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Scandal at medical institution yields lessons for risk managers

Multiple suits, accusations suggest need for better compliance oversight

It would be bad enough to be the risk manager at a large medical institution facing multiple lawsuits and allegations of kickbacks, retaliation against a whistle-blower, and violations of various federal regulations. But it could be even worse if investigators trace all the problems back to your office and ask why you didn't prevent the wrongdoing or stop it before it got out of hand.

That could happen when a scandal permeates a health care institution as thoroughly as it has at the University of Medicine and Dentistry of New Jersey (UMDNJ) in Newark, warns **Paul English Smith**, JD, FASHRM, CPHRM, vice president and general counsel at Cabell Huntington (WV) Hospital in Huntington. Smith is the president of the American Society for Healthcare Risk Management (ASHRM).

Risk managers at UMDNJ have not been implicated in any wrongdoing, but the head of the legal department has. UMDNJ is widely respected as a top producer of minority health professionals, but it has been embroiled in a

EXECUTIVE SUMMARY

An ongoing scandal at a respected medical institution in New Jersey is yielding a host of lessons for risk managers. Observers say the situation is a clear example of why health care institutions need a good compliance program.

- The institution is facing multiple lawsuits, including from a whistle-blower.
- Leaders at the institution acknowledge that compliance oversight was weak and needed improvement.
- The head of the legal department has been implicated, and the case illustrates how risk managers could be held accountable when scandal strikes.

chain of scandalous events over the past year. UMDNJ is the nation's largest freestanding public health sciences university with more than 5,500 students attending the state's three medical schools, its only dental school, a graduate school of biomedical sciences, and a school of health-related professions. The university is under the close scrutiny of a federal monitor, former federal judge Herbert J. Stern, JD, who was appointed by U.S. Attorney Christopher J. Christie after the first allegations of Medicaid fraud surfaced in December 2005.

Smith says the situation at UMDNJ should hold many lessons for health care risk managers. Some executives at UMDNJ may have found themselves in one of the most difficult situations you can encounter in risk management, he says. "One of the most difficult things you can face is when you go to your boss and say, 'What are we going to do about this problem?' and they say 'Don't worry about it,'" Smith says. "It can be very difficult to keep banging the drum when your boss is telling you to let it go."

But Smith says risk managers must sometimes take a stand. "It sometimes takes a lot of courage to be a risk manager," he says. For that reason, have a structure in place to minimize how much that situation can arise, Smith says. "Having an ethical code of conduct in place is one thing, but actually living up to it can be very difficult," he says.

Whistle-blower files suit

In December 2006, the institution was hit with a lawsuit from a former executive who claims he was forced out because he helped uncover allegedly illegal financial practices. Five other lawsuits already had been filed against UMDNJ in 2006, all of them disputed by the university. **(See p. 28 for more background on the UMDNJ scandal.)**

The latest plaintiff is James Lawler, former chief financial officer at UMDNJ's University Hospital in Newark, who claims that university officials tried to coerce him into signing a fraudulent and illegal Medicare report and forced him to quit his job when he refused to cooperate. Lawler is seeking unspecified damages along with severance pay and legal fees. Lawler's resignation a year ago was one of the key moments in the run-up to the filing of charges by federal prosecutors against UMDNJ as part of a multimillion-dollar Medicare fraud case. The charges and financial problems at the medical center led to a series of firings and the appointment of a federal monitor to oversee the scandal-plagued institution.

Lawler "was put in the position of either signing the report, which had the potential of exposing him to criminal charges, or leaving his position," according to a statement issued by Lawler's attorney, **Bruce McMoran**, JD, of Manasquan, NJ. "He felt he had no alternative but to leave rather than signing a fraudulent report."

UMDNJ spokeswoman **Anna Farneski** says the institution denies the claims in Lawler's lawsuit. "James Lawler voluntarily resigned his position as CFO of University Hospital, and we will

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dispute any assertion to the contrary," Farneski tells Healthcare Risk Management. **(UMDNJ recently enacted a new process for employees to report problems and new protections for whistle-blowers. See p. 28 for more information.)**

Compliance program is key

The troubles at UMDNJ could happen at any health care institution unless there are sufficient safeguards in the form of a compliance program, Smith says. Farneski says UMDNJ leaders admit that the institution's compliance program was inadequate. An important part of the compliance program is a reporting and complaint system that people trust, Smith says. **(See p. 29 for Smith's outline of a good compliance program. See the story on p. 28 for more on ethics lessons from UMDNJ.)**

"In this situation, if someone had called on an anonymous hotline and if the problem had been taken care of through that process, that would have been a part of the checks and balances that kept the program from going as far as it did," Smith says. His hospital has an outside hotline run by National Hotline Services in Fredericksburg, VA. **(See the resource box for more information on the company.)** "People can call and give an anonymous report, and we're obligated to follow up on those reports," Smith says.

He notes, however, that it is not enough to declare that fraud will not be tolerated and set up the mechanism for reporting. You also have to create a culture in which employees are not afraid to report wrongdoing and supervisors do not punish them for it. That atmosphere comes only over time and by setting examples, Smith says.

"We have to remind department heads that you can't take scalps when someone makes a report," he says. "That is very hard to do and a constant challenge for me to get that message across. For a staff person who wants to do the right thing, they sometimes don't want to get involved because they think only bad things can happen to them."

The compliance program also must ensure that reports receive proper attention. Smith frequently calls on outside counsel or an accounting firm to investigate problem reports because they can involve coding and billing issues that are quite complicated.

Pre-emptive compliance also can be a good idea. When Cabell Huntington Hospital wanted to provide physicians with personal digital assistants (PDAs) to improve communication, Smith first checked with outside compliance counsel to make sure that the arrangement did not violate any rules. When the PDAs were handed out, Smith made it clear to the physicians they were to facilitate accessing lab results and other patient information.

"We made sure people understood from the outset that this was being done to improve patient care and streamline some work processes, that these weren't just a gift to physicians," he says. "We wanted that clear to the physicians, but also to the employees who might otherwise think we were just handing out some nice gifts to the doctors."

