died as a consequence. He wonders if the hospital encouraged the legal maneuver because it feared a lawsuit from family members who disagreed vehemently with Maria Duran's wishes. Ridley says he can't understand why the first court granted the request for legal guardianship, except to suppose that everyone fell prey to the emotion of the moment. He predicts that any such action would never make it past an appellate court.

"The lasting effect of this could be that people don't take the DPA seriously and providers will think they can go around them whenever they disagree. Or it could be a wake-up call so you go out and see what your doctors and nurses are actually doing when confronted with these situations," Ridley says. "You have to respect the patient's clear instructions. Otherwise, do you survey the family members on every thing you do? Do you say the patient wants a heart bypass but then you go out and take a show of hands from the family?"

Reference

1. In *re Duran*, No. 805 WDA 2000 (Pa. Super. Ct. Feb. 21, 2001). ■

Blue Cross/Blue Shield, MN reach agreement

Blue Cross and Blue Shield of Minnesota (BCBSM), based in St. Paul, has agreed to allow an independent review committee to oversee its coverage decisions as part of a larger settlement with the state attorney general.

Officials of the Minnesota Blues plan and Attorney General Mike Hatch said the pact resolves allegations that the insurer routinely denied medically necessary treatment for children and young adults suffering from mental illness, eating disorders, and chemical dependency. In addition to the pact, BCBSM agreed to pay $8.2 million to resolve claims owed to the state of Minnesota.

Mark Banks, MD, president and CEO of BCBSM, says the state's lawsuit "compelled us to move more aggressively and quickly on steps we were taking to build a better system of care for those with mental health and eating disorders, autism, and chemical dependency."

According to the settlement, the health plan and the state will create a three-member committee to independently review certain mental health and chemical dependency claims denied by Blue Cross. The attorney general also may appoint an auditor to review BCBSM's books, records and personnel every six months and to assess the company's information flow with respect to mental health benefits.

The plan also must pay for treatment ordered by a court of law as long as that treatment is based on the evaluation and recommendation of a physician, licensed psychologist, or other specified health professional. ■

Liability insurance offered for Internet-based care

Healthcare First, a unit of insurance broker Arthur J. Gallagher & Co., announced recently the first professional liability insurance policy in the country developed specifically for managed care transactions that take place on the Internet.

RLI Insurance Co., a unit of Peoria, IL-based RLI Corp., will underwrite the policy. All applicants must be accredited by URAC, a Washington, DC-based health care standards-setting body.

Health care First's new policy is designed to address health care providers' web-related information technology risks and liability exposures, such as contingent bodily injury resulting from web site content and breaches of privacy.

"This new Internet liability coverage will indemnify electronic-based transactions that healthcare organizations use to manage, process, and disseminate information — including access

to this information by the consumer via a web browser," says John S. Fisher, assistant vice president at Healthcare First in San Francisco.

URAC, formerly known as the Utilization Review Accreditation Commission, has standards for health care web sites. The standards cover sensitive issues such as data disclosure and privacy as well as issues of content, linking, and accountability. ■

Docs who gave up narcotics licenses still not in NPDB

A new report says that almost 2,600 doctors who have voluntarily surrendered their federal narcotics-prescribing licenses over the past 11 years have not been reported to the National Practitioner Data Bank (NPDB).

The report was released recently by the consumer advocacy group Public Citizen. Sidney M. Wolfe, MD, director of Public Citizen's Health Research Group, urged the Department of Justice to make good on a 4-year-old promise to provide the NPDB with such information. The Drug Enforcement Administration (DEA) is supposed to report the physicians to the data bank.

"We urge you to immediately order the DEA to provide the NPDB with all the information on these physicians," Wolfe wrote in a recent letter to Attorney General John Ashcroft. "This is a matter of extreme urgency since every day that goes by with the NPDB failing to include information about these 2,592 doctors is a day when people making the thousands of daily inquiries of the NPDB are being misled by the absence of information concerning serious offenses by doctors."

Physicians who voluntarily surrender their DEA narcotic-prescribing licenses "do so only because of impending revocation, after having been found to have violated the federal Controlled Substances Act or to have engaged in other unacceptable medical practices."

