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Surgeon loses $3.3 million verdict after saying to family that he's sorry

Real problem may be that he said more than that

A $3.3 million verdict against a doctor who apologized to his patient's family for her death is leading some healthcare professionals to wonder if the push for apologies and transparency has a dark side. Are risk managers encouraging physicians to say something that actually will work against them in court?

Michael Knapic, DO, and his attorney certainly think so. They say he is being punished for expressing regret about his patient's death and that the Ohio apology statute intended to protect such statements has no value. Others say Knapic lost the case not because he said he was sorry, but because of what else he said.

The plaintiff, **Leroy Davis** of Glenmont, OH, sued Knapic, of Wooster Orthopaedics and Sports Medicine in Wooster, OH, after his 49-year-old wife, Barbara Davis, passed away following a lumbar microdiscectomy performed on July 23, 2004. The plaintiff accused him of severing Davis's left common iliac artery, lacerating her iliac vein, and "failing to timely diagnose and treat" the resulting medical condition, according to court records.

According to the trial transcript, Davis testified that, after the surgery, "Dr. Knapic … said the back surgery went OK but he nicked an artery, and he takes full responsibility and it was my fault." Later, the jury heard

EXECUTIVE SUMMARY

A plaintiff was awarded $3.3 million from an Ohio orthopedic surgeon in a case that hinged on how the surgeon told the patient's family he was sorry for the outcome. The doctor argued that his comments should have been protected by the state's apology statute.

- An appeals court ruled that while the apology was not admissible, the doctor's statement of responsibility was.
- The doctor claims that his statement taking responsibility was part of the apology statement and should be protected.
- The case illustrates the importance of teaching physicians exactly what to say and what not to say when apologizing.

Davis's adult daughter, **Pamela Bickel**, testify that, after the surgery, Knapic "said as far as the back surgery, everything went fine, but … when they rolled her over that her blood pressure started to drop and they did an ultrasound and s[aw] that she was bleeding, that at some point an artery was nicked. . . . And he said, 'It's my fault. I take full responsibility.'"

During her pre-trial deposition, Bickel reported that Knapic said he was "sorry." However, that testimony was not submitted as evidence during the trial.

Broad interpretation needed, doctor says

Both sides involved in the case agreed that Ohio state law prohibits a healthcare professional's statement of sympathy as evidence in malpractice cases. They differed sharply, however, on whether or not admissions of liability or fault could be admitted.

Knapic's attorney, **Christopher Humphrey**, JD, of Canton, OH, argued that the definition of "apology" implies an expression of fault and admission of error. The state law intends to protect the physician-patient relationship following adverse medical events, he told the court, and so the legislature must have wanted Knapic to be able to say he took responsibility without that being used against him in court.

The plaintiff, however, argued that the law does not exclude a direct admission of fault as evidence. The trial court agreed. Knapic and his practice group challenged the verdict, but the Ohio Court of Appeals upheld the lower court's ruling. The court of appeals stated in its decision that the intent of the law is "to protect pure expressions of apology, sympathy, commiseration, condolence, compassion or a general sense of benevolence, but not admissions of fault." *(See the story on p. 111 for more on how to avoid admissions of fault.)*

The court went on to explain that a "physician may speak with a patient or a patient's family members and express his heartfelt sympathy for their pain following a negative outcome without risk of that expression of sympathy being used against him in court." *(See the story on p. 112 for more details from the appeals court opinion.)*

The case will be appealed to the Ohio Supreme Court, says **Christopher Humphrey**, JD, an attorney with the law firm of Buckingham, Doolittle & Burroughs in Canton, OH. The appeals court interpretation of the Ohio apology law effectively renders the statute meaningless, he argues. "I think a risk manager has to advise people now that until this is clarified you can't really say anything because we don't know what is fair game," Humphrey says. "The court is essentially saying that you can say you're sorry, but anything after that is an admission against interests."

Knapic denies that is admitted liability to the patient's family, Humphrey says. The case should have hinged on whether the surgeon was liable for nicking the artery or whether that was a known risk of the procedure and the doctor did not violate the

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standard of care, he says. Instead, Humphrey says the trial was focused on what the surgeon said to the family afterward.

Under the rulings of the trial court and appeals court, Humphrey says, a doctor can say only "I'm sorry" and not much else. That is not realistic, he says. "If you say anything other than 'I'm sorry that that happened,' you're essentially saying 'I violated the standard of care in a way that directly and proximately resulted in harm, and you're entitled to damages,'" he says. "In that case, the statute is meaningless. If you say you're sorry, and the family and asks 'for what?' and you say you can't comment any further, you've just made it worse."

SOURCES

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Take a pause after the apology

Physicians who already were skeptical about apologizing to patients might start citing the recent malpractice case against **Michael Knapic**, DO, as evidence that, rather than diminishing their malpractice risk, an apology could seal their fate in court. That's a misinterpretation of this case, says **Doug Wojcieszak,** founder of the Sorry Works! Coalition in Glen Carbon, IL, which promotes apologies from healthcare providers.

Telling the family he was sorry was not what lost the case for Knapic, Wojcieszak says. It was telling them he was responsible.

"The real issue is that physicians have to be careful about exactly what they say and can't blurt out confessions of liability in addition to saying they're sorry about the events that transpired," Wojcieszak says. "For me, a better statement following the back surgery would have been, 'The back surgery itself went fine, but when she was rolled over, the blood pressure dropped and a ultrasound discovered bleeding. I am sorry this happened. And we are going to learn how this happened.'

Wojcieszak goes so far as to say the Ohio apology statute and all others like it are unnecessary and can even be counterproductive when they lead to debates such as the one in this case.

Some of the most successful disclosure programs in the country operate without apology laws, and even those that do have laws on their state books don't pay attention to them, he says.

"What's the secret to their success? Good event management. Teaching their staff to be proactive with empathy and customer service, but pause before admitting anything," he says. "Even if the staff believes a mistake was truly made, there is plenty of time down the road to cross that bridge with the patient and/or family. Hunches in the heat of the moment are often wrong, but once you've admitted fault, it's hard to go back over that bridge."