Audits also are important to ensuring compliance and avoiding impropriety, Smith says. When a new service is offered at his hospital, compliance officers often perform an audit a few months later just to make sure all the safeguards are working as planned. "A lot of people flip the switch on a new program, and then it just goes on autopilot. People move on to the next issue and no one bothers to check in on the one that's up and running," Smith says. "It's easy to think that someone else is going to take care of it, so you need a system that calls for you to go back and check on how things are actually working."

Risk managers should watch for any indication that some people get favorable treatment in the compliance program, Smith advises. A good system will treat everyone the same — from the newly hired housekeeper to the CEO.

"The thing that will kill a compliance program is when you see people treated differently depending on who they are," he says. "The first time you kind of turn a blind eye to someone who is important to you, like a high-admitting physician, and say you know they didn't really mean to do wrong, then

RESOURCES

- **As part of the oversight by a federal monitor**, information concerning UMDNJ's troubles and ongoing efforts to improve compliance is posted on the institution's web site at www.umdnj.edu. Click on the "federal monitor" tab at the bottom of the home page.

For information on implementing an outside hotline, contact:

- **National Hotline Services**, 620-B Kenmore Ave., Fredericksburg, VA 22401. Telephone: (877) 267-1930. Web: www.hotlines.com.

everyone gets the message that this is just a paper plan. You see that in a lot of institutions, with people deciding that it's all talk." ■

Problems at UMDNJ not likely a surprise to leaders

The problems at the University of Medicine and Dentistry of New Jersey (UMDNJ) in Newark probably were known to insiders long before they became public, says **Diane Swanson**, associate professor of management at Kansas State University in Manhattan and an expert in business ethics and compliance. With ethical lapses and fraud, there usually are early warning signs that provide the opportunity to act, she notes.

"None of this should have just blown up at the last minute and surprised everyone. If these warnings are attended to early on, you can save a lot of time, money, and grief," Swanson says. "When there is a wide-ranging problem like this in an institution, that usually is the lesson that people learn."

Most business scandals follow the same pattern, Swanson explains. At first there are internal warnings and signs that those in key leadership positions should recognize. Then they have the opportunity to act. If they don't, the next stage usually involves media coverage and whistleblowing. Then the next stage is litigation and government intervention.

"At that point, you can see that it didn't have to go that far if good people in power had attended to the initial signals," she says. ■

UMDNJ troubles include kickback and fraud charges

The long list of allegations against the University of Medicine and Dentistry of New Jersey (UMDNJ) in Newark began in 2006 with a report that UMDNJ paid $83,700 to chauffeur the director of the volunteer advisory board from her home in Pennsylvania's Poconos to the Newark campus in a hired car, according to media reports and information posted on the school's web site by the federal monitor.

Then two more scandals surfaced, including disclosure of a system in which job applicants were formally graded based on their political connections and a secret political slush fund used to get favors with the powerful and elite.

The situation worsened significantly when a cardiology kickback scheme came to light. Local cardiologists were given high-paid, no-show jobs and in return, they would funnel their patients into a heart surgery program the state had placed on probation.

UMDNJ spokeswoman **Anna Farneski** says two people have been placed on paid administrative leave pending the outcome of the investigations: Ronald Pittore, JD, managing director of the UMDNJ legal department, and Jerrold Ellner, MD, professor of clinical medicine. Ellner also resigned his position as chairman of the Department of Medicine, Farneski says.

On Nov. 15, 2006, interim UMDNJ president **Bruce C. Vladeck**, MD, sent a memo to dean Robert Johnson directing him to immediately implement a new reporting and data collection system to track how often employees come to work and how many hours per week they are putting in. "This is the first step, and certainly not the last, in a review process to ensure that all physician compensation and employment relationships at UMDNJ are fully in compliance with all applicable laws and regulations," Vladeck wrote.

In addition, Farneski says the salaries of nine cardiologists were reduced and two were terminated as a result of the cardiology scandal.

Farneski acknowledges that "the compliance program was inadequate, and the Board of the Trustees has undertaken a complete overhaul and restructuring of the department to ensure UMDNJ meets all federal and state laws and regulations." ■

UMDNJ enacts new policy to protect whistle-blowers

The Board of Trustees of the University of Medicine and Dentistry of New Jersey (UMDNJ) in Newark recently unanimously approved a sweeping new universitywide policy for faculty, staff, and students to report suspected ethical and legal concerns — and to protect those whistle-blowers from any form of retaliation.

The board's action has the effect of codifying and expanding the existing guidelines for accepting complaints and protecting whistle-blowers,

which are being enforced by the UMDNJ Office of Ethics and Compliance, explains UMDNJ board chairman **Robert Del Tuf**.

"As we move the university forward, it is imperative that we create an atmosphere that fosters ethics and professionalism," Del Tuf says. "We need a coherent policy that encourages employees to come forward with information and protects them from adverse reaction."

The policy reinforces the obligation of every UMDNJ staff member, student and administrator to engage in lawful behavior and, if suspicious of possible misconduct, to report that behavior to an appropriate authority. The policy says that a good-faith suspicion of misconduct is sufficient, and that no disciplinary action may be taken against an employee who honestly makes an allegation of misconduct — even if a subsequent investigation of the whistle-blower's charge finds no misconduct.

Six chains of command

The policy also spells out how and where such reports may be made. Such reports may be taken anonymously; also, if the whistle-blower discloses his or her name, it must be kept confidential to the extent possible under law.

Any one of these six chains of command may serve as an "appropriate authority" to take such a report, depending upon what the individual believes is the proper forum:

- an employee's immediate supervisor;
- the UMDNJ Office of Human Resources;
- the UMDNJ Office of Affirmative Action and Equal Employment Opportunity;
- the UMDNJ Ethics and Compliance Office, including complaints taken on the office's existing telephone line and existing web site (www.umdnj.edu/complweb/forms/forms_06reporting.htm);
- the Audit Committee of the UMDNJ Board of Trustees;
- the federal monitor for UMDNJ, Herbert Stern; and/or the Office of the U.S. Attorney for the District of New Jersey, Christopher Christie, as appropriate.

