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Joint Commission warns of pediatric medication errors, urges action

Most errors involve improper dose or quantity

The Joint Commission is ringing the alarm bell on pediatric medication errors, saying the health care community has not responded aggressively enough to the increased risk children face when a health care provider administers drugs to them. The chance of medication error is significantly higher with young patients, and the Commission says providers must take deliberate steps to protect them.

This is the first time the group has singled out the problem so specifically, and it is offering many strategies risk managers can use to reduce the risk. The risk of medication errors with children is three times higher than it is for an adult, The Joint Commission notes. Part of the problem, the group says, is that most hospitals' policies and procedures are not designed with children in mind. Most medications also are formulated and packaged for adults, which means that staff must make adjustments for children, and each manual alteration of the dosage increases the potential for errors.

Peter Angood, MD, vice president and chief patient safety officer for The Joint Commission, says risk managers must take action. "We can —

EXECUTIVE SUMMARY

The Joint Commission is making a big push for improving pediatric medication safety, reminding providers that children are at increased risk for drug errors. The group is urging providers to take specific steps to reduce errors, in light of facts such as:

- The risk of drug errors is three times higher with pediatric patients.
- Physical safeguards and pharmacy oversight can prevent many errors.
- All children should be weighed on admission to facilitate better dosing.

and we're obligated — to do better," he says.

Matthew Scanlon, MD, assistant professor of pediatrics-critical care at the Medical College of Wisconsin in Milwaukee and a member of The Joint Commission's Sentinel Event Advisory Group, says the risk of pediatric medication errors has been neglected, even as the health care community focused more on patient safety in recent years. **(See the story on p. 63 for more on the recent research regarding pediatric medication errors.)**

"Sadly, there seems to be a lack of widespread appreciation even among health care providers that children have unique safety and medication needs," he says. "The issues of having to adapt products, be it technology or medications, that were created for adults and apply those to pediatric patients is terribly problematic and really is the source of a great deal of work that has to be performed on a daily basis among pediatric health care providers."

Pediatric medication errors have received increased attention in recent months, most notably with an incident that threatened the lives of actor Dennis Quaid's young twins. Quaid's twins Thomas Boone and Zoe Grace nearly died in November 2007 at Cedars-Sinai Hospital in Los Angeles when they were mistakenly given a heparin overdose. The Quaid twins were mistakenly given the drug, an adult-strength blood thinner, instead of Hep-Lock, a version of the drug a thousand times weaker that is routinely used to clear IV lines in pediatric patients. **(For more on the Quaid incident and how to reduce heparin errors, see *Healthcare Risk Management*, February 2008, pp. 13-17.)**

Weighing children is first step

One of the most important ways to reduce pediatric medication errors actually is one of the simplest, Angood says. Because staff must calculate the correct dosage for pediatric patients rather than using the standardized doses intended for adult patients, and because even small calculation errors can have a major impact with small patients, knowing the child's weight is critical, he says. That is why The Joint Commission is recommending that all pediatric patients be weighed on admission — every time. And in kilograms, not pounds.

"The vast majority of countries utilize the metric system, and the recommendations for pediatric medication use are based on the metric system," Angood says. 'This should become the standard of recording pediatric patient weights."

The Joint Commission's April 11, 2008, *Sentinel Event Alert* addresses pediatric medication errors, and urges greater attention to precautions such as medication standardization, improved medication identification and communication techniques, as well as the use of kilograms as the standard weight measurement to calculate proper dosages.[1] **(See p. 64 for more of the risk reduction strategies suggested by The Joint Commission.)**

Most of the harmful pediatric medication errors tracked during the past two years by U.S. Pharmacopeia involved either an improper dose or quantity, according to the *Alert.* Problems typically arise

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when hospitals and clinics are forced to prepare special volumes or concentrations, because the drugs are formulated and packaged primarily for adults. The need to alter the original medication dosage requires a series of calculations and tasks that increase the chance for error.

Another problem is that younger patients cannot participate in their health care the same way adults can, says **Mark R. Chassin**, MD, MPP, MPH, president of The Joint Commission.

"Children often lack the communication skills to tell caregivers if something is wrong, which increases the responsibility of caregivers to carefully monitor their care to keep them safe," he says. "Organizations and caregivers must commit themselves to using effective risk reduction strategies to make a difference in preventing pediatric medication errors."

Medication dosing errors also are more common in pediatrics than adults because of fractional dosing and the need for decimal points, says **Stu Levine**, PharmD, an informatics and pediatric specialist with the Institute for Safe Medication Practices in Horsham, PA, an organization which serves as a resource for information on how to improve medication practices. In the *Alert,* Levine notes that research shows that the potential for adverse drug events within the pediatric inpatient population is about three times as high as among hospitalized adults.

The *Alert* also encourages organizations: to be open and transparent if an error occurs in order to facilitate learning so that future errors can be prevented; drug manufacturers to develop pediatric-specific formulations and to standardize labeling and packaging of all medications; and parents to seek out information and ask questions about their child's medications and to repeat back instructions to health care professionals in order to avoid mix-ups.

Latest research shows error risk with kids

A new study, the first to develop and evaluate a trigger tool to detect adverse drug events in an inpatient pediatric population, identified an 11.1% rate of adverse drug events in pediatric patients, far more than described in previous studies. The study also showed that 22% of those adverse drug events were preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively.[1]

During calendar years 2006-2007, the MEDMARX database from the U.S. Pharmacopeia in Rockville, MD, shows nearly 2.5% of pediatric medication errors led to patient harm. The most common types of harmful pediatric medication errors were: improper dose/quantity (37.5%), omission error (19.9%), unauthorized/wrong drug (13.7%), and prescribing error (9.4%), followed by wrong administration technique, wrong time, drug prepared incorrectly, wrong dosage form, and wrong route. Medication errors involving pediatric patients were most often caused by: performance deficit (43%), knowledge deficit (29.9%), procedure/protocol not followed (20.7%), and miscommunication (16.8%), followed by calculation error, computer entry error, inadequate or lack of monitoring, improper use of pumps, and documentation errors.

The MEDMARX Data Report reveals that approximately 32.4% of pediatric errors in the operating room involve an improper dose/quantity compared with 14.6% in the adult population and 15.4% in the geriatric population.

Reference

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Risk reduction can work

The risk reduction strategies suggested by The Joint Commission can have a major impact, says **Sara White**, MS, FASHP, a pharmacy leadership coach in Boston who previously was director of pharmacy and clinical professor for Stanford Hospital and Clinics in Palo Alto, CA, and was faced with the responsibility of managing patient safety. She says a strong partnership with the risk management department at Stanford Hospital and Clinics was essential to reducing pediatric medication errors.

"The first thing a risk manager should do is meet with the director of pharmacy and offer to help. I'm certain that offer will be well received," she says. "Ask what the pharmacy needs help with, and pull from your different resources."

Risk managers should make sure they are on the distribution list for any publications or alerts regarding medication errors, White suggests. The Institute for Safe Medication Practices (ISMP) in Horsham, PA, is a valuable resource, and White urges risk managers to visit the group's web site at www.ISMP.org to access tools and information

SOURCES

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that can be used to reduce errors.

"We had ISMP come in and do an assessment for us. They looked at us with outside eyes and gave us recommendations for how we could tighten our system up," she says. "Even though you think you have a tight system, somebody from the outside can find ways to improve. It costs a little bit of money, but so does a lawsuit."