And when you try to backtrack, it will look like a cover-up, Wojcieszak cautions. "The patient or family will truly start to hate you, and litigation will soon follow," he says.

That pause is crucial, he says. Physicians must learn how to say they are sorry without babbling on to say it was their fault, which is a fine distinction sometimes but absolutely vital, Wojcieszak says.

Fault comment was the real problem

Such control can be difficult in the highly stressful, emotional conversation with a patient or family member after a bad outcome, says **Grena Porto,** RN, MS, ARM, CPHRM, principal with QRS Healthcare Consulting in Hockessin, DE, and former president of the American Society for Healthcare Risk Management (ASHRM) in Chicago. For many people, their sympathy and regret compel them to take responsibility, and they say too much, Porto says.

"As human beings, we like to confess. We really buy into the notion that confession is good for you and makes you feel better," she says. "That's what I think that was, an attempt to for himself to feel better by taking ownership and responsibility. You can do that, but there's a risk. You can't unring the bell. You have to be prepared to live with that statement."

In the Knapic case, Porto says the court correctly distinguished between the surgeon's apology and his additional statement of responsibility. Risk managers should urge physicians to consult with them for a primer on exactly what to say and what not to say before speaking with the patient or family, Porto says. *(See the story on p. 112 for more on how to word an apology.)*

"Taking responsibility is a statement of fact, not

an apology," Porto says. "Even saying 'I nicked an artery' is not necessarily an admission of liability, since that is a known risk of the procedure. But saying 'It was my fault' is hard to get away from. The apology itself is not the reason this guy was found liable." ■

Court weighs 'I'm sorry' vs. 'I'm responsible'

In the recent opinion from the Ohio Court of Appeals concerning a malpractice case against Michael Knapic, DO, by plaintiff **Leroy Davis**, the court carefully considered the question of what the Ohio legislature meant to protect with its apology statute.

"Dr. Knapic has argued that drawing a distinction between an acknowledgment of fault and an expression of sympathy violates the intent of the statute because the word 'apology,' as commonly defined, includes an expression of fault, admission of error, or expression of regret for an offense or failure," the court wrote in its opinion. "Dr. Knapic has also argued that the statutory intent behind Section 2317.43 is to avoid the obvious detriment to the physician-patient relationship that can follow an adverse medical outcome, especially if the doctor refuses to show some compassion and speak to the patient or the family. According to Mr. Davis, however, a direct admission of fault and responsibility is not what is intended by the plain and unambiguous words of the statute."

The court noted that among the 36 states that have adopted similar laws, the majority explicitly distinguish between statements of sympathy and admissions of fault or liability. Under California's apology law, for example, only "[t]he portion of statements … or benevolent gestures expressing sympathy or a general sense of benevolence relating to the pain, suffering, or death of a person involved in an accident … shall be inadmissible as evidence of an admission of liability in a civil action. A statement of fault … which is part of, or in addition to, any of the above shall not be inadmissible pursuant to this section."

Seventeen of the states that have explicitly distinguished between expressions of sympathy and admissions of fault have chosen to admit expressions of fault while excluding from evidence any part of a statement that expresses sympathy. On the other hand, eight of the states that have explicitly made the same distinction between expressions of sympathy and admissions of fault have chosen to exclude both types of statements from evidence.

"For instance, by adding the term 'fault' to the same litany of sentiments found in Ohio's statute, Colorado's statute makes it clear that both admissions of fault and expressions of sympathy are inadmissible. In Colorado, 'any and all statements … expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a health care provider … to the alleged victim [or] a relative of the alleged victim . . . which relate to the discomfort, pain, suffering, injury, or death of the alleged victim as a result of the unanticipated outcome of medical care shall be inadmissible as evidence of an admission of liability or as evidence of an admission against interest.'

Knapic's attorney argued that the word "apology" could reasonably include at least an implication of guilt or fault. But the court noted that an apology does not always imply taking responsibility, saying that "when hearing that someone's relative has died, it is common etiquette to say, 'I'm sorry,' but no one would take that as a confession of having caused the death."

"Thus, looking to the rules of grammar and common usage, the appearance of the term 'apology' in Section 2317.43(A) creates some ambiguity. Reading the term in context with the litany of other sentiments to be excluded under the statute, however, leads us to believe the General Assembly did not intend to include statements of fault within the statute's ambit of protection. The other five protected sentiments clearly do not convey any sense of fault or liability, indicating that the statute was intended to protect apologies devoid of any acknowledgment of fault."

The court concluded that "[t]he statute was intended to protect pure expressions of apology, sympathy, commiseration, condolence, compassion or a general sense of benevolence, without excluding from trial a medical professional's admission of fault for a claimed injury."

The entire text of the appeals court opinion can be found online at http://tinyurl.com/3lqzbem. ■

Must be 50 ways to say you're sorry

Paul Simon said there were 50 ways to leave your lover, and **Grena Porto,** RN, MS, ARM, CPHRM, says there are at least that many ways to

say you're sorry … without admitting responsibility.

Porto, a principal with QRS Healthcare Consulting in Hockessin, DE, and former president of the American Society for Healthcare Risk Management (ASHRM) in Chicago, rejects the idea that an apology naturally segues into an admission of guilt. It just has to be phrased correctly.

If you only say "I'm sorry" and leave it at that, then the patient is likely to ask, "Sorry for what?" And in the heat of the moment, a stressed and regretful physician might blurt out something like, "I'm sorry for nicking the artery and causing her to bleed out."

Above all else, don't use words like "my fault" or "my mistake" or "I made an error," she says. "Once you use a word like 'fault' in this scenario, you're behind the eight ball," Porto says. "You may regret that later."

In the immediate aftermath of a bad outcome, the right way to apologize is to say you're sorry for the situation and the effects on the patient, rather than stating as fact what caused that outcome, she says. A full statement of what happened and why might come later after a proper investigation.

These are some possible ways to apologize without admitting fault:

"I'm sorry this happened to you."

"I'm sorry for the suffering this caused you."

"I'm sorry this means you will have to undergo additional treatment."

"I'm sorry this didn't go as well as we hoped."

"I'm sorry this procedure was not a complete success."