Public Citizen compared information in NPDB's public use files (in which the names of physicians are deleted) with DEA actions listed in Public Citizen's "20,125 Questionable Doctors" database. Wolfe says there was not one report in the NPDB of a physician who surrendered his or her DEA license from Sept. 1, 1990 through Dec. 31, 1999. ■

Wrong surgery, wrong patient ID, wrong dosage

The big mistakes still happen, as evidenced by three recent events around the country in which doctors and hospitals had to explain major errors.

In Tampa, FL, Charles E. Cox, MD, the head of the Moffitt Cancer Center's breast cancer program was fined $5,000 for removing a woman's breast when he was supposed to remove only a tumor. The Florida Board of Medicine said its investigation determined that the doctor and operating room staff had confused her with another patient.

The Board of Medicine ordered Cox to attend five hours of risk management classes and give a one-hour lecture to his colleagues about how the mistake happened and how it could have been avoided. However, the board did not issue a formal reprimand.

Cox told the board he had performed a left mastectomy on the wrong patient, a 66-year-old woman with cancer of the left breast, in November 1998. The woman was scheduled for a lumpectomy but she was brought into the operating room when Cox called for the next patient, a woman of similar age who also had cancer of the left breast but was scheduled for a mastectomy.

In a hearing before the board, Cox admitted that he failed to verify he had the right patient before starting the operation and did not learn of the error until he was almost finished. The incident happened three years ago but only recently came to light.

Cox heads the Comprehensive Breast Cancer Program at Moffitt and is widely known and respected among cancer surgeons. He has performed 2,500 to 3,000 breast surgeries in the past 18 years.

In Washington, DC, a 9-month-old girl died at Children's Hospital from a classic medication error: Hospital officials said a misplaced decimal point caused a nurse to administer a massive overdose of morphine. The child was supposed to receive two 0.5 mg doses of morphine, but she was given two doses of 5 mg each. According to information released by the hospital, the error was the result of sequential mistakes by the prescribing physician, a transcriptionist, and a nurse. The doctor wrote the prescription as "5 mg" instead of the preferred "0.5 mg."

The hospital reports that the nurse had 10 years experience. Even though the prescription was for 10 times the normal amount of morphine, she injected it without confirming the dosage with the doctor.

Another type of error occurred at Lakeland (FL) Regional Medical Center, where the staff mistakenly told a woman that her daughter had died in the hospital. According to statements released by Lakeland Regional, the hospital chaplain called Bridget Brantley at home to tell her that her 41-year-old daughter was dead. After driving to the hospital, Brantley was consoled by the chaplain for half an hour before a nurse told her there was a mistake.

It turned out that her daughter was alive. Another patient on the same nursing unit had died, and a nurse had given the wrong medical chart to the chaplain, according to a hospital spokeswoman. Both patients had undergone chest surgery, but the dead patient was an 81-year-old white man and Brantley's daughter was a 41-year-old black woman.

The hospital apologized, sent a basket of flowers, and informed Brantley's daughter that she would not be charged for her stay. ■

Feds warn: Beware advice on illegal billing practices

Federal investigators told a Senate committee recently that some health care consultants are advising physicians about boosting their incomes in ways that often are illegal.

Robert Hast, an investigator with the General Accounting Office, told the committee that investigators attended two workshops and found that some of the advice was "inconsistent with federal law and guidance provided by the Department of Health and Human Services' Office of Inspector General."

Hast played a tape of a consultant advising doctors who discover errors in their favor to change their behavior in the future, but not to report the overpayments. The consultant said reporting the error is "the reddest of red flags."

Another consultant advised doctors to give preference to patients with higher-paying insurance plans. Medicare and Medicaid patients should not get the best appointment times, the consultant said. "So they get scheduled only 10 to 11:30 in the morning, and 2 to 3:30 in the afternoon. That's it. Now there are always exceptions, but we didn't want them getting the best appointment slots. We want the best appointment slots to go to the best payers."