Also, if a whistle-blower suspects retaliation or harassment as a result of a report of possible misconduct, they may turn to the UMDNJ Office of Ethics and Compliance, a designated compliance officer at his or her school, or the audit committee of the UMDNJ board of trustees to request an investigation. A new disciplinary review committee will meet weekly to ensure that requests by supervisors for disciplinary actions against staff, including termination, are being made for cause and not in retaliation against a whistle-blower. A new database is being developed to allow for tracking of complaints and diagnostic reviews. Additionally, the policy calls for mandatory ethics education and training. ■

Compliance program should have hotline, regular audits

This outline of the key elements in a compliance program is provided by **Paul English Smith**, JD, FASHRM, CPHRM, vice president and general counsel at Cabell Huntington Hospital in Huntington, WV. Smith is the president of the American Society for Healthcare Risk Management (ASHRM).

1. **Written Standards of Conduct.**
- Written policies and procedures on:
— claims development and submission processes;
— code gaming;
— financial relationships with physicians and other health care professionals.
- Adherence to compliance as an element in evaluating managers and employees.

2. **Designation of a Chief Compliance Officer.**
- Heads the corporate compliance committee. Charged with the responsibility of operating and monitoring the compliance program
- Reports directly to the CEO and the governing body.

3. **Development and implementation of regular, effective education and training programs for all affected employees.**
4. **Hotline or other complaint process:**
- adoption of procedures to protect anonymity of complainants;
- adoption of procedures to protect whistleblowers from retaliation.

5. **System to respond to allegations of improper/illegal activities:**
- enforcement of appropriate disciplinary action against employees.

6. **The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas.**
7. **The investigation and remediation of identified systemic problems:**
- the development of policies addressing the nonemployment or retention of sanctioned individuals. ■

Football theme helps motivate staff for quality

A medical center in Baltimore has come up with a unique way to encourage interest in patient safety and quality. It's a "football league" in which staff form teams and can gain points by taking steps to improve safety or improve patient care.

The program at Levindale Hebrew Geriatric Center and Hospital is called SCORE, which stands for Safe Care of Our Residents/Patients & Environment. **Andrea Carr**, RN, MSN, director of performance improvement, explains how the game works: Each of Levindale's units or departments forms a team. The team that achieves the most points quarterly receives a prize of $250 to spend on something fun, such as a staff party or outing.

Teams can earn points in two ways. The first way is with "good catches." A good catch is made by an individual team member who prevents unsafe conditions or accidents. Good catches not only help an employee's team, but also the individual who makes the good catch because the name of that person will be entered into a monthly drawing for a $20 gift certificate. These are some examples of good catches:

- notifying crucial people about worn pad keys and damaged screens on intravenous pumps;
- alerting the maintenance department to unauthorized use of electrical cords in a room;
- realizing lab results are mislabeled.

The second way to score points is with "offensive plays." An offensive play is when a whole department develops plans or performance improvement initiatives that quash potential risks. These are examples of offensive plays:

- giving flu shots to prevent influenza spread in the facility;
- starting a hydration cart program to prevent dehydration;
- beginning "quiet time" to minimize agitation of dementia residents.

The Levindale Safety Committee assigns point values to the good catches and offensive plays. Both are combined for one team score at the end of the quarter. Team standings can be checked at any time during the year on a scoreboard placed in a central location.

Carr says the SCORE program was developed two years ago to help staff identify more closely with patient safety and feel personally involved, as opposed to it being simply a task imposed on them. Football is popular among the staff, so the theme seemed a natural fit, especially as a way to engage front-line staff in positive, proactive behavior. The program is consistent with Levindale's commitment to a "just-culture" approach to patient safety, Carr says. **(For more information on just culture, see *Healthcare Risk Management*, January 2006, p. 1, and *HRM*, February 2006, p. 17.)**

Results are hard to measure because it is difficult to pin down any safety improvements strictly to the SCORE program, Carr says. The same staff might have alerted someone to the problem without the motivation of the football league scores, but Carr says the overall impression among hospital leaders is that the program significantly raises awareness about safety issues.

"We've heard from pharmacy managers that they think significantly more medication errors are being reported because of SCORE," she says. "That's a good thing, and we think we're improving patient safety every time someone reports something, large or small."

Fliers and posters get the word out

The SCORE program is heavily promoted throughout the medical center with fliers, posters, paycheck inserts, and any other way the safety committee can think of to get the word out. A typical flier starts off reminding staff about the SCORE program and the football theme, then it provides this information about how to report potential problems:

"Let your fingers do the walking if you spot a patient safety issue not being addressed. Call Levindale's Patient Safety Hotline 24 hours a day, seven days a week. The phone number is (410) 601-7067. If you would like a response to your

EXECUTIVE SUMMARY

A patient safety effort with a football theme is helping one medical center get staff more involved. The program is aimed at clinical and nonclinical staff.

- Staff are formed into football teams to collect points.
- Points are awarded for efforts that improve safety or quality of care.
- Winning teams get a prize, and individuals also can earn rewards.

message, you can leave your name and a contact number. This hotline is listened to once a day Monday through Friday. For emergencies, contact a staff member immediately."

The hospital also provides free key chains to staff in the shape of a football, with the SCORE program name and the hotline number for reporting problems. Levindale bought 1,000 of the key chains from a local supplier for 57 cents each, including printing. **(Levindale also has a patient safety effort involving poker hands. For more on that program, see article, below.)**

Staff participation is consistently high, says **Luna Barkley**, environmental services manager. She notes that employees sometimes have to be reminded to report their good work and get their SCORE points because they often think they're just doing their jobs and can feel sheepish about asking for credit.

"That's where we depend on managers to reassure them that it's fun and productive to play the game, that there's nothing wrong with getting credit for even the small things you do during the day," she says.