"I'm sorry that you developed complications."

"I'm sorry that there was a bleeder during the surgery, and we did everything we could to repair it." ■

How to disclose errors by another provider

Disclosing a medical error is never easy, but it can become especially complicated when you need to tell the patient that a previous provider was in the wrong. This delicate situation often requires communication with the other provider before you tell the patient anything.

Once you have identified that an error occurred with another provider, or you suspect so, there should be no question about following up, says **John C. Metcalfe,** JD, FASHRM, vice president of risk management services with Memorialcare Health System in Fountain Valley, CA. It is unacceptable to simply ignore the situation and make no effort to inform the patient, he says. *(That does happen, however. See the story on p. 114 for discussion of a case in which the hospital did not inform the patient's family.)*

EXECUTIVE SUMMARY:

Discovering that a patient has been harmed by the error of a previous provider can lead to questions of whether to inform the patient and how to do so. Most experts agree that the patient should be informed, but the process should be handled carefully.

- In most cases, you should contact the other provider before notifying the patient.
- Be careful not to jump to conclusions before studying the situation and speaking with the other provider.
- Liability is possible if the situation is handled poorly.

However, in many situations, it is important that you not simply tell the patient as soon as you suspect there has been an error, he says. The second provider should contact the first and discuss the concerns, he says. "We contact the other hospital and make a determination in collaboration with that hospital about the disclosure," Metcalfe says. "We give the other hospital the opportunity to follow their own procedures for disclosure, because they might not have known about the error or the consequences of the error."

That collaboration might not always be possible, however. If a patient's X-ray in the ED reveals a retained sponge or needle from surgery at another facility, for instance, Metcalfe says there would be no time for collaborating because the patient would need immediate surgery. In such a case, Metcalfe's hospital would inform the patient right away and then alert the other provider about the finding.

Even determining the provider that committed the error can be difficult, Metcalfe says. If the patient had undergone a series of surgeries, for instance, it might not be clear who left a sponge behind. "We've had cases in the past where the patient indicated they had undergone a surgery fairly recently, and the easy assumption is that's where the error occurred," Metcalfe says. "Then we found out that the error actually occurred up the road a bit more, two or three surgeries back."

When the provider at fault is not clear,

Metcalfe's hospital tries to contact all the providers that might be responsible to alert them and let them figure out the answer. But he says the hospital ultimately is not obligated to determine which other provider committed the error and sometimes must simply inform the patient and let him or her pursue the matter further.

Each case must evaluated individually, says **Vivian Barker Miller**, CPHQ, LHRM, CPHRM, FASHRM, senior risk management specialist with American Society for Healthcare Risk Management (ASHRM). There is no single correct way to address disclosing another provider's error, she says. "The goal must be to do the right thing for the patient, the family, and also the provider," she says. "Don't forget that this will be a significant issue for the provider. They are going to feel awful about this error and the consequences."

Although swift disclosure is necessary in some cases, providers usually should take a step back and carefully consider the situation before informing the patient that another provider erred, says **Matson Sewell,** MS, MPH, CPHRM, principal with Matson Sewell Healthcare Consulting in Sacramento, CA. Sewell has held multiple risk management positions with healthcare providers and was chair of an ASHRM task force on disclosure after adverse outcomes.

Providers should be cautious in declaring that another hospital erred because it did not treat the patient as they would have, Sewell says. *(See the story on p. 115 for one doctor's experience with disclosing another's error. See the story on p. 115 for potential risks from being too quick to disclose.)*

First determine if the other hospital's treatment falls into an acceptable range of treatment, Sewell advises. "Are we assuming that if they didn't do it exactly the way we would have done it, that it's an error?" she says. "Sometimes it's absolutely clear cut that they took the wrong approach, but I've often seen people assume it was a wrong approach when it really just wasn't the way they would have done it."

SOURCES

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Parents weren't told link between error and death

The question of whether to inform patients of a previous provider's error was highlighted recently in a discussion posted by the Agency for Healthcare Research and Quality (AHRQ). **Thomas H. Gallagher**, MD, associate professor in the Departments of Medicine and Bioethics and Humanities at the University of Washington in Seattle, discussed the case of a 4-year-old boy whose brain swelling was not detected in a CT scan.

The hospitals were not named. Gallagher provides this summary of the case: The boy presented to an emergency department (ED) with three days of vomiting associated with lethargy and fevers. A CT scan was performed, and the radiologist reported the results were normal. A rapid test for streptococcal pharyngitis (strep throat) was positive, and the child was admitted to the hospital for ongoing care and given intravenous hydration and antibiotics. Over the next 24 hours, the child became increasingly confused, disoriented, and lethargic. The following morning, his condition worsened, and he had a respiratory arrest. He was placed on a ventilator and transferred to the intensive care unit (ICU).

In the ICU, he was noted to have fixed and dilated pupils on neurologic exam, a sign of serious neurologic injury. A repeat CT scan of the brain revealed severe cerebral edema (swelling of the brain) with evidence of herniation of the brain through the base of the skull.

He was transferred from this hospital to a tertiary care center for ongoing management. At the tertiary care center, the child was evaluated by neurology and neurosurgical teams. Further testing revealed a diagnosis of venous sinus thromboses (blood clots in the veins of the brain), which had led to edema and herniation. Unfortunately, the brain damage was too advanced, and the child was determined to have no chance to survive.

As part of their routine evaluation, the neurology, neurosurgical teams, and the radiologists at the tertiary care center reviewed the CT scan that had been performed in the original ED. Although the findings were subtle, they found that the scan

was not normal (as had been reported) but demonstrated clear evidence of cerebral edema. The initial hospital had not recognized these findings and therefore had not pursued further work-up for the cause, which would have been indicated. The neurology and neurosurgical teams thought that if the brain swelling had been recognized at the time, the child could have been transferred earlier, received surgical management, and might have survived.

When it was clear the child could not survive, the pediatricians met with the mother and father to explain that their child was brain dead. Angry and upset, the parents asked repeatedly, "How could this happen? How could the CT scan have been normal and then be so bad in less than 48 hours?"