Assistant HHS Inspector General Lewis Morris says his office is prosecuting several consultants for advising clients to pursue illegal billing practices. The Inspector General's office also issued a "Special Advisory Bulletin" warning providers that relying on a consultant "does not relieve a provider of responsibility for ensuring the integrity of its dealings with the federal health-care programs." ■

Cheney's heart doctor hit with a $15 million lawsuit

A $15 million lawsuit has been filed against George Washington University Hospital in Washington, DC, on behalf of a patient who died from an overdose of heparin.

According to the plaintiff's attorney, the man was admitted to George Washington University after suffering chest pains. He bled to death in the hospital due to an overdose of heparin. The primary treating physician was Vice President Dick Cheney's cardiologist, Jonathan Reiner, MD.

Willie Gary, JD, of Gary, Williams, Parenti, Finney, Lewis, McManus, Watson & Sperando in Stuart, FL, filed the medical malpractice suit demanding $15 million in damages in the Superior Court of the District of Columbia.

Negligence in administering heparin?

The suit alleges that the hospital's nurses negligently administered the heparin overdose and that several nurses and doctors negligently failed to identify the overdose, failed to appropriately assess and monitor vital signs, failed to appropriately monitor the patient's condition, failed to recognize and report medical complications to supervising health care providers, and failed to administer an appropriate antidote for the overdose.

At the time of his death, the 48-year-old patient was vice chancellor for business and finance at the University of Nebraska-Lincoln. He had been invited to Washington to give a speech. ■

Humana will pay $8 million to settle fraud allegations

Humana Medical Plan, one of the country's largest health maintenance organizations, will pay almost $8 million to settle charges that it billed Medicaid and Medicare for the same services.

Florida's attorney general announced the settlement, saying the company had not admitted any wrongdoing but agreed to revise its billing practices to ensure they don't double bill in the future. An investigation by Attorney General Bob Butterworth's office showed Humana, based in Louisville, KY, received duplicate payments from Medicare and Medicaid for the same people on a monthly, per capita basis from July 1, 1992, through Dec. 31, 2000.

Butterworth said Humana would reimburse all funds it collected from Medicaid when compensation was also provided through Medicare. ■

Manufacturer warns of patient warming device

The manufacturer of a popular patient warming device is warning risk managers that hospital staff often misuse it in a way that can lead to serious patient injury and lawsuits.

Augustine Medical in Eden Prairie, MN, makes the "Bair Hugger" device used for perioperative temperature management. Forced air warming devices consist of a warming unit, hose, and a special blanket, but Augustine issued a special

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There also are links to every article published in *Healthcare Risk Management*'s *Patient Safety Quarterly* and *Patient Safety Alert* supplements from January 1999 to present.

HRM's 2000 salary survey also is available in its entirety. The 2001 salary survey will be available in November.

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. ■

warning recently about a dangerous practice called "hosing."

"Hosing occurs when forced air warming devices are used improperly. Traumatic thermal injury — sometimes third-degree burns — can result, and some lawsuits have already been filed against hospitals and clinicians," the company says.

Company launches awareness campaign

Hosing is a practice in which clinicians fail to attach a blanket to the hose, instead using the hose itself to focus heat directly onto the patient. The company says this practice can lead to serious injury. Augustine Medical has launched a campaign to raise awareness of the danger of hosing through advertisements in industry periodicals, by sponsoring clinician speakers and case studies, through labeling on forced air warming devices and through other targeted efforts.

V. Doreen Wagner, RN, MSN, CNOR, a risk management claims specialist with WellStar Health System in Marietta, GA, says she has seen the negative effects of this dangerous practice.

"This is not a common practice among clinicians; however, it does occur and patients have been severely injured," she says. "My hope is that clinicians will realize the potential dangers of hosing and will work toward curbing this practice in their institutions."

Wagner has educated clinicians about hosing through presentations and articles on the subject. Forced air warming devices are typically used in surgery, trauma and emergency situations to keep patients warm and to bring patients' body temperature back to normal.

When used properly, forced air warming is not only safe, but it can be the most effective way to treat surgical hypothermia. Forced air warming prevents mild hypothermia — a core temperature between 33 degrees C and 36 degrees C — which is a common event during anesthesia.

