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Often neglected, the world of pediatric security can morph into a major risk

You need the same precautions as the labor and delivery department

Have you made your labor and delivery unit a veritable fortress with high-tech equipment and strict policies to prevent infant abductions, while leaving the back door wide open? Children in the pediatrics unit can be just as vulnerable as infants, experts say, but risk managers too often put all their focus on protecting the newborns while devoting relatively few resources to other young patients.

Risk managers have put a lot effort in recent years into preventing infant abductions from newborn areas, and the latest data show the work pays off. Health care risk managers started paying much more attention to the risk of infant abduction in the 1990s, and prevention efforts kicked into high gear in 1999 when the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a *Sentinel Event Alert* about the danger.

Data indicate that infant abductions have dropped significantly. Infant abductions represented 3% of all sentinel events in 1996 and dropped sharply to less than 1% in 1999, then to less than 0.5% in 2003, according to JCAHO data.

A recent infant abduction occurred Dec. 25, 2003, at Beth Israel Medical Center in Newark, NJ, when a woman befriended a new mother, convinced her to take a shower, and then walked out with the baby after removing the child's security tag. It was the first infant abduction from a hospital in 22 months, the longest stretch without any cases since 1983, suggesting that prevention efforts are working. The irony, however, is that the same hospitals with elaborate systems to prevent someone from walking off with a newborn may have virtually no systems in place to stop a stranger — or more likely, an estranged family member — from taking an older child from any other area of the hospital. **(See p. 52 for more on where abductions take place.)**

And abductions are not the only risk. Children also are at risk of being abused if access to pediatric units is not tightly controlled. The lack of pediatric security is a growing concern among some insurers, says **Susan**

Chmieleski, APRN, JD, CPHRM, formerly director of health care risk management with the Chubb Group of Insurance Companies in Simsbury, CT. She spoke on the topic at the recent meeting of the American Society for Healthcare Risk Management in Nashville.

"Underwriters are going to ask about it," she says. "The problem these days is not necessarily the security of newborn and nurseries, but in pediatric units. A lot of hospitals don't have dedicated pediatric units anymore, particularly in smaller hospitals, and the security of these kids is forgotten."

Serious liability risk

Abduction or abuse of a child is a highly emotional tragedy that will have far-reaching liability implications, experts say. The financial is great from lawsuits — almost certain to be filed after such an incident — but the losses will include more than money.

The organization will suffer extremely bad publicity in the community, possibly for years afterward, as people remember your hospital as the one in which a child was harmed. And an infant abduction automatically qualifies as a sentinel event with JCAHO. That means the event will prompt a nightmare of investigations and reports.

Information from the National Center for Missing and Exploited Children, which monitors infant abductions from health care facilities, indicates that the hospital is more likely to be sued in cases where the abductor impersonated a hospital employee than in those cases in which the abductor used another method to obtain the child.

Smaller facilities also may be more at risk now that people are more aware of the sophisticated security systems in larger hospitals, according to the center.

Hospital expands security to pediatrics

Some risk managers are realizing that tight security in the labor and delivery department is not enough. **Kathy Haig**, RN, director of quality resource management, patient safety officer, and risk manager at OSF St. Joseph Medical Center in Bloomington, IL, says her facility has spent about $10,000 in the past few years to expand security for pediatric patients and is planning a major upgrade soon.

"Everyone is so tuned in to babies. When you hear about abductions everyone thinks babies, but babies can be in peds too," she says.

The hospital had a sophisticated security system in obstetrics for several years before adopting similar precautions in pediatrics, she says. The improvement was spurred in part when Haig became risk manager and saw young patients in the hallways and doors left open on the pediatrics unit.

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"I looked at that and said, 'C'mon guys, this just isn't good,'" she says. "These are little kids, and we have to more careful."

The hospital's precautions in pediatrics now mirror those used in the labor and delivery unit, with sensor tags on the children that set off alarms when they approach exits. Haig says she recently encouraged the director of obstetrics to put in a capital budget request to replace the entire system because it is about 10 years old and the original maker no longer services the equipment.