Due to concerns of legal liability, the hospital administration and the risk management department at the tertiary care hospital had instructed the physicians and other providers to not disclose the misinterpretation of the original CT scan. In fact, they were instructed not to comment on the care provided by the initial hospital in any way. Therefore the parents were never told that an error had been made that may have contributed to their child's death.

Gallagher concludes that the tertiary care hospital was wrong. "In the case discussed, the two hospitals should have had an open dialogue about the case," he writes. "If they determined that a clear error occurred, providers should have found a way to disclose the error openly and honestly to the parents. This outcome would have been ethical, collaborative, and patient centered.

The entire commentary can be found online at http://tinyurl.com/444oca3. ■

Doc tells about error, other provider unhappy

Doing the right thing doesn't guarantee that everyone is going to be pleased, says **Frederick S. Southwick**, MD, professor of medicine in the Division of Infectious Diseases and quality projects manager for the senior vice president for health affairs at the University of Florida Shands Health System and the University of Florida College of Medicine in Gainseville.

Shands has a policy of transparency when it comes to medical errors, Southwick explains. When an error occurs, the policy is to immediately inform the patient and offer restitution. The result has been a marked reduction in malpractice insurance premiums, Southwick says.

"Legal fees have plummeted, and the money they spend goes to the people who deserve remuneration: the injured patient and their family," he says. "Under the standard approach, over 60% of malpractice funds go to the lawyers."

Southwick once encountered a situation in which had to disclose to a patient that an error had occurred under previous care by another physician, and he says the experience shows how difficult that can be. "As an infectious disease consultant, I was asked to see a patient who had a severe postoperative infection after a prolonged delay in the initiation of antibiotics. The patient asked me if he should have been treated earlier, and in the spirit of honesty and openness, I told him, yes he should have been treated earlier," Southwick says. "I then informed the physician who had consulted me about the patient's concerns, and we together contacted our risk management team. They in turn discussed in detail the patient's concerns with him, and they forgave his hospital bills and provided him with compensation for his lost time at work."

The patient was satisfied, Southwick says, but the other physician's initial reaction was not positive. "The physician who inadvertently delayed the initiation of antibiotics was unhappy with my response, but after I explained that this strategy would greatly reduce the likelihood of a malpractice suit, he understood my approach, and we remained friends and close colleagues," he says.

SOURCE:

• **Frederick S. Southwick**, MD, Professor of Medicine, Division of Infectious Diseases Quality Projects Manager for the Senior Vice President for Health Affairs UF & Shands System, University of Florida College of Medicine ■

Hasty disclosure can damage other providers

Tertiary care providers can be so influenced by seeing the end results of a supposed error — the patient's condition is worsened — that they make overly harsh judgments about the previous provider's care, says **Matson Sewell**, MS, MPH, CPHRM, principal with Matson Sewell Healthcare Consulting in Sacramento, CA. Those judgments can cause serious damage to the hospitals.

What seems to be an error or substandard care

should be judged not with perfect hindsight but in light of what information was available to the provider at that time, Sewell says. "That's the mistake that I see people make: an assumption of error without investigating whether an error really occurred," she says. "I'm afraid a lot of tertiary care facilities do have a certain amount of professional arrogance with respect to the community hospitals' care."

The provider that discovers the error can assume it is doing the right thing by immediately informing the patient, but that self-satisfaction can come at a price. Rushing to disclose a supposed error to the patient, without first confirming that the other hospital truly was at fault, can damage your relationship with that hospital, Sewell cautions. "Unfortunately what I see usually happen, and around Boston this is almost epidemic, the provider basically criticizes the care of the referring hospital, never even tells that hospital there was even a concern, and that is taking professional potshots from a distance," she says. "It does cause problems. In small communities you have to work and shop and go to PTA meetings with the doctor you're criticizing, so you just want to be sure about what you're saying."

Sewell also points out that disclosing a provider's error might lead to a legal claim, and the doctor who discovered it might be called as an expert witness. This is not reason to avoid disclosing a true error, but it is reason to avoid being overly judgmental about the other provider's care or too hasty with disclosure, she says.

"The other thing to know is that if litigation is initiated, your own care will come into scrutiny," Sewell says. "I've seen cases in which the disclosing physician ended up being the primary defendant, not the person whose error he disclosed, and the plaintiff was awarded damages." ■

EMRs, other tools count as medical devices

A rule from the Food and Drug Administration (FDA) is causing healthcare providers to reassess what is considered a medical device and what the classification might mean in terms of liability and reporting requirements.

The FDA issued a long-awaited final rule reclassifying Medical Device Data Systems (MDDS) as class I, 510(k)-exempt, medical devices in February. The final rule comes almost three years after the Agency's Feb. 8, 2008, issuance of a proposed rule seeking to classify MDDS as class I, 510(k)-exempt.

Now that the rule is final, companies involved in manufacturing and developing MDDSs have to implement a system to comply with these new rules since their products are now subject to FDA regulation. They have until April 2012 to comply.

That might sound like a problem for manufacturers, not healthcare providers. However, in some circumstances, hospitals and health systems can be obligated to comply, particularly if you develop your own software for electronic medical records (EMRs), personal health records (PHRs), and similar systems, says **Yarmela Pavlovic,** JD, an attorney with law firm of Hogan Lovells in Philadelphia. "The FDA is saying that anything that fits into the category of healthcare information technology — and that includes software used in the hospital, electronic charts, or pretty much anything used in a hospital to treat patients — is a medical device," Pavlovic says. "For years there wasn't any action on these products, so this rule is a first step into the technology space."

This rule can also apply to healthcare providers creating their own software, Pavlovic says.

"Some have argued that they should not fall under the FDA's jurisdiction. Hospitals, for example, are heavily regulated by other sectors of the government, but not FDA," Pavlovic says. "For a long time the FDA has left hospitals alone to do what they wanted, and this is the first time they've been considered medical device manufacturers. If a healthcare organization creates a program or significantly modifies one from a manufacturer, they could be a manufacturer for FDA purposes."

The good news is that the FDA has said it is not actively enforcing the rule as it applies to EMRs and PHRs, Pavlovic says.