For more information on hosing and how to stop it, contact Augustine Medical at (800) 733-7775. ■

Healthcare Risk Management's
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Improper treatment of broken arm results in brain damage: $6.5 million settlement in Washington

By **Jan Gorrie**, Esq., and **Mark K. Delegal**, Esq.
Pennington, Moore, Wilkinson, Bell & Dunbar, PA
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News: A child whose arm fracture was so severe the bone broke the skin was taken to an emergency department (ED), where the arm was temporarily set. After several delays in receiving appropriate follow-up care, a massive infection set in and was discovered too late for proper treatment. The child now suffers from permanent brain damage and epilepsy. Combined, the treating physicians and hospital settled the case for $6.5 million.

Background: A 9-year-old girl fell from the monkey bars at her school and broke her forearm. The fracture was severe enough to have caused the bone to pierce her skin. She was taken to a small community hospital ED, where the ED physician ordered X-rays that showed a fracture of the midshaft at the left radius and ulna. The ED doctor also noted that she had sustained a puncture wound, which the doctor presumed was caused by her bone breaking the skin.

The emergency physician called an orthopedic surgeon for a consultation. He was in surgery and asked that the patient be sent to his office.

The two physicians, who eventually became defendants in the controversial case, report conflicting versions of what happened next.

The ED doctor testified that it was critically important to advise the surgeon of the puncture wound so that he could prescribe antibiotics immediately. She contended that she:

- called the surgeon's office to impress upon his staff the need to tell him of the puncture wound;
- told the patient's mother that it was critical she take the child to the surgeon's office and tell him of the wound;
- highlighted in yellow the information regarding the puncture wound on her handwritten ED note and gave it to the patient's mother to give to the referral doctor.

The surgeon, the surgeon's staff, and the mother denied under oath having been on the receiving end of any of these steps. The surgeon claimed that if he had known of the wound, he would have had taken the child to surgery and placed her on antibiotics within six hours of the accident.

When the surgeon saw the child, he reviewed the X-rays but did not unwrap the arm. He scheduled a procedure to set the bones the next day and sent her home. The patient missed the appointment to have her arm re-set and, the next day, returned to the surgeon's office with significant swelling in the arm.

She was admitted to the hospital and a fasciotomy was performed with internal fixation to improve circulation. Due to postoperative symptoms of infection, an order for a blood work-up was written by an infectious disease nurse. When the orthopedic surgeon saw the order, he canceled it, saying it was unnecessary.

The next day, nurses noticed a brownish drainage, which had a bad odor. The nursing staff contacted the infection control director, who took a wound culture.

The blood work-up showed low sodium, which can cause brain swelling. Approximately one-half hour after the blood was drawn, the child showed indications of neurological compromise. The nurses gave the blood results to the surgeon, who failed to respond. Later that night, a nurse noted the dressings surrounding the wound were completely saturated and smelled foul.

The surgeon was called again, and he told the nurses to loosen the dressing. The nurse then re-contacted the infectious control director, who found the signs — in the blood-test results and wound drainage — consistent with a developing infection.

By the next morning, the patient showed signs of more neurological problems. Because the operating orthopedic surgeon was going out of town, the patient's care and treatment were transferred to the operating physician's partner, who then failed to address the critically low sodium level and failed to recognize she had developed a serious wound infection.

The child began having grand mal seizures. Despite the doctor's order for close monitoring, the nursing notes did not indicate that this occurred. The child was eventually transferred by helicopter to another hospital, where it was determined that hyponatremia (low sodium) caused the seizures.

The child now suffers from epilepsy and permanent, uncontrolled daily seizures, and through the process sustained significant, permanent organic brain damage.

The plaintiff claimed that care by the ED doctor and both orthopedic surgeons fell below the standard, and that their combined negligence created irreversible harm. The plaintiff maintained that the hospital failed to provide medically prudent follow-up care.

The defendants claimed that the others were at fault. The ED physician blamed the orthopedic surgeon for not following up on her notification of the gravity of the situation, surgeons blamed the ED physician and the hospital for not communicating, and the hospital blamed the surgeons for failing to respond to repeated calls.