Barkley notes that the SCORE program is a good way to get nonclinical staff involved in patient safety and to reward them for their willingness to help. An environmental services employee might alert a nurse that a patient is wandering off the unit, for instance.

"That interaction helps them buy in to the idea that they are part of patient safety," she says. "The SCORE program helps them see that we really want them to participate, that this isn't just something for nurses and doctors." ■

Staff collect quality cards to get best poker hand

If football isn't your favorite pastime, maybe you're more into poker. At Levindale Hebrew Geriatric Center and Hospital in Baltimore, a patient safety program with a football theme is supplemented by another with a poker theme.

Janine Boulad, volunteer coordinator at the medical center, helped developed the "Betting on Excellence" program by making decks of cards with questions from The Joint Commission taped to them. The idea was to get staff to study Joint Commission-related issues and gather the best poker hand by answering the questions correctly. Levindale ran the poker program for about a month recently, and Boulad says she plans to repeat it on a regular basis.

"Once they started drawing cards, it drew people over to see what they got and whether they could answer the question, too. If you didn't know the answer, you were allowed to ask someone for help," Boulad says. "Even when people didn't want to fully play the game and keep up with what hand they were getting still were being drawn in. It was very effective in getting people talking about some of these issues."

Here's how the game worked:

- A new game started every Monday from Sept. 11, 2006, to Oct. 1, 2006.
- Any employee could find a "dealer" during the work day and pick a card, for a total of seven cards per week. Dealers were unit managers and other designated people wearing "dealer" hats and aprons. For the aprons, the Levindale team bought 12 regular aprons for $4 each and sewed the bottoms to make them shorter like a dealer apron. A dozen caps cost $2 each, and Boulad added handmade "dealer" tags to them. Two decks were used: a blue deck for clinical staff with clinical questions, and a red deck for others with nonclinical questions. Each card had a question and answer written on it. The dealer read the question to the employee.
- If the employee answered the question correctly, he or she kept the card. If not, the employee could try one more time with that dealer that day. The employee still can go to a different dealer that day and try again, but he or she could collect only a total of seven cards during the week.
- The goal was to collect at least five cards during the week and make up your best poker hand with those cards.
- On the following Monday, participants with at least five cards submitted their hands, and the best poker hand won a small prize, such as a $10 gift certificate to Wal-Mart. ■

Multimedia consent helps with pediatric patients

Informed consent can be a challenge with any patient, but it is particularly difficult with pediatric cases. One option is a multimedia presentation that can help get the necessary information across to the patient and family members in a

EXECUTIVE SUMMARY

A new web-based informed consent system can help ensure the parents of pediatric patients receive all necessary information. The system is based on a similar one used for adult patients.

- The system is intended to supplement a one-on-one conversation, not replace it.
- Users can go back and review information as needed.
- Risk managers could see a benefit from less litigation tied to informed consent claims.

more engaging way than the standard discussion.

Nemours, a health care system based in Jacksonville, FL, developed the program through a collaborative agreement with Emmi Solutions, a multimedia communications company based in Chicago. **Linda Pilla**, JD, MBA, chief risk officer for Nemours, explains that the two companies developed and implemented a pediatric-specific program to address an issue commonly confronted by health care organizations: How to provide better and more consistent education about procedures that will enhance outcomes and lower the risk associated with an inadequate informed consent process.

The EmmiKids program uses animated web-based, interactive modules to facilitate parental informed consent for pediatric medical and surgical procedures. It is used in several major pediatric organizations. The pediatric system is the latest version of the Emmi program already used for adult patients.

Pilla notes that the traditional informed consent process is highly variable and dependent on individual practitioner preferences regarding timing, content, process, and the clinician obtaining the consent. Yet, the need for a uniformly high-quality pre-procedure education is clear. The perception of incomplete or improper informed consent is an element in up to 35% of medical malpractice actions, Pilla says.

"The impetus for this is that those of us in risk management know that informed consent is often a major factor in litigation cases," Pilla says. "Our goal was to find a way to provide a better and more consistent informed consent process, which we hoped would lower our risk overall while improving patient satisfaction."

In searching for a solution, Nemours came across the Emmi system, which already was in use for supplementing the informed consent process for adults. Pilla then worked with Emmi to develop a pediatric-specific program.

The web-based, animated process developed by Nemours provides the necessary elements of appropriate informed consent to parents and guardians prior to signing the consent. Content for a pre-procedure education module is presented through Flash-based animation with narration and includes the definition and description of the procedure, indications, benefits and risks, alternatives, and post-care. The Internet-based system allows parents/guardians to view the presentation at a time most convenient for them. The viewer has control of the pace and can pause or sign off and return later. During the presentation, parents can return to prior segments or skip previously viewed portions. Viewers can ask questions via e-mails to their physician or printouts to review later. Parents without Internet access can view the presentation as they complete the necessary pre-procedure visit on-site.

The average module takes approximately 20 minutes to review. School-aged children with a parent/guardian can view most of the content, but parents are advised to view some material on their own, such as that pertaining to the risk of death. Documentation of completion of the entire module along with the times and dates the module was visited is documented and stored for future use. Brief questions at the conclusion solicit feedback regarding parent satisfaction with the process and content.

Module topics include general anesthesia, tonsillectomy and adenoidectomy, bilateral myringotomy, interventional cardiac catheterizations, inguinal hernia repair, repair of undescended testicles, hypospadias repair, and upper endoscopy. An additional program is EmmiSafety. This five-minute presentation provides families with information to improve patient safety, promote better outcomes, and encourage their active participation in their child's medical care. These programs have been endorsed by the American Society of Healthcare Risk Management (ASHRM).

B.J. Clark, MD, vice-president of physician practices for Nemours Delaware, says the web-based consent process is a more consistent way of providing the necessary information about a procedure and acts as a sort of backstop for the physicians. It is not a substitute for a good face-to-face informed consent conversation, he says, but rather a supplement to make sure all important points are understood.