"Meanwhile, other sectors of the government have been discussing whether to regulate those products and how to enforce standards," she says. "I think there is a lot of government debate about that. The Institute of Medicine is currently studying patient IT products, and the FDA has said they're going to wait until that report is released — probably this winter — before they start enforcing the rule with health IT."

SOURCES

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Palm scan technology improves patient safety

A New York City hospital is taking patient identification into the 21st century by using palm scans to avoid identity confusion and improve patient safety.

New York University Langone Medical Center (NYU Langone) recently began using PatientSecure, a biometric technology from HT Systems in Tampa, FL, to identify patients, says **Bernard A. Birnbaum**, MD, senior vice president, vice dean and chief of hospital operations at NYU Langone.

"Patient safety is the primary reason we investigated this technology," Birnbaum says. "I'm a radiologist by training, and we radiologists were always frustrated by and scared of duplicate medical record numbers. The primary reason we implemented this system was to combat duplicate medical records."

Those duplicate records are generated when people use slight variations of their name during the admissions process, such as Michael Smith, Mike Smith, and Michael B. Smith. Employees and the software system should be able to stop the duplication, but nevertheless some will slip through, Birnbaum says. "It's a dirty little secret in most health systems," Birnbaum says. "Nobody wants to talk about it."

Using a palm scanner enables the hospital to instantly tie that palm print to the correct medical record, Birnbaum says. Utilizing near infrared light to map an image of the blood-flow pattern through the veins in a person's palm, the digital palm image is converted into a unique patient identifier that interfaces with the medical center's electronic health record system. "Vein patterns are 100 times more unique than fingerprints," Birnbaum says. "As a result, PatientSecure provides a safe, secure, easy and fast way for our patients to register for care at the medical center. It not only protects privacy and enhances quality, but transforms the patient experience."

The advanced technology of PatientSecure helps to ensure each patient is correctly linked to the right medical record, a task which is not always as straightforward as it sounds, Birnbaum says. For example, at the medical center alone, two or more patients with healthcare records share the same first and last names more than 125,000 times, he notes. As a result, with PatientSecure, a patient simply places his or her hand on a small black box and their unique identifying palm portrait automatically registers them and accesses his or her electronic health record, reducing the chances of misidentification and minimizing the need to present other identifying information after initial enrollment, such as a driver's license or Social Security number.

Streamlining the traditionally cumbersome registration process also helps enhance the overall patient experience from the moment the patient walks in the door and provides added protection from medical identity theft because patients no longer need to share personal identifying information, Birnbaum says.

NYU Langone piloted the palm scanning technology in May 2011 at their Internal Medicine Associates faculty group practice. Following the hospital implementation in June, more than 5,000 patients embraced PatientSecure in just one week, and the numbers continue to rise, Birnbaum says.

Birnbaum notes that if a patient without identification arrives at the medical center unconscious or unable to communicate, PatientSecure can be a lifesaving tool that quickly identifies the individual, opens his or her electronic health record, and alerts medical professionals to crucial information, including medical history, allergies, and current medications.

Registration using PatientSecure is available for inpatient registration at the medical center's three hospitals: Tisch Hospital, the Hospital for Joint Diseases, and the Rusk Institute of Rehabilitation Medicine. It is also available for outpatient services at the medical center, including radiology and lab tests, as well as at a growing number of physician offices affiliated with NYU Langone. There is no cost to patients to participate in PatientSecure.

NYU Langone has 250 of the palm scanners in place. Birnbaum estimates that the first-year cost was about $200,000, which included acquiring the hardware.

"Patients love it. They describe it as a VIP process and they're all in favor of it reducing errors and identity theft," Birnbaum says. "It really expedites the registration process because they scan their palm and their records come right up."

SOURCE

• **Bernard A. Birnbaum**, MD, Senior Vice President, Vice Dean, Chief of Hospital Operations at New York University Langone Medical Center, New York City. ■

Hospital sued after poisoning death

A Philadelphia hospital is facing a lawsuit from the relatives of a man whose chemist wife is accused of poisoning him with thallium.

Xiaoye Wang, 39, a computer engineer also known as Alex Wang, died on Jan. 26, 2011, at University Medical Center of Princeton, NJ. He had been admitted on Jan. 14 complaining of abdominal pain and a lack of feeling in his hands or feet.

His wife, Tianle "Heidi" Li, 40, a chemist at Bristol Myers Squibb, was charged with murder for allegedly slipping him thallium, an odorless, highly toxic metal, both at their home and as he lay in his hospital bed. A wrongful death suit filed by relatives of Wang in New Jersey's Camden County Superior Court names the drug company, the hospital, and six doctors. *(For more on the risk of hospitals being drawn into murder cases, see* Healthcare Risk Management, *May 2011, p. 58.)*

Robert Mongeluzzi, JD, an attorney with Saltz Mongeluzzi Barrett & Bendesky in Philadelphia, represents the family and said at a news conference that Li was accused of killing her husband with the radioactive substance that is employed to diagnose coronary artery disease but if used improperly can cause a slow and painful death. She was charged with giving Wang thallium over two months until he died in the hospital. She has pleaded not guilty to murder and is being held in lieu of $4.1 million bail.

The lawsuit alleges that Li obtained the highly toxic drug from Bristol-Myers Squibb, which has several research sites in New Jersey. Court papers claim the company failed to impose rigorous safety and security controls on dangerous drugs such as thallium to guard against unauthorized access.

The lawsuit says Wang told doctors on the day he was admitted to the hospital that he and his wife were expecting to be divorced. Court documents quote a note that a doctor placed in his medical chart that said Wang thought he was being poisoned and asked to have his urine tested for signs of poison. "The fact that he is accusing his wife of poisoning him may suggest the presence of a paranoid syndrome, although one has to first exclude the possibility of any kind of poisoning," the doctor wrote.

Rather than take Wang's complaints seriously, "They allowed Li unrestricted access to his hospital room until Wang was found unresponsive," Mongeluzzi's firm said in a statement.

Another note from the medical chart, quoted in court papers, said Wang's wife acted strangely during a visit. "Wife should be monitored if comes to visit and patient shouldn't be left alone," the note said.