And, in the end, all of the defendants settled for a combined amount of $6.5 million.

What this means to you: When errors on the part of health care providers are apparent, and particularly when coupled with an extremely poor outcome, it is often best to settle rather than to pursue costly litigation.

"In this instance, it was appropriate that all defendants settled, for not one of them communicated effectively with other health care professional and follow-up care was inexcusably absent after each encounter," says **Cheryl A. Whiteman**, RN, MSN, CPHRM, a risk manager for Cigna Healthcare of Florida Inc., whose opinions do not necessarily reflect Cigna's.

While the ED physician may have professed to have recognized the need for prompt follow-up treatment, it seems she did not provide any follow-up herself.

"The emergency department physician simply relied on leaving messages with another physician's office staff and with a distraught parent," Whiteman says.

"Even if she did leave these messages, it is obvious that physician-to-physician communication would have been more effective, if in fact, her message was to convey the fact of the puncture wound. Had the [ED] physician spoken directly to the surgeon, it is likely that the child would have been admitted to the hospital and immediately scheduled for debridement surgery.

Further, antibiotic therapy could well have been initiated in the ED or shortly after admission, which would have also mitigated the opportunities for the impending massive infection to set in.

"A critical aspect of physical examination is to visually inspect and palpate the injured area. Radiological films should be utilized to determine a diagnosis in conjunction with the physical findings. The surgeon was remiss in omitting this element in his examination," she explains.

"Another opportunity to get the child to surgery and start antibiotics was lost as a result of his incomplete physical exam," she says.

"Treatment at this juncture or in the [ED] would have prevented the circumstances that led to the missed appointment that further delayed necessary and required treatment. As a result, when this child was finally taken to surgery, she required a fasciotomy in addition to the internal fixation of the bones," adds Whiteman.

"Once [the patient was] admitted, both the physician and hospital staff further contributed to the child's infection and electrolyte imbalance. The infectious disease nurse should have had the

authority to write orders for blood work when clinically indicated without interference from the physician. This should routinely be a part of the check-and-balance system provided by an infectious disease program.

"Had the blood work been drawn as initially ordered, early recognition of a drop in her sodium level may have occurred.

"When the order was cancelled, the infection control director should have been notified rather than waiting another day when the wound starting draining brown, foul-smelling secretions. Those tell-tale signs were indications that things had gone too far. Without prompt recognition of hyponatremia, the child's neurological status was significantly compromised," she says.

"When the surgeon first failed to respond and then did not recognize the severity of the situation, the nursing staff should have utilized their chain of command," she adds. "The infectious disease nurse and infectious disease director should have been involved with notifying nursing administration and the chief of surgery, particularly when the signs of infection were so apparent.

"Prompt action was not taken and, in fact, when the operating surgeon handed the care of this patient to his partner, he was obviously not informed of the potential seriousness of her situation," observes Whiteman.

"Had the initial delays in surgical intervention and antibiotic therapy not occurred, the adverse sequence of events in this case may well have been averted. In the absence of prompt emergency department and/or surgeon's treatment, a more aggressive infectious disease program could have prevented the devastating epilepsy, uncontrolled seizures, and significant organic brain damage," she adds.

"Time is critical, particularly in the treatment of a pediatric patient. A missed or delayed diagnosis is always possible in the absence of repeated thorough assessments. Positive outcomes often hinge on effective communication between health care professionals. Further, a facility's infectious disease program cannot be effective if members of the medical staff are allowed to simply override infectious disease orders," Whiteman explains.

"And, finally, members of the nursing staff must advocate for the patient, which may include reporting potentially critical situations to administration when they believe appropriate care is not being provided.

"Had any or all these things occurred, this little girl's arm would have probably healed and she would have returned to a normal life," concludes Whiteman.