"One of the driving principles of this effort was to provide a complete and uniform body of information for a family of a child undergoing a procedure," Clark says. "The family can review the program at their own pace, as many times as they wish and with as many family members as they wish. The Emmi program does not replace the actual consent process by the physician but allows this process to be improved by the Emmi experience."

Clark notes that the EmmiKids system allows the family to review important information about an upcoming procedure between the time they're informed that the child needs treatment and the time of the procedure. That timing can help overcome the parents' sense of being overwhelmed with information when first told of the treatment plan.

"There is a real question about how much information gets through to parents when they are still shocked and scared by what you've just told them. With this, they can take the time to adjust and then go online and review the information when they're more in control," he says. "Plus, there's the issue of the doctor who has to go over this information 35 times a day and he's under stress. He's not likely to do it the same way each time, so the EmmiKids helps ensure that the right information is always provided." **(Editor's note: More information about pricing and other specifics of the system is available at www.emmisolutions.com.)** ■

Pediatric cases benefit from better consent

The EmmiKids informed consent system is particularly needed because parents often are so upset over their child's health problem that they have a hard time absorbing information during a talk with the physician, says **Neil Izenberg**, MD, founder and chief executive of The Nemours Center for Children's Health Media, in Wilmington, DE. The Nemours Center creates online, print, and video information to educate families about children's health issues. By using the multimedia system, parents can go back and review information to make sure they fully understand what they discussed with the doctor, Izenberg says.

"It really comes down to the ethical responsibility of the organization to make sure the families really understand what is going on," he says. "It's just not enough to say the information and write down that you said it, so then you can say you've done your duty. The real goal is to make sure the parents understand fully, and that's where this system helps."

EMMI Solutions in Chicago, which developed the system with Nemours, a health system based in Jacksonville, FL, recently surveyed 35,600 patients and parents about their experience with the multimedia informed consent systems for adults and children. The results were overwhelmingly positive:

- 96% said Emmi improved their understanding of what to expect.
- 90% of patients said Emmi gave them a better understanding of how to take care of themselves before and after their procedure.
- 84% said Emmi covered risks that they didn't know about previously.
- 80% said Emmi answered questions they had planned to call their doctor to discuss.
- 92% received new information about their procedure through Emmi.
- 89% were more comfortable about their upcoming procedure after viewing Emmi.
- 87% of patients experienced increased confidence in their doctor due to Emmi. ■

Malpractice crisis called hoax, a few docs blamed

The belief that the United States is in the throes of a medical malpractice lawsuit crisis can be blamed on just a small group of negligent doctors, says a new watchdog report.

According to "The Great Medical Malpractice Hoax," just 5.9% of doctors have been responsible for 57.8% of all medical malpractice payments, based on research spanning 1990 through 2005. The study found that each of these doctors made a least two payments, while conversely, the vast majority of physicians — 82% — have never even had a medical malpractice payment. The report was released by Public Citizen, an advocacy group founded by Ralph Nader and known as a critic of big business.

The real problems are a lack of attention to patient safety, the high incidence of preventable medical error, and the lack of accountability for a

EXECUTIVE SUMMARY

A new report claims that there is no malpractice lawsuit crisis, as health care providers have said. Rather, a large percentage of malpractice lawsuits can be traced to a small number of doctors.

- The report comes from Public Citizen, a non-profit advocacy group considered by many legal experts to be critical of big business.
- Just 5.9% of doctors have been responsible for 57.8% of all medical malpractice payments, according to the study.
- Attention to patient safety issues will be more effective than malpractice reform, the group argues.

small set of doctors who account for most medical malpractice payments, says Public Citizen president **Joan Claybrook**. The report also presents several recommendations for Congress, state governments, and hospitals to reduce health care costs and save lives. **(To access the report, go to the Public Citizen web site at www.citizen.org and select "publications" at the top of the page. Then scroll down the page to find "The Great Medical Malpractice Hoax" posted on Jan. 24, 2007.)**

Not a surprise to some

The report confirms what he and many other plaintiffs' attorneys have contended for some time, says **Allan Zelikovic**, JD, head of the Medical Malpractice Unit at Weitz & Luxenberg, a law firm in New York City.

"We've been telling the legislature and the public about this for years. Now we finally have the data to prove it," Zelikovic says.

Public Citizen reviewed publicly available information from 1990 to 2005 from the federal government's National Practitioner Data Bank (NPDB), which contains data on malpractice payments made on behalf of doctors as well as disciplinary actions taken against them by state medical boards or hospitals. According to the analysis, the total number of malpractice payments paid on behalf of doctors, with judgments and settlements, declined 15.4% between 1991 and 2005, and the number of payments per 100,000 people in the country declined more than 10%. In addition, the average payment for a medical malpractice verdict, adjusted for inflation, dropped 8% in the same period.

The numbers show that patients do not win large jury awards for less serious claims, but that payments usually correspond to the severity of injury, says **Laura MacCleery**, director of Public Citizen's Congress Watch group. In 2005, less than 3% of all payments were for million-dollar verdicts, and more than 64% of payments involved death or significant injury — while less than one-third of 1% were for "insignificant injury."

Despite assertions by the medical and business lobbies that physicians are leaving practice because of burdensome malpractice lawsuits, the number of doctors is increasing faster than the population, MacCleery says. "In recent years, medical malpractice insurers have been reaping huge profits, not paying out excessive jury awards," she says. "The false claims of a malpractice lawsuit crisis are really about putting profits ahead of patients. They distract from real health care reform designed to improve patient safety, enhance efficiency and cut costs." ■

Cheap, low-tech methods can slash infection rates

Hospitals can quickly slash the rate of common, costly and potentially lethal catheter-related bloodstream infections in their intensive care units (ICUs) by using cheap, low-tech, common-sense measures such as hand washing, timely removal of unneeded catheters, and use of sites other than the groin to place lines when possible, according to a recent report.

Peter Pronovost, MD, professor of medicine and medical director of Hopkins' Center for Innovation in Quality Patient Care, led researchers in their review of 103 Michigan ICUs, before, during, and after implementing measures designed to reduce such infections.[1] He says the researchers were impressed by how much could be improved with so little effort.