SOURCE

• **Robert Mongeluzzi**, JD, Saltz Mongeluzzi Barrett & Bendesky, Philadelphia, PA. Telephone: (215) 575-2989. E-mail: rmongeluzzi@smbb.com. ■

Few med mal claims lead to settlement

Healthcare providers know that many medical malpractice claims are without merit, but the common wisdom is that a great many of those are settled anyway. A new report, however, indicates that only one in five malpractice claims against doctors leads to a settlement or other payout.

Each year about one in 14 doctors is the target of a claim, and most physicians and virtually every surgeon will face at least one in their careers, according to the report in *The New England Journal of Medicine*. *(The full text of the report is available free online at http://tinyurl.com/4x2khw8.)*

The study was one of the largest ever to assess the risk and impact of malpractice claims. Researchers used data from one of the nation's largest national malpractice insurers and analyzed the experiences of about 41,000 physicians who bought coverage from 1991-2005.

The study found that about 7.5% of doctors have a claim filed against them each year, a figure a bit higher than that in the recent American Medical Association survey, in which 5% of doctors said they had dealt with a malpractice claim in the previous year.

Fewer than 2% of doctors each year were the subject of a successful claim, in which the insurer had to pay a settlement or court judgment. About 19% of neurosurgeons and heart surgeons were sued every year, which makes them the most targeted specialties. Pediatricians and psychiatrists were sued the least, with only about 3% of them facing a claim each year. However, when pediatricians did pay a claim, it was much more than other doctors. The average pediatric claim was more than $520,000, while the average for all other

physicians was about $275,000.

"Our study uncovered an important aspect of malpractice liability: the high likelihood of claims that do not result in payments to a plaintiff. Annual rates of claims leading to indemnity payments ranged from 1% to 5% across specialties, whereas rates of all claims ranged from 5% to 22%," the authors write. "Our projections suggest that nearly all physicians in high-risk specialties will face at least one claim during their career; however, a substantial minority will not have to make an indemnity payment."

The authors note, however, that the low percentage of claims resulting in payout does not ameliorate the malpractice fear among physicians. Even those claims that do not result in payment still take a toll on physicians, they say.

"The perceived threat of malpractice among physicians may boil down to three factors: the risk of a claim, the probability of a claim leading to a payment, and the size of payment. Although the frequency and average size of paid claims may not fully explain perceptions among physicians, one may speculate that the large number of claims that do not lead to payment may shape perceived malpractice risk," they write. "Physicians can insure against indemnity payments through malpractice insurance, but they cannot insure against the indirect costs of litigation, such as time, stress, added work, and reputational damage." ■

Humana fined $3.4 M for not reporting fraud

The Agency for Health Care Administration (AHCA) in Florida has fined Louisville, KY-based Humana $3.4 million for failing to report suspected or confirmed Medicaid fraud to the state on a timely basis.

Florida state law requires that healthcare providers report fraud within 15 days. The agency informed the company of two penalties: one for $660,400, a rate of $200 per day for violating its contract with the state; and another for $2,732,000, a rate of $1,000 per day as prescribed by state law.

AHCA reports that Humana had discovered the instances of suspected fraud far back as September 2009 and as recently as January 2010 before reporting them to the state. The longest violation was 536 days past the 15-day requirement.

The fines related to 16 suspected fraud cases, 12 of which were investigated but then closed with no findings of fraud, and the other four remained under investigation by Humana, AHCA reports. Of the 16 suspected cases, one involved "provider shopping," five were suspected upcoding, three concerned "questionable charges," one involved "services not rendered," and the remaining six were investigations of "excessive services." ■

CNE INSTRUCTIONS

Nurses participate in this CNE/ CME 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.

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 health care for hospital personnel to use in overcoming the challenges they encounter in daily practice.

COMING IN FUTURE MONTHS

- Lessons from Leapfrog's top hospitals
- Hospitals banning early inductions, C- sections
- Temp staff: Safety, liability risk?
- Protecting IT from inside threats

CNE QUESTIONS

1. In the malpractice case filed against Michael Knapic, DO, which of the following is true regarding his statements to the plaintiff?
   A. Knapic said he was "sorry." However, that testimony was not submitted as evidence during the trial.
   B. Knapic never said he was sorry or took responsibility for the patient's injury.
   C. Knapic said he was "sorry." That statement was submitted as evidence during the trial, and Knapic confirmed having said it.
   D. Knapic said he was "sorry." That statement was submitted as evidence during the trial, and Knapic denied having said it.

2. What did the Ohio Court of Appeals conclude concerning the state's apology statute in the malpractice case filed against Knapic?
   A. The statute was intended to broadly protect all expressions of apology, regret, and admissions of responsibility by a healthcare provider after an adverse outcome.
   B. The statute was unconstitutional because it barred the admission of relevant evidence by the plaintiff.
   C. The statute did not apply in the Knapic case because the facts of the case clearly demonstrated negligence by the physician.
   D. The statute was intended to protect pure expressions of apology ... without excluding from trial a medical professional's admission of fault for a claimed injury.

3. What does John C. Metcalfe, JD, FASHRM, vice president of risk management services with Memorialcare Health System in Fountain Valley, CA, do when it appears a patient has been injured by a previous provider, but it is not clear which previous provider is at fault?
   A. Metcalfe's hospital immediately informs the patient and takes no further action.
   B. Metcalfe's hospital tries to contact all the providers that might be responsible, but ultimately is not obligated to determine which other provider committed the error.
   C. His hospital notifies the state board of medicine, which initiates an investigation.

4. Under the final rule reclassifying Medical Device Data Systems (MDDS) as class I, 510(k)-exempt, medical devices, when might a hospital be considered a device manufacturer?
   A. Never
   B. When the hospital develops its own software, such as an electronic medical record, or significantly modifies a product from a vendor
   C. When using certain technology products with most patients

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

Alleged delay in delivering baby leads to birth asphyxia, $20M settlement

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News: A woman with a normal pregnancy was admitted to the hospital after going into labor. The woman first was seen by the attending OB physician, who later went off duty. Another physician assumed responsibility in the afternoon and was extremely busy. An examination of the woman showed that the baby was occiput posterior. On multiple occasions and between deliveries, the physician tried to rotate the baby, but was unsuccessful. Seven hours after the second stage of labor had begun, the woman was taken to the operating room for an emergency C-section. The baby was born dead, but later was resuscitated. The baby suffered from birth asphyxia and now has cerebral palsy with quadriplegia. The parties settled for $20 million.