The risk manager also can be involved in obtaining the automated systems that can reduce many medication errors, White says. Remember that getting the automated dispensing system or similar electronic safeguards in place only is the first step. You have to keep the technology current, she adds.

"The pharmacy director can make the case for why you need it, but the risk manager can help with some of the politics in the organization — getting things approved and funded," she says. "The risk manager also can be great help in getting the message to caregivers about how and why procedures have to change. It makes a big difference when, after I make the case to a caregiver, another person from the organization comes along and reinforces that message."

Automation is key step

Automated systems are often cited as the way to reduce human error in medication administration, and **Bill Churchill**, MS, RPh, executive director of pharmacy services at Boston's Brigham and Women's Hospital, says that is the case at his hospital. For the past six years, the hospital has been on a quest to eliminate medication errors, and a key part of that effort has been increasing patient safety and hospital staff efficiency through the use of automated medication management systems.

Churchill says the first step in reducing medication errors is to understand what systems you have in place now, and what type of errors are occurring. Risk managers can contribute to that analysis and data collection, he says.

"Everyone needs to understand where the weaknesses are before you go forward," he says. "The worst thing you can do is automate a bad system."

Brigham and Women's uses a number of high-tech methods to reduce the risk of errors, including bar code technology used throughout the pharmacy and at all points in the dispensing process, including at the bed side. The hospital has pharmacy professionals on the units who can communicate with the central pharmacy wireless connections, and the automated dispensing systems are all interfaced with the electronic medication records system and the automated infusion pumps. The interconnectedness is all designed to eliminate errors that happen when one person — or one system — doesn't know what the other has done with a patient's medication, he says.

"That kind of multifaceted approach requires a team approach," he says. "You need pharmacy, physicians, nursing, and risk management to drive this through. Risk management can play a huge role by being a champion for the effort, someone to carry this forward and to constantly make the case for this change with senior management."

Reference

1. The Joint Commission. Preventing pediatric medication errors. *Sentinel Event Alert* 2008; Issue 39, April 11, 2008. ■

Training, standardized procedures are key

The Joint Commission's April 11, 2008, *Sentinel Event Alert* offers a number of risk reduction strategies for pediatric medication errors.[1] Here are some highlights of The Joint Commission's advice:

• Standardize and identify medications effectively, as well as the processes for drug administration.

• Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use.

• To prevent timing errors in medication administration, standardize how days are counted in all protocols by deciding upon a protocol start date, such as Day 0 or Day 1.

• Limit the number of concentrations and dose strengths of high-alert medications to the minimum needed to provide safe care.

• For pediatric patients who are receiving compounded oral medications and total parenteral nutrition at home, ensure that the doses are equivalent to those prepared in the hospital (i.e., the volume of the home dose should be the same as the volume of the hospital-prepared products).

• Use oral syringes to administer oral medications. The pharmacy should use oral syringes when preparing oral liquid medications. Make oral syringes available on patient care units when "as-needed" medications are prepared. Educate staff about the benefits of oral syringes in preventing inadvertent intravenous administration of oral medications.

• Use The Joint Commission's National Patient Safety Goals and Medication Management Standards to guide safe medication practices for pediatric patients.

• Require prescribers to write out how they arrived at the proper dosage, as dose per weight, so that the calculation can be double-checked by a pharmacist, nurse, or both.

• Use pediatric-specific medication formulations and concentrations when possible.

• Clearly differentiate from adult formulations all products that have been repackaged for use in pediatric populations. Use clear, highly visible warning labels. To prevent overdoses, keep concentrated adult medications away from pediatric care units. Avoid storing adult and pediatric concentrations in the same automated dispensing machine/cabinet drawer.

• Ensure comprehensive specialty training for all practitioners involved in the care of infants and children, as well as continuing education programs on pediatric medications for all health care providers. Training and education should include information on how adverse effects should be reported.

• Communicate verbally and in writing information about the child's medication to the child, caregivers and parents/guardians, including information about potential side effects. Ask the caregiver/parent/guardian to repeat back their understanding of the drug and how it is to be administered. Encourage the asking of questions about medications.

• Have a pharmacist with pediatric expertise available or on-call at all times.

• Establish and implement medication procedures that include pediatric prescribing and administration practices.

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Patient safety can help your bottom line

When it comes to patient safety, everyone says they want to do the right thing for patients. But that noble intention sometimes isn't enough when it comes time to look at the budget and decide which good intentions get funded this year.

Maybe your argument should be that your program can achieve two goals. More research is showing that, if you do it right, a patient safety effort actually can save money while it saves lives. Investing in patient safety initiatives saves lives and money, according to a new analysis published by researchers with Lumetra, a nonprofit health care consultancy in San Francisco. Medical errors, adverse drug events and hospital-acquired infections are among the most prevalent and preventable patient safety hazards, costing patient lives and loss of productivity and hospitals billions of dollars each year, says **Allison Snow**, MHA, vice president for healthcare process improvement with Lumetra.

EXECUTIVE SUMMARY

More evidence is accumulating that patient safety efforts can save money for a health care organization. Risk managers may be able to use this data to convince senior leadership of a safety effort's value.

- A recent report includes examples of major cost savings.
- Reducing length of stay and readmissions can yield cost reductions.
- Risk managers should be sure expenses are offset with potential savings.

The researchers compiled evidence and expert-based patient safety data that demonstrate how hospitals save money and lives by improving overall safety.[1] The analysis draws on national case studies to highlight the dramatic costs of patient safety violations; the benefits of patient safety interventions; and the technological trends safety leaders are investing in to create an environment that fosters increased safety, she says.

"For health care providers, investing in patient safety initiatives is the right thing to do," Snow says. "It also just makes great business sense. Patient safety initiatives protect the bottom line, provide better patient care, improve patient satisfaction, increase employee productivity, foster improved systemic changes, and build goodwill."

Examples show cost savings

The Lumetra report lists these examples of how patient safety efforts can have a positive effect on the bottom line:

• Standing orders, clinical pathways, fast-track protocols, and comprehensive case management systems reduce the average length of stay, improve clinical outcomes, increase patient satisfaction, and produce annual savings that range from $15,000 to $187,000.

• A large, acute care hospital invested $3,674 to develop and implement a set of standing orders and clinical pathways for its 400 acute myocardial infarction (AMI) patients each year. This process change has reduced the average length of stay, resulting in a financial benefit of $53,000 annually.

• Heavily publicizing a new fast-track protocol for patients with chest pain allowed an acute care hospital to admit additional patients while reducing average length of stay, increasing patient profits by nearly $135,000 annually and reducing the hospital's exposure to denials of payment for unnecessary admissions.

• Creating a set of clinical pathways allowed one hospital to ensure that its pneumonia patients receive antibiotics more quickly. This intervention resulted in a sizeable average length of stay reduction and staff efficiencies, saving the facility more than $30,000 annually.

• One urban medical center developed a comprehensive case management system for pneumonia patients, involving standing orders, physician reminders, and patient education resulting in $187,000 in annual cost savings as a result of an average length of stay reduction. *(Editor's note: To see the full Lumetra report, go to www.lumetra.com/about-lumetra/index.aspx?id=3450.)*

SOURCES

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Sharp Grossmont Hospital in La Mesa, CA, has seen significant cost savings from implementing evidence-based practice for heart failure patients, says **Colleen Austel Nadeau**, BSN, RN, senior cardiac specialist in heart failure at Sharp Grossmont. Beginning in July 2005, the hospital implemented a patient safety process that includes identifying heart failure patients with stickers on the patient chart to remind staff about their special needs. The hospital also began adhering to a number of best practice guidelines for cardiac care, including early use of certain drugs and a specific protocol for cardiac discharge.