"There's just no reason any more not to do these relatively simple things," Pronovost says. A common misperception among hospital-based clinicians is that it often costs much too much money and time to significantly improve patient safety, he says. "Our data destroy this myth by showing that profound improvements can be made with minimum cost and effort, as long as clinical teams are committed to improving safety

and willing to diligently observe relatively simple safety measures," Pronovost says.

Nationwide, an estimated 80,000 bloodstream infections occur each year as a result of central venous catheters, which are tubes inserted through a blood vessel that ends near or in the heart to deliver treatments and monitor care, the study notes. Bloodstream infections are involved in up to 28,000 deaths in the United States alone among these ICU patients. Economically, the toll is enormous, Pronovost says, with an average cost to the health care system of $45,000 per patient for treatment and billions each year nationwide, "far more than it costs to implement steps to prevent the infections in the first place."

In the Michigan hospital system, which served as a pioneering pilot site for infection prevention measures, efforts included training physicians and nurses about infection control; using special, standardized central-line supply carts that are controlled for one-time use; requiring use of a cockpit-style "checklist" to ensure adherence to infection-control practices such as hand washing; avoiding catheter placement through the femoral artery in the groin, an area notoriously difficult to keep sterile; using and changing gloves, gowns, and masks for each procedure; cleaning patients' skin with chlorhexidine; and removing catheters as soon as possible, even if there's a chance they might be needed again at some point.

The safety plan also requires immediate "stop now" orders by any member of the health care team when a checklist is not followed to the letter and feedback to each member of the care team about the number and rates of catheter-related bloodstream infections at weekly and quarterly meetings.

Pronovost said the study team gathered information in Michigan representing 375,757 ICU catheter-days, collected quarterly for up to 18 months after implementation of the safety measures. The results were dramatic when the steps were implemented, he says. The median rate of catheter-related bloodstream infections per 1,000 catheter-days decreased from 2.7 at baseline to 0 after implementation of the safety measures, and the mean rate decreased from 7.7 at baseline to 1.4 at 16 to 18 months of follow-up.

Reference

1. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Eng J Med* 2006; 355:2,725-2,732. ■

CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

- **Describe** legal, clinical, financial, and managerial issues pertinent to risk management in health care.
- **Explain** how these issues affect nurses, doctors, legal counsel, management, and patients.
- **Identify** solutions, including programs used by government agencies and other hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

COMING IN FUTURE MONTHS

- ED death ruled homicide by coroner
- Best method for patient safety rounds
- Hiring an ergonomic specialist to reduce falls
- New focus on avoiding misdiagnosis

CNE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity with the **June** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

9. According to Paul English Smith, JD, FASHRM, CPHRM, which of the following is true?
   A. The troubles at the University of Medicine and Dentistry of New Jersey (UMDNJ) could happen at any health care institution unless there are sufficient safeguards in the form of a compliance program.
   B. The troubles at UMDNJ are unique and not likely to happen at another institution.
   C. Misconduct occurred at UMDNJ despite the presence of a completely adequate compliance program and, therefore, its cause is unrelated to risk management activities.
   D. The alleged misconduct at UMDNJ is not of the type that would be covered by a compliance program.
10. According to Anna Farneski, how has the institution responded to concerns about its compliance program?
   A. The institution denies there was any shortcoming in its compliance program.
   B. The institution acknowledges that the compliance program was inadequate and the Board of the Trustees has undertaken a complete overhaul and restructuring of the department to ensure UMDNJ meets all federal and state laws and regulations.
   C. UMDNJ is waiting for the federal monitor to decide whether its compliance program was adequate.
   D. UMDNJ's position is that the compliance program has nothing to do with the allegations of misconduct.
11. What does Andrea Carr, RN, MSN, say is one indication that the football-themed patient safety program is working?
   A. Pharmacy managers are recording more reports about medication errors.
   B. Fewer malpractice cases have been filed.
   C. The medical center is paying less for malpractice insurance.
   D. There have been fewer sentinel events.
12. Why does Public Citizen say past claims of a malpractice crisis were false?
   A. Research shows that a small number of physicians are responsible for a large percentage of malpractice claims.
   B. The number of malpractice claims has dropped steadily for 30 years.
   C. States with malpractice reform laws have seen no positive effect.
   D. Multimillion-dollar awards are never made for medical malpractice.

Answers: 9. A; 10. B; 11. A; 12. A.

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

Mislabeled blood sample leads to inappropriate diagnosis of HIV, $20,000 settlement, and $52,000 verdict

By **Blake J. Delaney**, Esq.
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News: A woman who was eight months pregnant was informed by her obstetrician that recent bloodwork had tested positive for HIV. The woman went into labor within 24 hours of hearing the news, and hospital personnel administered antiretroviral therapy to the woman and, following the delivery, to her newborn son. Two weeks later, the woman was informed that there was a mix-up at the laboratory and that the woman was not, in fact, HIV-positive. The woman sued the hospital and the laboratory for negligence. The laboratory settled the case for $20,000, and a jury returned a verdict against the hospital for $52,000.

Background: A woman in her eighth month of pregnancy decided to switch obstetricians. At her first visit with the new doctor, the obstetrician ordered a complete round of baseline tests, including HIV, hepatitis C, and CBC. The woman's blood was drawn at the hospital, which served as the site collection for the laboratory interpreting the results.

Ten days later, the obstetrician advised the woman that she had tested positive for HIV. She was referred to an infectious disease OB/GYN, who instructed her to begin taking antiretroviral medication to lessen the chances of the unborn baby contracting HIV during the birth. Within 24 hours of hearing the news, the woman went into premature labor. She was rushed to the nearest hospital, which was different from the hospital where her bloodwork had been performed. Because the OB/GYN had informed the woman that no one could be in the delivery area at the time of birth unless they knew of the woman's HIV-positive status, the expectant mother told her parents and in-laws that she had tested HIV-positive. At the hospital, personnel began intravenous antiretroviral therapy and administered additional blood tests. Following the delivery, the newborn was taken to the ICU and given antiretroviral medication as well.