Background: Looking forward to the birth of her first child, a woman presented to a hospital in the second stage of labor about 9 p.m. The first stage of labor had proceeded smoothly, and the woman's contractions appeared normal. The OB physician on duty initially saw the woman, but shortly thereafter, the physician's partner came on duty. At 9:40 p.m., the new physician saw the woman and determined that the baby was occiput posterior, or facing the mother's abdomen. Shortly after 11 p.m., the physician delivered the first of five babies that would be born over the course of the evening.

About 12:30 a.m., the physician saw the patient again and tried to manually rotate the baby but did not document this action in the patient's chart. Between 1:30 a.m. and 2:12 a.m., the physician delivered three more babies. At 2:30 a.m., the physician again visited the woman and noted that the baby still was in the anterior position. The physician planned to have the woman's epidural injected and then attempt delivery with forceps. If delivery with use of forceps was not successful, the physician was planning to take the woman for a C-section.

While the epidural was injected, the physician left to take a nap. At 3 a.m., the woman signed a consent form for the C-section, but the physician was not called until 4 a.m. After unsuccessfully attempting delivery with forceps, the woman was prepped for surgery. During this time, the fetal heart strip was showing an increased baseline with persistent variable decelerations. The physician called the original attending several times and indicated

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that he might need assistance with the delivery, but the original attending was at home, had gone back to sleep, and did not respond.

The woman finally was taken to the operating room at 4:27 a.m., at which point the electronic fetal monitor was disconnected and never reconnected. After the spinal block was administered, a nurse checked the fetal heart rate with a Doppler. Although she received a normal reading, no documentation was entered into the chart to that effect.

The baby ultimately was delivered at 5:06 a.m. and essentially was dead. Initial Apgar scores were 0, 0, and 0 at one, five, and 10 minutes. No neonatologists were available at the hospital for resuscitation, and the neonatal nurse practitioner did not arrive until seven minutes after delivery. Resuscitation efforts commenced, and a fetal heart rate finally was found 24 minutes after birth.

The baby suffered birth asphyxia with consequent athetoid and spastic cerebral palsy affecting her arms and legs. The baby also developed seizures.

The woman sued the hospital and the physicians for negligence. Experts for the plaintiff testified that both physicians violated the standard of care by failing to deliver the baby sooner. They testified that this failure led to the infant's permanent injuries. The plaintiff's experts also argued that the hospital's nurse failed to properly monitor the fetus just prior to and during the C-section. The plaintiff offered various testimonies showing that the nurse failed to comply with various hospital policies and procedures, and the testimony also indicated that the delay in resuscitation was a violation of hospital policy.

The defendants' experts testified that an eight-hour second-stage delivery complied with the standard of care, and that an unrelated and unanticipated cord occlusion minutes before deliver led to the baby's injuries.

Medical expenses were estimated to be in the range of $833,967. Future expenses were projected to be $13 million, with the child's life expectancy raning from as little as 31 years to 70 years.

The parties participated in mediation, which resulted in no resolution. Shortly after mediation, the parties entered into a settlement in the amount of $20 million, with the hospital paying about $9.9 million of that total.

What this means for you: Labor and delivery of a newborn baby is made up of two stages. During the first stage of labor, the infant positions itself into the birth canal as the mother's cervix thins (or effaces) and dilates (or opens). There are three defined phases within the first stage of labor: The early phase, from the onset of labor until the cervix is dilated to about 3 cm; the second active phase, with harder labor and which continues until the cervix is dilated to 7 cm; and the third and final phase, which is known as the transition to the second stage.

The early first phase of the first stage can last for hours, and the patient is generally encouraged to remain at home and engage in moderate activity while also timing her contractions. In the second active phase, contractions will be stronger, longer, and closer together. This is the time that the physician generally tells the patient to go to the hospital or birth center.

The active phase is usually about three to five hours, with contractions stronger and longer, separated by three to five minutes of rest. For first-time mothers, this second phase can extend out many hours and is contingent on the strength of the contractions, the size and presentation of the baby, and the mother's pelvic anatomy. The third phase of the first stage of labor, or transition, is the final step toward the second stage of labor or the birth of the baby.

Transition is the hardest phase, but it also generally is the shortest, lasting between 30 minutes and two hours. The cervix completes dilation to 10 cm, and the birth canal thins so that the baby's head is resting against the mother's perineum. Contractions are intense and close together, but once the cervix is completely effaced and dilated, the second stage of labor begins and ends with the birth of the infant.

During the second stage of labor, the baby's head will turn to one side, and the chin automatically will rest on the chest so the back of the head can lead the way. The cervix is fully dilated, and the baby's head and torso begin to turn to face the mother's back, as the head enters the birth canal. The baby's head will then begin to emerge, or "crown," through the vaginal opening. Once the head emerges, the head and shoulders again turn, allowing the baby to easily slip out. The entire process of the second stage generally lasts anywhere from 20 minutes to two hours. A second stage in excess of two and a half hours becomes suspect

of possible problems for mother and infant.

In this case, the woman already was at the second stage of labor when she arrived at the hospital and was admitted to the birthing unit. Why she waited so long to get to the hospital is not addressed, but for a woman to arrive fully dilated should have signaled the nursing staff who admitted her that delivery was imminent within a relatively short time. From the narrative, there appeared to be no sense of urgency.

The woman was seen by the on-call OB and then his partner less than an hour later. The partner examined her and determined that the infant was in the posterior, or face up, position. This is not particularly uncommon, as studies have shown that many more babies are posterior at the beginning of labor than when they're born, and it is common for a baby's position to change during labor, often more than once. Estimates vary, but between 5% and 12% of babies are face-up at delivery, and the percentage is higher among first-time mothers. For a first-time mother who was completely dilated, the physician should have been more attentive to the possibility of a prolonged and dangerous labor.