The results of the program are encouraging, she reports. Readmissions and length of stay are both down significantly.

"Our preliminary numbers show that by reducing readmissions, we save about $2,000 per case," Nadeau explains. "We've had a 3% reduction in readmissions, so overall the cost savings on readmissions amounted to about $47,000 over a year, which is a pretty nice cost savings."

Similar cost savings come from reducing the length of stay, she says. The cost per day is about $462, so the reduction in length of stay from the cardiac initiatives saves about $169,000 per year.

Joyce McGinty, MS, RN, cardiac program manager at the hospital, suggests that risk managers can use that kind of data to actively support efforts to implement patient safety programs.

"We're also finding that we can sustain these numbers," she says. "You implement these kinds of changes because you care about quality and patient safety, but the cost savings are undeniably a benefit as well. When you're looking at possible expenses,

you have to look at these potential savings, too."

Reference

1. Sabogal F, Snow A, Sawyer L. The business case for patient safety. *Calif Assoc Healthc Qual J* 2008; 1:10-34. ■

Ethics guidelines need risk manager input

Health care providers are taking a hard look at how to restrict the free gifts, meals, and travel from pharmaceutical companies and device manufacturers that have become a standard part of the health care business, and risk managers have a major role to play.

The trend clearly is for health care providers to restrict freebies, and some are going so far as to ban them outright. One of the most comprehensive and restrictive policies was enacted recently by the University of Pittsburgh Medical Center, where the policy bans gifts such as pens, notepads, and food provided by industry representatives. It applies to about 50,000 faculty, staff, and students of the university's Schools of the Health Sciences and other professionals and staff employed or contracted by UPMC's U.S. operations. **(See p. 68 for more on the UPMC policy.)**

Risk managers should be deeply involved in the development and monitoring of industry relations guidelines, says **Edgar Bueno**, JD, an attorney with the Pillsbury Winthrop in McLean, VA. Bueno focuses on fraud and abuse and compliance counseling, and he previously worked at the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services in Washington, DC.

EXECUTIVE SUMMARY

More health care providers are implementing strict policies and procedures on how employees may interact with vendors. Risk managers should be involved in formulating these policies and enforcing them.

- Providers are sharply restricting what employees may accept in the form of gifts, meals, and travel.
- Some health care providers are banning gifts outright.
- A prudent policy might allow some small gifts but not anything of significant value.

"The line as to what is appropriate or legal can get pretty murky, but the ramifications are potentially quite large," he explains. "The risk manager has to step in and protect the organization."

Bueno says these are the primary laws that providers need to worry about with industry relations guidelines:

- The anti-kickback statute, which is a criminal law;
- The federal False Claims Act, which allows the government to recover huge penalties and treble damages for fraudulent claims submitted as a result of an impermissible kickback relationship;
- An OIG program exclusion which would prevent an individual or entity from doing business with any of the federal health care programs. "If freebies are being offered or provided to patients, then certain patient inducement laws may also be implicated," Bueno says.

He notes that there is no requirement to have industry relations guidelines in place, and up to this point, many providers have had none or only a loosely worded, rarely enforced policy. But not having a policy means you must depend entirely on your employees knowing what is and is not acceptable, trusting that they won't get you in a load of trouble by accepting a free dinner or a trip to the Bahamas. (An academic group has proposed a total ban on such gifts. **See p. 69 for more information.)**

"When it comes to whether you need a policy, a lot depends on how much of the perception issue the institution is willing to manage. Put another way, how much is the institution willing to defend its conduct or its physicians if ever questioned by regulators?" Bueno contends. "Is there reasonable justification for an entire department to be accepting free pens, lunches, or gift certificates from a drug sales rep?"

The first step for a risk manager should be to determine what is going on in your institution, he says. If you work at a large academic medical center, you probably know already that industry representatives are offering gifts at every opportunity. That type of facility is most in need of a comprehensive and strict policy such as that recently put in place at UPMC, he says. But if you are a risk manager at a smaller institution with no teaching affiliation, the gifts in question might just concern the ink pens, writing tablets, drug samples, and an occasional lunch. A policy on those gifts still might be appropriate, Bueno says, but a UPMC-style policy that addresses every possible scenario might be overkill.

"The scale of the gift has a lot to do with it.

UPMC policy covers gifts, meals, consulting

The University of Pittsburgh Medical Center (UPMC) is the latest large academic medical center to implement a comprehensive set of industry relations guidelines. The policies are far-reaching and restrictive.

Because of sharply differing opinions on the value of drug samples that can be passed on to patients, doctors were given the option of whether to continue offering samples. UPMC reports that some doctors have chosen instead to provide patients with information about other ways to obtain their medicine, such as manufacturers' assistance programs. The university is putting together a centralized process for UPMC to accept samples from companies, and then provide them to doctors' offices.

Here are some of the other provisions of the UPMC policy:

- Sales and marketing representatives can continue to visit physicians but only when invited. They may bring along samples, but the representatives must comply with other policy provisions, including completion of an online training and a quiz about the new guidelines.
- Nearly all gifts from industry, including food, are banned. There are some exceptions, such as food provided at continuing education events.
- Consulting relationships with industry must be monitored and there are restrictions. UPMC expects to be apprised of attendance at off-campus industry-sponsored meetings, and industry support for scholarships and fellowships.

Penalties for UPMC employees can include mandatory counseling, written reprimands, revocation of hospital privileges, fines, or termination. Companies repeatedly violating the policy could have their sales and marketing personnel suspended from UPMC and the Health Sciences schools for a year or more.

The complete policy and related information is available online at www.coi.pitt.edu/Industry Relationships. ■

I don't think anybody's going to argue that something nefarious is happening because your doctor took a free pen," Bueno says. "But if your entire surgery department is taking free vacations and going to lavish dinners provided by a device manufacturer, and your risk management department doesn't even know about it, then obviously there is a compliance risk there."

Gabriela Cora, MD, MBA, president of the Executive Health & Wealth Institute, a consulting practice in Miami, and managing partner of Florida Neuroscience Center in Fort Lauderdale, has seen the whole range of practices throughout her career. Working at hospitals she has seen extensive interaction with industry representatives, but then when she worked at the National Institutes of Health in Bethesda, MD, there was virtually no exchange of gifts. Cora says risk managers can expect considerable resistance from physicians if you try to restrict gifts.

"Some physicians will tell you that it is not an ethical issue because they can spot the bias and know when they are being manipulated," she says. "That is not really true. It can be difficult for a doctor to know when a free gift is influencing a decision. I know of cases in which patients were treated with certain drugs just because the free samples were available."

Cora says risk managers should combine education with awareness about regulatory issues. That tactic will be more productive than simply declaring that certain practices are prohibited and threatening disciplinary action, she adds.

"Enlist some people from their field to discuss how bias works, that it is a psychological process that can be very subtle. Show them how it occurs," Cora says. "Combine showing them the data on this with explaining the procedures you expect them to follow. You will make much more headway if you can first convince them that there is a real risk of bias from these gifts that seem so harmless."

Cherie Fieri, MHSA, a health care specialist with LECG, a consulting firm in Chicago, says she has seen a trend toward a more conservative approach to industry relations guidelines. That is generally good advice for risk managers, she says.