Two weeks later, the woman's obstetrician called to inform her that there had been a mix-up at the laboratory and that she was not HIV-positive. The physician informed the new mother that the results of all of the follow-up HIV tests were negative and that he believed her blood sample had been mislabeled at the laboratory. The antiretroviral treatment immediately was stopped.

The woman, her husband, and their son sued the hospital and the laboratory for negligence. The woman sought damages for mental anguish and physical pain, and she feared what effects her baby would experience as a result of the unnecessary administration of antiretroviral treatment following his birth. The woman claimed that she was not mad about the laboratory mix-up until it was clear to her that no one cared about the anguish she had been through during those two weeks.

The laboratory settled with the plaintiffs for $20,000 before trial, but the hospital denied liability. It claimed that on the same day that the woman

learned of the positive result, her physician had told her that the test result was not confirmed and that additional tests were needed to verify that the initial result was accurate. The defendant hospital pointed out that an HIV test taken less than 24 hours after the woman initially was informed that she was HIV-positive had returned with negative results, and that the woman's HIV-negative status was confirmed over the next several days by additional tests. The woman claimed in response that she was not informed of these test results until two weeks had passed. After trial, the jury returned a verdict of $52,000 for the plaintiffs to compensate them for their mental anguish and physical pain.

What this means to you: "Patient identification is the very first step in providing safe care," says **Cheryl Whiteman**, RN, MSN, HCRM, clinical risk manager for Baycare Health System in Clearwater, FL.

Although many health care providers think of the administration of a medication or the verification before a surgical procedure as "patient identification," Whiteman is mindful that the term also ensures that an order is entered into the computer on the right patient, the right test results are entered on the correct medical record, and — as in this case — specimens are correctly labeled. Indeed, The Joint Commission has recommended a National Patient Safety Goal (NPSG) for 2008 mandating that specimens are labeled in the presence of the patient to help avoid errors such as this one.

Whiteman notes that risk managers should evaluate their facility's process and policy of labeling specimens. In anticipation of the NPSG, risk managers should consider how to implement the policy of labeling all specimens in the presence of the patient. Whiteman recognizes that staff education may be needed and that, in accordance with the risk management process, a monitor should be utilized to verify staff compliance with the policy.

Continuity of care in this case was confounded by the multiple practitioners involved with the patient in a very short period of time. The patient electively changed obstetricians late in her pregnancy, was subsequently referred to an infectious disease obstetrician based on the incorrect HIV result, and was admitted to a hospital other than the one where previous care and testing had been provided. "But even though the various personnel involved may have contributed to the confusing situation, it still appears that there was a delay in informing the patient of a confirmed negative HIV status. It is easy to see how the patient may have been left with no loyalty to any of the providers, which could easily lead to the perception that no one cared about her plight," says Whiteman.

In conclusion, Whiteman emphasizes the movement in health care toward transparency and providing honest information in a timely manner. "The principles of disclosure include a *caring* attitude, as well as a since apology when warranted," notes Whiteman.

Reference

- Texas District Court, Harris County, Case No. 2003-47465-A. ■

Broken neck during birth causes permanent injuries

$28.3 million awarded by jury

News: During childbirth, a baby's shoulders became stuck, which led doctors and nurses to attempt additional maneuvers to deliver the fetus. Although the parties disagreed as to which particular techniques were attempted, the baby ultimately was born with severe physical injuries, including intracranial bleeding, bruising, and a broken neck. The baby's parents sued the hospital for negligence, and they claimed in part that their daughter's injuries resulted from the hospital's failure to notify a neonatologist that a high-risk delivery was being performed. A jury returned a verdict in favor of the plaintiffs for $28.3 million, including $2.8 million in punitive damages.

Background: A 25-year-old pregnant woman was diagnosed as being at high risk for obstetrical and delivery complications because she was an insulin-dependent diabetic and because she previously had two miscarriages. She also had exhibited poorly controlled blood sugar levels during the pregnancy, and doctors suspected that the baby might have large shoulders and a large trunk due to her being so large as compared with her gestational age. Even though sonograms suggested that the baby was healthy and was moving her head and limbs without any problem, doctors scheduled the woman for an induction.

During the delivery, the normal gentle downward traction failed and the baby's shoulders became "stuck," a condition known as shoulder

dystocia, which required the woman's obstetrician to attempt additional maneuvers to deliver the fetus. The woman's husband and sister, who were both present in the delivery room, claimed that a nurse on the health care team pressed on the woman's abdomen. They claim the nurse applied fundal pressure to help move the baby out, a technique widely criticized and regarded as dangerous because it can aggravate shoulder dystocia. The doctors and nurses, however, denied that fundal pressure had been applied, and they pointed to the lack of any such indication in the medical record. Instead, they suggested that the nurse merely was palpating the woman's abdomen for contractions so that the nurses could coach her in pushing. The doctors and nurses further claimed that the only pressure applied was at the mother's pubic bone, not at the top of the uterus, in an attempt to allow the baby's shoulders enough room to move free. Doctors and nurses also stated that McRobert's maneuver was used, wherein the mother's legs were flexed toward her shoulders to expand her pelvic outlet.

The 10.1-pound child ultimately was born flaccid, with no respirations, and without muscle tone. After an initial attempt to intubate the newborn by two nurses from the neonatal intensive care unit (NICU) was unsuccessful, a neonatologist arrived approximately 33 minutes after the birth. Although he successfully intubated the baby, she was found to have suffered intracranial bleeding and bruising, bleeding outside the brain, several broken bones including her neck, nerve damage, and a spinal cord injury. She also had no bowel or bladder function. The mother also suffered injuries, including complete paralysis of her left arm as well as partial paralysis from her mid-chest level down, which inhibited her ability to breathe.