Also troubling here is the lack of any documentation to support that the providers actually obtained ultrasound images or any other definitive diagnostic information from the woman. In fact, what is glaring about this case is the documentation, or rather lack thereof. There is no information provided about meconium-stained amniotic fluid, heart tones, deceleration and recovery during and after contractions, frequency and intensity of contractions, duration of fetal monitoring, the mother's pain intensity, or any other indications of a non-progressing labor and ensuing fetal distress.

It is standard practice in birthing units for highly trained nurses to observe and document a patient's labor intensely by reviewing fetal monitor strips at assigned intervals and to document that the nurse has done so by initialing the strip. Also, fetal monitoring generally continues throughout the delivery process, but that does not appear to have been the case here.

There is no information provided that the infant was in distress until 4 a.m., when the fetal heart strip was showing an increased baseline with persistent variable decelerations. At 4:27 a.m., the woman was taken to the operating room for a C-section, and the electronic fetal monitor was disconnected and never reconnected. This was most likely a huge divergence from standard hospital policy, as this infant already was showing compromise, and a Doppler is not sufficiently sensitive to be reliable, other than as a quick measure for transferring the patient from the labor area to the operating room.

The entire episode speaks to an overworked, understaffed situation, without adequate physician support. During the evening, the OB department was exceptionally busy, with five deliveries in as many hours. At 12:30 a.m., after more than three and one-half hours of what was likely hard labor, the physician tried to manually turn the infant and was unsuccessful. This is a major obstetric intervention in terms of safety and outcome, and yet there was no documentation as to how it was attempted and what the plan was going to be if it was unsuccessful. It is likely, though not documented, that the infant already was in distress, yet it was another three and a half hours before the physician intervened again.

At this point the patient was well past the two-hour threshold for the second stage of labor. The patient also had a confirmed posterior presentation that was obviously extending hard labor and impeding delivery, which would in a short time compromise the health and safety of the mother and the infant. Yet nothing was done to expedite what was the most likely outcome: a C-section.

The attending OB physician did not respond to his partner's request for help, and the on-duty physician seems to have been overwhelmed by the excessive volume of deliveries in a short period of time. Preparing for and carrying out a C-section with only one physician available in-house and so many expectant mothers nearing delivery would have been impossible without additional backup.

There is no mention of the coverage agreement that the physicians had with the hospital, or if physicians from other practices would have been available for such emergency situations. In some smaller and/or rural hospitals, surgeons are called in for C-sections if there is insufficient or untrained obstetrical staff to manage the situation. Whatever the agreement was that was in place, it was either insufficient or unenforced, and it clearly failed.

In addition, there were no preparations for a possible anoxic infant, which also violates

the usual standard of care. Hospitals generally have policies requiring the neonatal staff to be readily available when a C-section is contemplated, as emergency surgical deliveries are far more risky in terms of infant viability. In this case, no neonatologists were available at the hospital for resuscitation, and the neonatal nurse practitioner did not arrive until seven minutes after delivery.

Response time for OB and neonatology should be a matter of enforced policy and consistent with safe practices. In this case, this failure was obviously shared between both services and the hospital's medical executive committee oversight. A root cause analysis of other traumatic births with neurological injury should have been conducted in conjunction with this incident to establish whether a pattern existed and to determine whether the physician agreements were in fact appropriate to the volume and presentation of births delivered at the hospital.

When the baby was delivered at 5:06 a.m., its initial Apgar scores were 0, 0, and 0. The Apgar score is a number that scores a newborn baby's heart rate, respiratory effort, muscle tone, skin color, and response to a catheter in the nostril. Each variable is scored at 0, 1, or 2 points, with a cumulative 10 indicating a perfectly healthy infant. Scores of less than 3 at one minute post-delivery demand immediate resuscitation, which was delayed in this case until the neonatal nurse practitioner arrived seven minutes later. A fetal heart rate was not found until 24 minutes after birth.

The delivery room nurse should have attempted resuscitation without delay, as the effects of anoxia are near immediate. After 15 minutes without a heartbeat, there would certainly be ethical issues to consider if resuscitation were to continue. While state laws differ on this issue, at that point the infant is technically dead, and if resuscitated will be severely damaged beyond a reasonable quality of life. Certainly the parents should have some decision-making capabilities, but that is not addressed.

And finally, it is worth noting that the physicians and the hospital essentially split the $20 million settlement, with the hospital paying slightly less than $10 million. The hospital might have been lucky to pay only that amount, as more medical malpractice attorneys these days are seeking to hold hospitals and healthcare facilities liable for the acts of all providers who provide services within their facility, even independent contractor physicians. In this case, the doctors apparently were independent contractors, but the fact that they were not employees of the hospital is not always obvious to patients. As such, risk managers should be not only intimately involved in the review of all contracts with independent contractors, but should also take steps to inform patients that their contracted physicians are not their "agents."

Agency, through which an entity will be deemed to be vicariously liable for the acts of an individual, is a concept that plays a significant role in the legal aspects of claims. Even if the hospital's bylaws or some other documentation clearly indicates that the physician is not an employee, a jury still can find the physician to be an agent, thereby exposing the facility to liability. Risk managers should take steps to reduce the chances of a finding of agency, such as requiring physicians to wear coats identifying their employers, providing patients with documentation explaining that the hospital does not employ the doctor, ensuring that the hospital does not assign or control the physician's work, and ensuring that physician and facility charges on patient bills are sent to the patient separately. Risk managers should become familiar with the tests applied in their states to recognize and assess the level of risk exposure in a contract for the provision of services.

In sum, this is an incredibly sad case, as it appears that negligence or, at a bare minimum, an indifference to the enormity of the situation as it unfolded was responsible. The $20 million settlement might not be sufficient to compensate the family, as the birth injuries rendered the child a lifetime of full custodial dependency. Had the Labor and Delivery unit been properly staffed, including neonatal coverage, had the nurse been less negligent in her responsibilities, and had the parents been afforded end-of-life decisions, the outcome would have been far different.

REFERENCE

Superior Court of Washington, King County, Case No. Not Available ■