"The pharmaceutical companies are responding in the same way, by minimizing the logos on the small gifts they hand out, by trying not to be so blatant about getting their names out there," she says. "My advice to clients is to be very conservative with this topic and formulate guidelines that make it clear you expect people to err on the side of caution. Make clear the intent of your organization, that you don't want to give the perception of any improper influence."

Everyone needs guidelines

It is not just large academic centers that need industry relations guidelines, Bueno says. Regulators tend to look at the biggest, most obvious targets first and then move on to smaller institutions where they know the same problems exist, he

SOURCES

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says. (The problem doesn't just concern pharmaceuticals and device manufacturers either. **See article, below right, for other concerns.)**

Developing a policy should not require re-creating the wheel; many institutions have made their industry relations guidelines public, and a risk manager can start there to establish the basic components of a policy, Bueno says. However, he warns risk managers against rushing to a complete ban on gifts and policies so strict that employees can't have any meaningful contact with industry representatives. Such a complete ban is easier to enact sometimes because you don't have to argue over the details of what should and should not be allowed. The downside, he says, is that you can deny your employees important contact with others in the health care business.

"The other possible risk is that you have made the policy so restrictive and ironclad that you're setting yourself up for failure," he says. "Either your employees try to comply but just can't because the policy is not realistic, or they just forget it altogether and do what they need to do." ■

Group says all gifts should be banned

While many health care providers wrangle with exactly how to monitor and restrict gifts from vendors, an influential college association has come up with a direct solution: Ban all drug and medical device companies from offering free food, gifts, travel and ghost-writing services to doctors, staff members and students in all 129 of the nation's medical colleges.

The proposed ban is the result of a two-year effort by the Association of American Medical Colleges (AAMC) in Washington, DC, to create a model policy governing interactions between the schools and industry. The AAMC still must determine whether to fully endorse the ban. The ban would not be mandatory, but most schools follow the AAMC's recommendations.

In announcing the proposed ban, the AAMC noted that drug companies spend billions on freebies for doctors, even more than they spend on research or consumer advertising. Medical schools are hot targets because they have influential professors and financially strapped, impressionable, young doctors.

Pharmaceutical companies and device manufacturers routinely offer free food and gifts, but they also arrange lucrative consulting arrangements and ghostwriting services for professors.

Such forms of industry involvement tend to establish reciprocal relationships that can inject bias, distort decision making and create the perception among colleagues, students, trainees, and the public that practitioners are being 'bought' or 'bribed' by industry," the report said. In addition to the gift, food, and travel bans, the report recommended that medical schools should "strongly discourage participation by their faculty in industry-sponsored speakers' bureaus," in which doctors are paid to promote drug and device benefits.

The AAMC recommended that schools establish systems for accepting free drug samples or "alternative ways to manage pharmaceutical sample distribution that do not carry the risks to professionalism with which current practices are associated." Schools also should audit independently accredited medical education seminars given by faculty "for the presence of inappropriate influence," the report said. The AAMC said the rules should apply to faculty even when off-duty or away from school. ■

All types of vendors need guidelines

When discussing industry relations guidelines, most of the emphasis falls on pharmaceutical companies and device manufacturers, because they are the most prominent when it comes to gifting and buying meals. But good

industry relations guidelines should cover all aspects of a health care provider's operation, not just the physicians.

There are many more interactions with vendors that are less obvious and less flashy, notes **Gabriela Cora**, MD, MBA, president of the Executive Health & Wealth Institute, a consulting practice in Miami, and managing partner of Florida Neuroscience Center in Fort Lauderdale. Departments such as IT, maintenance, housekeeping, and supply management also may have interactions with vendors that should fall under the purview of your industry relations guidelines, she says.

"If one vendor becomes a little cozy with your people, then that supplier may have an edge over all their competitors," Cora points out. "Even setting aside any legal and regulatory concerns, your hospital may not be getting the best deal because the supplier is doing whatever makes the department head happy." ■

NY jury rejects rectal exam lawsuit

A New York City jury has decided that a hospital did nothing wrong when it tried to examine the rectum of a construction worker who had been hit on the head by a falling wooden beam. The man had sued the hospital, claiming that he was examined against his will after being sedated and restrained.

The jury deliberated for about an hour, according to a report by The Associated Press. The state Supreme Court jury found the hospital and its ED medical staff were not liable and awarded nothing to 38-year-old Brian Persaud, who had sued New York-Presbyterian Hospital for unspecified damages. Persaud's lawyer, Gerard Marrone, JD, of New York City, issued a statement saying Persaud might appeal.

Persaud was injured while working at a construction site in midtown Manhattan on May 20, 2003. He was taken to the ED at New York-Presbyterian Hospital and received eight stitches for a cut over his eyebrow, but when ED staff attempted to examine his rectum, Persaud refused. Persaud said in court that the doctors explained why they needed to do a rectal exam: when a patient is brought to the ED after a serious accident, the standard of care requires examining the patient for unseen injuries, including internal injuries or signs of spinal damage.

Persaud adamantly refused and protested as staff held him down for the exam. After he hit a doctor during the struggle, the staff gave him a strong sedative. There was conflicting testimony at trial as to whether the rectal exam was completed. Persaud woke up handcuffed to the bed and soon was charged with misdemeanor assault against the doctor.

A judge dismissed the misdemeanor assault charge before Persaud sued the hospital. **(For more on this case and the risk management issues involved, see *Healthcare Risk Management*, April 2008, p. 40.)** ■

Med-mal rates may not mean fewer doctors

The common wisdom is that states with high rates of medical malpractice cases, or those considered plaintiff-friendly, will see declining numbers of physicians and specialists in particular. But a new report suggests that might not be the case.

In fact, a state in "malpractice crisis" may see a rise in specialists, because the doctors shy away from difficult cases, meaning more doctors are needed per capita. Researchers from the Oregon Health & Sciences University in Portland recently reported those surprising results at the annual meeting of the American Association of Neurological Surgeons in Chicago.

There currently are an estimated 3,229 active neurosurgeons in the United States certified by the American Board of Neurological Surgeons (ABNS). This corresponds to about one neurosurgeon for every 100,000 people in the United States, notes **Zachary N. Litvack**, MD, a neurosurgeon at the university. Neurosurgeons incur some of the highest annual malpractice premiums of any specialty, averaging more than $100,000 and as high as $300,000 per year in some states, he says. In 2005 alone, neurosurgeons paid a total of $28 million in malpractice claims, with the highest average payment per specialist surgeon ($465,000), and the single highest payment of any claim in any specialty ($5.6 million).

In 2002, the Council of State Neurosurgical Societies (CSNS) performed a survey of practicing neurosurgeons to assess the impact of malpractice on the work force. The results were published,

along with a joint position statement from the two leading professional societies in neurosurgery — the American Association of Neurological Surgeons and Congress of Neurological Surgeons — as a report titled "Neurosurgery in Crisis." As a direct result of malpractice claims and increasing malpractice insurance premiums, the report said, nearly half of all respondents were likely to restrict their practice — for example, limiting their practice to only spine, or not providing emergency or trauma coverage at a local emergency department.

Nearly one-third of respondents at that time stated that they were considering retirement, rather than continue to practice in the face of increasing insurance costs. One-fifth stated that they were considering moving their practice to a state with "better" malpractice conditions. Those changes in practice patterns would result in patients not being able to access lifesaving neurosurgical care, complex neurosurgical care or neurosurgical care close to home.