Reference

• *Jane Doe, Minor vs. Drs. Does, et.al.,* anonymous county (WA) Superior Court. ■

Share your expertise with other readers

Anyone wishing to be considered as a commentator for *Legal Review & Commentary* may contact:

• **Jan Gorrie** at (813) 639-9599 or send an e-mail to: jan@penningtonlawfirm.com. ■

Genital mutilation: $2 million verdict

News: While recovering from extensive knee surgery in a hospital's rehabilitation unit, plaintiffs alleged that a patient's penis, genitals, and scrotum were mutilated. The patient died, but it was unclear if the attack occurred pre-mortem or postmortem. The survivors claimed the incident was the result of poor hospital security. The jury agreed, awarding $2 million in compensatory damages to the decedent's wife and adult children.

Background: A 58-year-old man went into the hospital for bilateral knee replacements. Eight days after surgery, as he was recuperating in the rehabilitation unit, an unknown assailant cut off the patient's penis, genitals, and scrotum. This mutilation occurred on Halloween night, apparently sometime between 4 and 4:30 a.m.

However, the mutilation was not officially discovered or reported until after the body was taken to a funeral home.

A wrongful death suit was brought by the patient's widow and their four adult children against the hospital and hospital employees who handled the body.

The plaintiffs claimed the death occurred because the hospital failed to provide the patient with a reasonable level of security. Before trial, the hospital denied any responsibility in the matter, claiming that the decedent's body must have been mutilated at the funeral home after the body had been transferred from the hospital. The hospital maintained that patient had a fatal heart attack, the sole cause of death.

The hospital eventually admitted that the mutilation occurred on its premises, but denied that it was the result of poor security or that the mutilation was the cause of death. The two hospital employees who had handled the decedent's body were eventually dismissed from the suit. Prior to trial, the parties came close to reaching a $1.5 million settlement, but the plaintiffs withdrew from the settlement negotiations when the defendant demanded that the plaintiffs sign a confidentially clause.

The plaintiffs then made a pre-trial demand of $1.5 million without a gag order, which the defendant unsuccessfully countered.

During closing arguments, the plaintiffs' counsel argued that the defendant hospital was clearly responsible for negligent security, regardless of whether or not the decedent's death was caused by the mutilation.

The jury found for the defendant on the claim of wrongful death, yet unanimously awarded $1.5 million to the patient's widow and $125,000 to each of the four adult children for a total verdict of $2 million in compensatory damages.

What this means to you: "Hospitals are 24/7 operations, and security staff are generally employed around the clock. Unfortunately, unless the hospital had reason to believe that there was a specific threat to a particular patient and the threat could be reliably verified, special security measures would not usually have been taken even on spooky holidays or full-moon nights — even though these are known for heightened levels of criminal activity. It is simply not possible for any hospital's security force to prevent every action that could take place in every patient room," says **Paul Ford**, director of safety, security, and transportation at Tampa (FL) General Hospital.

"For instance, if the patient was sedated, an approved visitor or staff member could have gone into the room, closed the door, committed the act, and left before anyone knew what happened. Unfortunately, this could have happened at any hospital," he points out.

"While there has been some debate in the nursing home industry about placing monitoring cameras in individual patient rooms, the debate has not yet reached the hospital arena. In either setting, it is possible for patients to be unable to call out for assistance, given their underlying situation, whether that be an age or sedation factor. However, much of the rationale for installing individual monitoring devices in nursing homes is related to long-term care issues such as abuse and failure to turn, change, or feed patients, not necessarily isolated instances of misdeeds," adds Ford.

"What is actually more disturbing in this case than the act itself, is how the facility handled the situation. Obviously, the facts are disdainful and bizarre, but it seems that the hospital was in denial and did very little to assist the family in resolving the situation," he adds.

"From the start it seems that the hospital was engaged in some covert cover-up, first claiming the act did not take place at its facility, and then once it finally admitted it occurred somewhere on its property, the hospital seemed more concerned about getting the family to sign the gag order, Ford explains.

"Generally, people respond better to open honesty, even when bad or highly unusual things have happened. It seems that this case was so demented and seemingly difficult to handle with the family that the hospital simply went into denial rather than responsibly addressing the situation. In the end, it probably only made the solution more expensive," he states.

Reference

• *Marion vs. Columbia Medical Center*, Maricopa County (AZ) Superior Court, Case No. CV 97-20134. ■