After delivery, the newborn was transferred to another hospital, where she remained for 1½ weeks in intensive care before ultimately being transferred to a children's hospital. Three months after delivery, doctors performed grafting surgery on the baby's left arm in an attempt to obtain some function for her. Three years later, the girl required a surgical procedure to have a titanium rib implanted, and she still was suffering from severe scoliosis due to the irreparable spinal cord injury. Although the titanium rib helped to straighten the girl's spine and relieve some of the pressure that the scoliosis was causing to her left lung, doctors fear that she eventually will develop severe restrictive lung disease. Still ventilator-dependent, the girl is unable to sit or stand on her own, and she requires 24-hour-a-day care from two full-time nurses. In addition to her medicine and equipment costs, the family, which lived in a modest trailer home, pays nearly $600 a month in electricity bills because of the girl's ventilator and humidifier.

The baby's parents, on their own behalf and on behalf of their daughter, sued the hospital and the obstetrician for medical negligence during the delivery, although the plaintiffs voluntarily dismissed their claims against the obstetrician after the first day of jury selection. As part of their negligence claim against the hospital, the parents pointed to the fact that the facility had not followed its own internal policy of notifying a neonatologist of an impending delivery by an insulin-dependent diabetic mother.

In its defense, the hospital claimed that its policy required notification only if doctors suspected that the baby would need resuscitation, which was not the case here. The hospital also maintained that the baby's injuries may have been the result of congenital defects or medical attention given to the baby after she was transferred to the second hospital. If the injuries were caused at the first hospital, however, the hospital argued that they were caused by the use of traction by the obstetrician during delivery, which was necessary given the emergency situation that arose. Finally, the hospital claimed that the child received adequate ventilation with bag/mask ventilation while awaiting the arrival of the neonatologist, as evidenced by the fact that the baby became "pink" soon after delivery. The treating neonatologist testified that bag/mask ventilation can substitute for intubation temporarily, as long as someone is pumping the bag, and that the NICU nurses did a good job of keeping the baby ventilated pending his arrival.

After a three-week trial in which five experts testified for the plaintiffs and eight experts testified for the defense, the jury concluded that the hospital's labor and delivery nurses extensively injured the baby girl during her birth. The jury awarded $28.3 million in favor of the plaintiffs, including $2.8 million in punitive damages and $1.9 million in past medical expenses and likely accounting for the plaintiffs' suggested $15 million life plan for their daughter. The jury also apparently awarded nearly $10 million in noneconomic damages; ironically, soon after the plaintiffs' lawsuit was filed, the Texas legislature passed legislation limiting noneconomic damages in medical malpractice suits against hospitals or doctors to $250,000. That legislation, however, did not affect the jury's award in this case because it was not

implemented before the lawsuit was filed.

What this means to you: "This is just the kind of case that a defense counsel never wants to take to a jury," says **Ellen L. Barton**, JD, CPCU, a risk management consultant in Phoenix, MD. "Regardless of the facts or a determination of liability, the plaintiff's injuries seem to demand compensation, meaning the defense is starting from a negative position." Cases like this one must be settled before trial if at all possible.

One fact that stands out in this case is that not only was the patient's husband in the delivery suite, but so was the patient's sister. "Although the presence of family members and others in the delivery rooms is often used as a promotional device, it is a practice that needs to have some constraints, such as requiring family and others not directly providing care to leave the delivery suite when complications arise," advises Barton. This practice is not suggested as a means of hiding or covering up evidence of malpractice, but rather to allow the health care team to do its job without distractions. Barton has found that the presence of individuals who are not trained health care professionals allows for interpretations that may have nothing to do with reality.

Another issue raised in this case is the fact that the hospital did not follow its own policy of notifying a neonatologist of an impending delivery by an insulin-dependent diabetic mother. Given the fact that this patient was deemed to be high risk based on several factors, it would appear that the neonatologist should have been called, suggests Barton. "Although hospital policies and procedures must provide for discretion, they must not be worded such that they can be misinterpreted, as perhaps happened in this case," says Barton.

The facts also seem to indicate that the various defendants seemed to be more interested in pointing fingers and laying blame on others rather than in determining the exact cause of the child's extensive injuries. "To proffer that such injuries may be the result of genetic defects and not to offer proof via a placental pathology report borders on inappropriate behavior. This is the type of case that would benefit immensely from joint defense where the focus is on appropriate resolution of the claim and not engaging in the blame game," Barton says.

Reference

Hidalgo County (TX) District Court, Case No. C-2147-03-E. ■

Plan to attend medical error audio conference

Examining issues, questions and pitfalls that arise

Intense feelings of anxiety and humiliation, not to mention fears of being sued or professionally censured, are extremely common. Not surprisingly, the appearances of defensive and self-protective strategies that urge concealment are common as well. Nevertheless, ethics, as well as recent reports showing declines in malpractice claims and costs when disclosure and apology are implemented, are changing the ways health care organizations manage the aftermath of medical errors.

These issues will be addressed in our upcoming live audio conference: **When the Worst Happens: Techniques to Manage Medical Error Disclosures**, on March 13, 2007, from 2:30 pm to 3:45 pm EDT.

This presentation will examine a number of considerations bearing on error disclosure. Participants will gain an appreciation of the psychological factors that affect error disclosure conversations so that they might better manage their and their listeners' feelings and reactions. The latter half of the presentation will explore numerous communication strategies to employ at particularly significant moments in the disclosure conversation. Ultimately, this presentation will provide a glimpse into the overall 'architecture' of error disclosure conversations as well as discuss "what words to use," such that error disclosure occurs ethically, professionally, and empathically.

Our presenter, **John Banja**, PhD, is a medical ethicist at Atlanta's Emory University who is nationally regarded in the area of medical errors and their disclosure. His book, *Medical Errors and Medical Narcissism,* was published by Jones and Bartlett in 2005.

The fee of just $299 ($349 for the live conference and CD combo) allows you to invite as many listeners from your facility as you can accommodate around your conference telephone. Plus, you and your staff will benefit from the interactive question-and-answer segment immediately following the presenters' prepared remarks.

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