Based on the findings of the 2002 survey, Litvack and other researchers at Oregon Health & Sciences University decided to analyze ABNS data from 2005-2007, examining 4,584 active and retired neurosurgeons to look for a correlation between numbers of practicing and retiring neurosurgeons and the malpractice environment of each state.

"If malpractice has such a negative impact on practicing neurosurgeons, we hypothesized that states with high malpractice claims and high malpractice insurance premiums, the so-called 'crisis' states, would see a decrease in the number of practicing neurosurgeons over time, and an increase in the number of neurosurgeons moving or retiring from practice in that state," Litvack says. "Conversely, states without major malpractice issues would see an increase in practicing neurosurgeons."

The results Litvack presented at the recent meeting showed just the opposite. Statistical analysis showed that states in "crisis" realized a 5% increase in the number of practicing neurosurgeons. In the 10 states with the largest increases in the number of neurosurgeons, eight states were "severe" states and five were "crisis" states.

Noncrisis states realized a 2% decrease in the number of practicing neurosurgeons. The size of malpractice claims had no impact on the number of practicing neurosurgeons in that respective state.

Litvack theorizes that the results were exactly the opposite of the hypothesis because neurosurgeons are restricting their practices to limit malpractice liability. This means that additional neurosurgeons are needed in the same geographic area to cover the spectrum of diseases and surgical needs of the population. In other words, two neurosurgeons now are needed to perform the job that used to be performed by one.

"While malpractice claims do not on the surface appear to affect demographics alone, they inevitably erode the system of providing neurosurgical care to patients," Litvack says. "As more neurosurgeons limit their scope of practice, patients will find it more difficult to obtain the expert care they need, and that is an issue that indeed needs to be addressed. ■

PA med-mal suits decline for third year

The number of medical malpractice lawsuits filed in Pennsylvania declined for a third consecutive year in 2007, according to figures released recently by the state Supreme Court.

The number of suits, 1,617, represented a 4.5% decline from 2006 and a 40.8% drop from an annual average of roughly 2,700 malpractice lawsuits filed from 2000 to 2002. ■

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 hospitals, for hospital personnel to use in overcoming risk management challenges they encounter in daily practice. ■

COMING IN FUTURE MONTHS

- 'Falls cart' provides aids
- Real value of tail coverage?
- Contracts could replace med-mal
- Create a safety society at work

HIPAA Regulatory Alert

Supplement to *Healthcare Risk Management* and *Hospital Access Management*

Computer hackers step up attacks on health care records

Why is health care information attractive to hackers?

An 85% increase in the number of Internet hacker attacks on its health care clients has been reported by SecureWorks, a security-as-a-service provider. The company says attempted attacks have increased from an average of 11,146 per client per day in the first half of 2007 to an average of 20,630 per client per day in the last half of 2007 through January 2008.

SecureWorks Counter Threat Unit security researcher **Don Jackson** tells *HIPAA Regulatory Alert* criminals are looking for additional places from which identifying material can be obtained and have turned to health care companies. "We've seen attacks level out at the normal targets such as banks and financial services companies," he says. "People are asking where else they can find information and are turning to job sites and health care providers. They're turning over another rock."

Jackson says the increase in hacker attacks is likely due to several factors. First, there is an increase in client-side attacks (attacks against employees' PCs). Another factor is that health care organizations have large attack surfaces that hackers can try to break into. Third is the volume of personal, identifiable information and health insurance credentials that are stored by health care organizations; the final reason is the valuable computing resources that are available to health care organizations.

Jackson says hackers often "go after the low-hanging fruit" — health care facilities can be easy targets because they often have open networks able to conduct many different functions such as billing, transfer of patient records, and communication with different physician networks. "Health care facilities have to be able to speak many different protocols," he says, "and so there's a lot more doors to guard to be sure controls are in place. If you don't evaluate properly, you may have the wrong controls in place."

Because health care organizations store a lot of valuable personal identifiable information such as Social Security numbers, names, addresses, age, and banking and credit card information, they are valuable targets, Jackson says. Information scammers can develop complete profiles on victims, making them ripe for identity theft. He says the increase in the number of attacks on health care systems correlates to an increase in the price being paid for data that are fraudulently obtained.

Growing market for fraudulent cards

Health care information is particularly sought after, he says, because the criminals can defraud health care providers if they are able to obtain insurance contract and group numbers. There is a growing market, he says, for counterfeit health insurance cards that is being fueled by the increase in health care costs.

Jackson says some criminals involved in bringing illegal immigrants into the United States supply them with complete identity packages that include health insurance cards.

Health care organizations usually have high-bandwidth networks with many PCs connected and operations that run every hour of every day. That level of computing resources makes health care organizations an attractive hacker target because they not only have lots of PCs that can be harvested for valuable data, but the computers can be turned into spam bots that collect e-mail addresses from the Internet to build mailing lists. Also, the health care networks' high bandwidth and server computing power make them a prime target, giving hackers lots of resources in which

to run large phishing campaigns (attempts to acquire sensitive information), spam operations, etc.

Solid security plans needed

Jackson says implementing a solid information security and risk management program is a good step toward protecting a health care organization from hacker threats. "HIPAA compliance offers a good baseline," he says. "IT governance frameworks . . . provide broader guidance. These programs' ultimate product is a defense-in-depth system that matches the healthcare organization's business goals, risk profile, and regulatory compliance requirements."

According to Jackson, health care networks are often less protected than others because there are so many things to evaluate and analyze that those responsible for health information technology may not know where to begin.

HIPAA helped bring about a security culture in health care, he says, but that culture still is more mature in banks and the financial services industry.

"We see [health care organization] people doing their due diligence but not dedicating as much resources even though they have a larger attack surface," he says. "Most health care organizations need to have more people working in IT security than are in the same positions in the financial services industry."

[Editor's note: For more information, contact Don Jackson at (877) 905-6661.] ■

Tennessee sets up medical info exchange

The State of Tennessee has expanded an existing contract with AT&T to provide the country's first statewide system to electronically exchange patient medical information. Officials say the system is designed to securely transmit detailed patient information between medical professionals, allowing doctors to access medical histories, prescribe medicines over the Internet, and transfer images such as X-rays and MRI and CT scans.

"As patients, we really want our information to be available to physicians whenever and wherever it's needed," says AT&T director of health care marketing **Diane Turcan**. "And we certainly don't want to be copying paper records." She says the program is likely to be a model for other states and a springboard for interstate information-sharing networks.

To make the system work, AT&T is developing a private portal within the secure network it already provides for Tennessee state agencies. Doctors can use the system to remotely evaluate patients in rural areas who have less access to medical facilities. It also will link to the state health department for access to that agency's immunization and disease registries, death certificate processing, and medical license renewals.

Tennessee eHealth Council Director **Antoine Agassi** says the council and state legislature worked with AT&T to amend the current statewide network agreement so health care providers could tap into the network and purchase services at an attractive price.

"We're allowing doctors to leverage the state's purchasing power," he says, "and offering them a very sophisticated catalog of services. Doctors are not required to participate. But the state is offering them grants of $6,000 to help them get started. They can always choose not to participate, but we think we're offering very attractive pricing."

So far, Agassi says, the plan has been received enthusiastically by physicians, and agreements were reached with 165 sites within the first 45 days. "We're very encouraged," he says. "The feedback has been tremendous."

Doctor fee less than local Internet providers

Doctors will pay between $100 and $750 per month, depending on the bandwidth they need. Agassi says that monthly fee is considerably less than they would pay local providers.

Privacy is a major concern for the system, Agassi says. It is running on a private network that has firewalls and will require authentication of the physician users.

Not able to wait for a national data standard to be adopted, Tennessee has published its own minimum data standards that will be applied to the program.

"We believe we have made this attractive enough that it would be difficult for someone in health care not to participate," Agassi says. "The incentives are so great they will really have to do it." ■

NCVHS: Individuals should have control over disclosure

The National Committee on Vital and Health Statistics (NCVHS) says the Department of Health and Human Services (HHS) should adopt a policy for the Nationwide Health Information Network (NHIN) to allow individuals to have limited control, in a uniform manner, over disclosure of certain sensitive health information for purposes of treatment.

A Feb. 20 letter to HHS Secretary **Michael Leavitt** says the NCVHS recommendation is based on several critical considerations, including protecting patients' legitimate concerns about privacy and confidentiality, fostering trust and encouraging participation in the NHIN to promote opportunities to improve patient care, and protecting health care system integrity.

"We have concluded that NHIN policies should permit individuals limited control, in a uniform manner, over access to their sensitive health information disclosed via the NHIN," the letter says. "Public dialogue should be undertaken to develop the specifics of these policies, and pilot projects should be initiated to test their implementation."

NCVHS says its goal in making this recommendation is to improve patient safety and quality of care while developing a network that is practical, affordable, and inclusive and that protects confidentiality of individual health information.

Development of networks of longitudinal, comprehensive, and interoperable electronic health records provides great opportunities for enhancing coordination of care, avoiding duplication of services, and improving health care effectiveness and efficiency, NCVHS says. But the electronic network model of health information exchange is a major shift from the decentralized, disconnected, largely paper-based health record system now in use. And there are significant implications for individual privacy and confidentiality due to this shift. "Unless specific, privacy-enhancing measures are designed into networks," the letter says, "individuals could have significantly less privacy than they currently have and that they may reasonably expect would continue with EHR networks. With proper privacy-enhancing measures, however, we believe individual privacy will be reasonably protected across the NHIN."

NCVHS said it had considered various options and concluded that affording individuals the opportunity to restrict the flow of their personal information by categories is the most promising alternative. It recommends permitting an individual to sequester information based on predefined information categories. Under this proposal, every individual would have the option of designating one or more categories for sequestering. If a category is selected, all of the information in that category, as the category is defined, would be sequestered. Individuals would not have the option of selecting only specific items within the category to sequester. For any category that is so designated, health care providers accessing an individual's electronic health record via the NHIN would not see any information in that selected category. Individuals would be given the option to provide consent to a health care provider to access the sequestered information.

NCVHS says it recognizes that individuals differ in their opinions on what categories of health information should be considered sensitive and also recognizes that designating particular categories, and, even more critically, defining information to be included in each category, will be a complex and difficult undertaking.

But NCVHS says it's important to make the effort and that having uniform definitions of sensitive health information across the NHIN will be critical to establishing a solution that works well in a society where people travel frequently and receive care from multiple health care providers.

Possible categories, NCVHS says, include domestic violence, genetic information, mental health information, reproductive health, and substance abuse.

Legitimate concerns have been raised about how sequestering categories of health information could affect medical malpractice liability, the letter says. NCVHS believes liability could potentially be affected in at least two ways. First, sequestration of critical information might cause providers to give less than optimal advice or treatment because critical information is not considered. And liability also may be implicated as a result of violations of confidentiality due to imperfect sequestration of data by a provider and the provider's system. NCVHS says the implications for liability deserve additional consideration.

Increase provider trust in records

NCVHS believes that, to the extent permitted by law or regulations, health care providers

should be notified when information is being sequestered to increase providers' trust in the record's contents. It suggests that if providers knew that patients could sequester information but they would not be notified, providers could never really trust that their records were accurate and complete, and would be hesitant to treat patients based on those records.

"The inclusion of some notation that information is missing alerts a provider that caution and special care are appropriate," the letter says. "Furthermore, a significant advantage of the notation is that it provides an opportunity for providers to discuss with their patients concerns about the sequestration of information and the resulting impact on their health care."

NCVHS recommends procedures be put in place for emergency access to sequestered information such as instances in which an unconscious, delirious, or otherwise incompetent person is treated in an emergency department, physician's office, or other health care setting. If such a "break the glass" emergency access provision is used, NCVHS says, an audit trail should record the specifics of the incident and it should automatically trigger a review by the relevant privacy officer. In addition, the patient or patient's representative should be notified as soon as possible that the emergency access provision was used.

Once sequestered information has been accessed through a patient's authorization or emergency procedures, the information should still be treated as sensitive in future NHIN records exchanges unless otherwise consented to by the patient.

The letter says that if a provider accesses information that had been sequestered by the patient, the provider should be required in the future to ensure that the categories of information identified by the patient for sequestration continue to be sequestered when the patient's record is shared over the NHIN.

New care model

NCVHS says it recognizes that sequestering sensitive health information by category represents a new model of clinical care, and various health care providers may be concerned about the implications of an incomplete record for patient care quality and this concern must be addressed. "More than technological solutions will be needed to make this new arrangement successful," the letter says. "It will require substantial public and professional education as well as policies and procedures that consider the medical, social, psychological, cultural, and personal factors in patient care."

[Editor's note: You can download the letter at http://www.ncvhs.hhs.gov/080220lt.pdf.] ■

Health IT national strategy still missing

The Government Accountability Office says that even though the Department of Health and Human Services (HHS) is undertaking a number of activities to pursue President Bush's goal for nationwide implementation of health information technology, it still has not developed a national strategy that defines plans, milestones, and performance measures for reaching the goal of interoperable electronic health records by 2014. "Without an integrated national strategy, HHS will be challenged to ensure that the outcomes of its various health IT initiatives support the president's goal for widespread adoption of interoperable electronic health records," GAO said in testimony before Congress.

Among the activities that have been undertaken, according to the GAO testimony:

- the Office of the National Coordinator has taken steps to advance the implementation of both outpatient and inpatient electronic health records;
- HHS' secretary has recognized certain interoperability standards to be implemented in federal healthcare programs;
- the Office of the National Coordinator has begun trial implementation of a nationwide health information network at nine health information exchange organizations across the country;
- the Office of the National Coordinator has released a summary report and toolkit based on the results of its privacy and security solutions contractor's work.

But, GAO says, given the amount of work yet to be done and the complex task of integrating the outcomes of HHS' various initiatives, it is essential that a national strategy for health IT be defined. ■

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

Failure to perform emergency C-section leads to $38.5 million verdict in Connecticut

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News: A woman pregnant with twins delivered her first baby without incident, but then experienced complications as she was in the process of delivering the second baby. The second baby was experiencing cord prolapse, and his heart rate plummeted. The physician continued to attempt to deliver the second baby vaginally for 10 minutes, but she eventually called for a cesarean. Fifteen minutes later, the baby was born and was diagnosed with cerebral palsy. The baby's mother and family sued the physician and the hospital for medical malpractice, arguing that the physician should have attempted an emergency cesarean more quickly and that the hospital's nurses failed to speak up and advocate for one before the physician ultimately called for the procedure to begin. A jury returned a defense verdict in favor of the hospital, but it found the physician liable and awarded the plaintiffs $38.5 million.

Background: A woman who was 37 weeks pregnant with fraternal twins went into labor and was admitted to the hospital. The first twin, a girl, was delivered vaginally by forceps without injury. Shortly after the first baby was delivered, the physician prematurely ruptured the mother's membranes, and the second twin, a boy, developed a low fetal heart rate. The OB/GYN soon discovered that that the baby boy was experiencing cord prolapse, in which his umbilical cord was impeding blood flow to the brain. Instead of performing a "stat" emergency cesarean, though, the physician continued to try to deliver the second baby vaginally for an additional 10 minutes. She eventually did call for a cesarean, but the procedure took approximately 15 minutes from the moment it was called until the baby was delivered, at which point the baby boy had suffered 25 minutes of bradycardia and hypoxia.

Soon after birth, the baby boy was diagnosed with cerebral palsy. He spent the next month at the hospital for treatment of initial seizures and for diagnostic studies. He is a quadriplegic.

The mother, individually and on behalf of her son, sued the physician and the hospital for medical malpractice. She argued that once the complication was discovered, the physician should have delivered the second baby via emergency cesarean. She also claimed that once the cesarean was called for, it should have been performed on a "stat" basis, and that the physician's "meticulous" operation violated accepted standards of care. As for the hospital, the mother argued that its nurses failed to provide prompt and necessary support, failed to provide the physician with necessary instruments in a timely manner, and failed to speak up and advocate for a cesarean before the physician ultimately called for the procedure to begin.

At trial, the plaintiff presented the testimony of experts in economics, labor and delivery, life care

planning, pediatric neurology, and OB/GYN. The pediatric neurology expert opined that all of the baby's injuries occurred as a result of the acute severe hypoxia suffered during the delivery due to the doctor's and nurses' negligence. This opinion was shared by the plaintiffs' labor and delivery nurse expert, who testified that the hospital's nursing staff failed to communicate the fetal heart rate on a minute-by-minute basis to the physician.

As for damages, the family sought $1 million for past medical expenses. They pointed out that the baby boy required feeding through a nasogastric tube and had undergone several hospitalizations thereafter for aspiration pneumonia, which was ongoing, and seizures. The baby also had a permanent G-J tube surgically implanted, which eventually led to an improvement in his respiratory status.

The family also sought damages for future care. The plaintiffs' life care rehabilitation expert testified that the boy requires 24-hour nursing care, as well as other significant medical, rehabilitative, and supportive care. The plaintiffs' economist estimated that the future cost of care would be approximately $27 million, which he based on the life care plan and the estimation that the boy would live to about 50 years of age.

And finally, the family sought an unspecified amount for the mother's emotional distress for having witnessed the injuries to her son and $2 million for future lost earnings, which was based on the assumption that the boy would have attained a college education.

In presenting these damages to the jury, the boy's father narrated a 14-minute video showing a day in the life of his son. The video showed how the boy is fed through his J tube and the manner in which he communicates with his family by utilizing devices such as toys with buttons and by laughing, smiling, or crying. The father talked about his son's enjoyment of roughhousing, watching television, and playing with his sister, particularly, a game they call "freeze dance," whereby the boy presses a button to stop music from playing and his sister stops dancing until he lets the button go.

Both defendants denied that they acted negligently. The physician, a Harvard graduate who had been practicing for 20 years and who had been sued only once before — which such case was dismissed because the statute of limitations had expired — contended that she reacted reasonably to the baby's low heart rate by performing a vaginal delivery, which was the fastest way to achieve delivery. She pointed out that because the cord prolapse was "occult" rather than "overt," her attempts at vaginal delivery were more reasonable. She further argued that nothing that she did caused the baby's injuries, as he had suffered from chronic hypoxia prior to the cord prolapse, which was evidenced by a placental condition called chorangiosis.

The physician also rebutted the plaintiff's expert witnesses by calling her own experts in obstetrics, placental pathology, and pediatric neurology. The obstetrics expert testified that the physician acted appropriately in all respects, pointing out that cord prolapses, especially occult prolapses, are rare and that occult prolapses are managed differently than overt prolapses. The placental pathology expert testified that infants are "rarely" normal where there is evidence of chorangiosis. And the pediatric neurology expert testified that there was pathological and clinical evidence of chronic hypoxia in utero and that the pathology evidence proved the duration of the chronic hypoxia in utero. The expert also testified that chronic hypoxia caused "global" encephalopathy and that there was a continuum of injury reflected by formation of cytokines. Finally, the physician's experts testified that even if the physician were negligent, the baby boy was expected to live only 20 — not 50 — years, which would reduce the family's claim of $27 million in future expenses by 60%.

The hospital defended the lawsuit by arguing that the physician was solely responsible for the delivery plan, that the nurses could not order a cesarean given that the physician was the only one who could make that determination, and that the nurses complied with the standard of care. The hospital presented evidence demonstrating that the nursing staff communicated the fetal heart rate to the physician by projecting the heart rate through speakers in the operating room.

Nearly three years after the lawsuit was filed, the case went to trial. The judge's jury instructions reportedly included a statement that if the jury found the physician to have acted negligently, the damages award should include compensation for pre-birth injuries. The jury did, in fact, find the physician to be liable for medical malpractice and awarded the plaintiffs $38.5 million — $30 million to the family to cover past and future costs of caring for the boy, $7.5 million to compensate the boy for his suffering, and $1 million to the parents. The hospital was absolved from any liability.

The verdict is believed to be Connecticut's largest medical malpractice award ever, and perhaps even the largest personal injury verdict, surpassing a $36.5 million award in 2005 against a different hospital and obstetrician. The physician

has threatened to appeal the verdict, which she believes is contrary to the evidence. The physician's insurance will cover only a "tiny" fraction of the award, leaving the verdict "essentially uncollectible," according to the physician's attorney.

What this means to you: "This case illustrates the substantial risk of the practice of obstetrics and the underlying rationale behind the incredible cost of malpractice insurance for OB practitioners," says **Lynn Rosenblatt**, CRRN, LHRM, risk manager at HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL. "The information provided indicates that the physician felt that she had acted in good faith, believing that her continued efforts to facilitate a vaginal delivery would in fact be safer and quicker than any delay that would result from executing a C-section."

The testimony of her defense experts did not support that assumption, however. The entirety of the defense was based on a presumption that the second twin had suffered from chronic hypoxia over the duration of the pregnancy as a result of a placental abnormality known as chorangiosis. This introduced a completely different set of considerations for the jury that ultimately was more serious than negligent delivery management.

Perinatal adverse outcomes are closely associated with chorangiosis, which is an abnormal formation of the placenta villi and is thought to be of high consequence in such abnormalities of delivery as nuchal cord and placental abruption. Nuchal cord refers to a situation where the cord wraps itself around the baby's neck or is not sufficiently long to allow for vaginal delivery. Also, chorangiosis is associated with abnormal cord development, where there is only one cord vessel, which predisposes the infant to severe congenital abnormalities.

In this case, the fetus became hypoxic when the membranes ruptured, causing the cord to prolapse and impede the flow of blood to the brain. In defense arguments, the physician advanced that the cord was an occult prolapse as opposed to an overt prolapse. Umbilical cord prolapse refers to an abnormal position of the cord in front of the fetal presenting part so that the fetus compresses the cord during labor, causing hypoxia. Occult prolapse occurs when the cord is contained within the uterus and overt prolapse is where it slips into the vagina. They are managed differently, but are obstetrical emergencies nonetheless, and the standard of care in a litigious world usually is an immediate cesarean.

In occult prolapse, the cord is compressed within the uterus and the fetal heart rate evidences severe bradycardia on uterine contraction and variable acieration between contractions. Changing the mother's position may relieve the pressure if, in fact, the hypoxia is not a result of a placental abnormality, such as single vessel or shortened cord.

In overt prolapse, the cord floats out into the vagina when the membranes rupture. This is more common with breech (feet first) presentations and transverse lie of the fetus across the mother's pelvis, but it also can occur with a nonengaged vertex presentation. Since these were fraternal twins, the second baby was on top of the first in a separate sack. After the first delivery, the physician ruptured the membranes but the infant may not have been engaged in the birthing position and the rupture would have been sufficient to create an overt prolapse.

It appears that the physician felt that she could manipulate the fetus to avoid cord compression, as she seemed to believe she was dealing with an occult prolapse. She continued her attempt to accomplish a vaginal delivery, but after a dangerously long interval she realized that a surgical delivery was the only option.

OB practice has evolved over many huge judgments such as this one into a defensive service. Hospitals frequently keep a surgical suite "ready" should such a situation occur. Surgeons and anesthesia are readily available to assist. Instruments are a mere "lay-out" away. Other supplies are kept in stock to assure immediate availability. Staff nurses on OB units are frequently cross-trained to "scrub in" at a moment's notice. OB staff frequently conduct "drills of mock sections against time" to maintain a rapid response momentum.

Some smaller health care facilities where supplementary help may not be available will not accept high-risk labor patients for those reasons. And make no excuses, multiple birth pregnancies are high risk. Twins are double the baby with longer labors, greater danger of fetal abnormalities, lower birth weight and probable premature delivery. In this case, the team did respond relatively quickly, and they did assure that the physician was aware of the decelerations in the fetal heart rate, as the monitor was audible in the delivery area.

It was the physician who made a major miscalculation. The situation deteriorated greatly over the 25 minutes from the time the hypoxia was first noted to the actual birth. If she had moved to cesarean immediately, the baby would have been delivered within 15 minutes, which may still have been a problem, but perhaps not as severe. As time passed,

the reduction in oxygen to the brain compounded itself, so the effects of the last 10-15 minutes would have been greater than the initial 10 minutes when the physician was attempting vaginal delivery.

Another error in judgment was made by the nursing staff as they could have readied the OR suite when they realized the compromised situation to the baby that a possible cord prolapse can cause. While the staff needs an order from the physician to actually commence a cesarean, they could have initiated the setup without an order. No doubt there would be some expense to the hospital had the vaginal delivery been successful and the setup "wasted," but the cost would have been inconsequential in the grand scheme of things.

Had the room been made ready when the fetus first evidenced distress, the section would have been started and completed within the 25-minute window that it took to get to that point. If that had occurred, the outcome would most likely have been greatly improved.

Despite all of the above details regarding cord prolapse, the expert testimony focused on a very different causation. The opinions were heavily in favor of chronic uterine hypoxia due to chorangiosis and an abnormally developed placenta. The infant's retardation was attributed to global encephalopathy and a cascade of abnormalities as a result of long-standing oxygen deprivation.

In chorangiosis, the chorionic lining of the placenta contains an abnormal number of vascular channels. It is believed the cause of such abnormal findings is a direct result of long standing placental hypoperfusion or low-grade tissue hypoxia. Many maternal conditions contribute to abnormal placenta development such as pre-eclampsia/eclampsia, diabetes mellitus, drug ingestion, chronic pregnancy-related urinary tract infections, as well as several viral and bacterial infections such as rubella, cytomegalovirus, and syphilis.

In this case, there was no indication that the mother had any of the high-risk factors for chorangiosis. Additionally, there was no discussion of any evidence of fetal hypoxia during the last trimester of the pregnancy, when routine fetal heart monitoring and ultrasound would have been the standard of care for prenatal visits.

With a multiple gestational pregnancy, the placenta for both sacks frequently merge into a single unit. It would stand to reason if the male infant suffered from intrauterine distress over a substantial period prior to labor, then the infant girl would have as well. Also, chronic fetal hypoxia is associated with meconium staining of the amniotic fluid. In this case, the fluid at the time the membranes ruptured was clear, indicating an acute issue such as an overt prolapsed cord was the cause of the rapid deceleration of the heart rate.

From the narrative, it is evident that the physician and her insurer chose to take the case before a jury, which after reviewing the alternate diagnosis of chronic intrauterine hypoxia secondary to chorangiosis as opposed to a spontaneous prolapse of the cord, one would certainly wonder why. The instructions to the jury, which included compensation for pre-birth injuries, would indicate that the judge may have suspected the physician's medical negligence extended to the prenatal care as well.

The plaintiff's case revolved around management of labor and delivery issues, which was no doubt suspect, as an immediate cesarean may have prevented or reduced to a lesser degree the profound disability that the child had sustained. The defense that there was a clinically sound belief that the infant was suffering from a longer standing problem introduced to the jury the very real possibility that the obstetrician had been maleficent over the course of the prenatal period. Had she anticipated that she was dealing with an extremely high-risk pregnancy, a scheduled cesarean would have been the standard of care.

The saddest part of this story is that while the family got their day in court and received equable compensation for their undoubtedly tragic loss; the verdict is "essentially uncollectible." Had the physician admitted to a tactical error in judgment and focused on the prolapse as the source of the infant's issues, the case may have been settled in a mediation setting rather than before a jury. This would have allowed discussion among all parties (the parents, the physician, the hospital, and the insurers), as to how best to arrive at an attainable settlement such as some sort of annuity that would have assisted the parents in the child's long-term care.

Had the physician accepted the fact that she was faced with an emergency that she could not effectively handle and moved forward with the cesarean, the outcome could have been much different. A significant element of the standard of care is for the practitioner to know and appreciate the limitations of skill and circumstances. Without that insight, tragedy always is lurking around the corner.

Reference

• Case No. DN X05 FST CV-05-4005513 S, Stamford-Norwalk (CT) Superior Court. ■

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. **The semester ends with this 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.

21. Why does Peter Angood, MD, say it is important to weigh pediatric patients on admission?
A. Staff must calculate the correct dosage for pediatric patients rather than using the standardized doses intended for adults, and because even small calculation errors can have a major impact with small patients.
B. Regulations from the Food and Drug Administration require keeping a log of the patient's weight during admission.
C. Weighing the patient on admission can alert the staff to certain medical conditions that might have been unknown.
D. Weighing the patient on admission provides an opportunity to counsel the patient about proper diet and exercise.

22. Most of the harmful peds med errors tracked during the past two years by U.S. Pharmacopeia involved:
A. an improper dose or quantity.
B. a mislabeled medication.
C. medication given to the wrong patient.
D. an allergic reaction.

23. According to Edgar Bueno, JD, which of the following is true regarding industry relations guidelines?
A. Federal law requires health care providers to have specific industry relations guidelines and nearly all providers have one.
B. There is no requirement to have industry relations guidelines in place, and up to this point, many providers have had none or only a loosely worded, rarely enforced policy.
C. There used to be a federal law requiring specific industry relations guidelines, but it expired in 2006.
D. A new law requiring specific industry relations guidelines for providers will go into effect in 2009.

24. According to a comprehensive set of industry relations guidelines recently enacted by the University of Pittsburgh Medical Center, what is the new policy on visits by industry representatives?
A. Sales and marketing representatives can continue to visit physicians but only when invited.
B. Sales and marketing representatives can continue to visit any time they want.
C. Sales and marketing representatives can visit physicians only once per month.
D. Sales and marketing representatives cannot visit physicians on the UPMC campus at all.

Answers: 21. A; 22. A; 23. B; 24. A.