OSF St. Joseph's also updated its policies and procedures to require the same sort of precautions in pediatrics that are common in newborn areas, such as checking the identity of all visitors and requiring that children never be left alone. The hospital expanded its Code Pink drills to include abductions of pediatric patients, not just newborn infants.

Sensors set off alarms, lock doors

The pediatrics unit has two sets of doors that could be used to exit the area, so both have alarms that are triggered by arm bands on the child, says **Karen DeLong**, RN, BSN, nurse manager for pediatrics. If a child with an armband gets within 10 feet of the door, an alarm sounds and the doors close and lock.

To reset the system, switches must be activated on two separate panels that are some distance apart, making it impossible for anyone to just reset the system and dash out the doors.

When patients must leave the pediatric unit to go to radiology, for instance, staff must hold the door open so they can get out, and then they have to do the same to get the patient back in.

"The alarms still go off, but that way we don't have to take the bracelet off and put it back on every time," DeLong says. "A lot of the risk involves custody battles with one parent thinking they can slip in and take the child. And then there's also the child who is feeling better, gets tired of being cooped up in the room, and wants to go exploring."

OSF St. Joseph usually has a small pediatric census, just a few patients at a time, but occasionally the pediatrics department will run out of the armband sensors. In that case, the policy is to put them on the youngest patients first.

In addition, OSF St. Joseph's depends on a high level of awareness among pediatrics staff, encouraging them to be familiar enough with the family to know who should and should not be on the floor, and whether there are any family disputes that could be problematic. Once you bring the problem to the staff's attention, everyone realizes how important it is to take these precautions with pediatric patients, Haig says.

"I can see how peds might be overlooked," she says. "But just imagine — the same infant you protected so tightly in the labor and delivery unit could be back in the hospital one week later on your peds unit. Why wouldn't we need to provide the same level of protection?"

Why not indeed, notes **Chuck Williamson**, CHSP, LHRM, director of risk management and safety at Boca Raton (FL) Community Hospital, where a high-tech system reflects his belief that pediatric patients must be watched very carefully. The hospital has spent about $350,000 on security technology for pediatric patients in the past five years, and Williamson budgets for some type of improvement every year.

That investment includes 68 cameras and 38 access ports that require an electronic key card to open. The system is monitored at the hospital's main security station that is located, by design, right outside the pediatric and newborn units. Access to the area is limited to those employees with reason to be there, along with visitors who have proper passes. When an employee swipes an identification badge to open a controlled door, the system automatically shows the security

guard a live camera shot of the person at the door and the photo appearing on the identification badge. If they don't match, the guard responds.

"This is more than most hospitals have. Our hospital is probably pretty far ahead of a lot of people, but we think it's worth it," Williamson says. "No matter how much you think you have you can always improve your security. With children, you need both physical security and technology."

Don't overlook system maintenance

Chmieleski says such high-tech systems are a great asset, but you should not depend on them as your only line of defense. Good policies and procedures are also necessary. For instance, what happens when a child leaves the safe confines of the pediatric unit? In Williamson's facility, children are not allowed to leave the unit on their own for any reason. The patient must be signed out by a staff member, and a family member is encouraged to accompany the child at all times for testing or surgery.

"When a parent can't go with them, someone from peds must go with the child and stay with them the whole time," he says. "That person cannot leave the child alone for any time at all."

If you use a sophisticated electronic system, Chmieleski says you should be sure to test the system frequently and document those checks. She recommends at least a basic system check every 24 hours.

Williamson also stresses the need for constant maintenance. At OSF St. Joseph, the high-tech security system is thoroughly tested every two weeks.

"There's nothing worse than something happening and saying, 'Oh no, that camera's not working today,'" he says.

Conduct regular drills

In any effort to prevent child abductions from health care facilities, drills are necessary. Regular infant abduction drills also are required by JCAHO. Boca Raton Community Hospital and OSF St. Joseph's both include pediatric scenarios in their infant abduction drills, which require the entire hospital to respond. At OSF St. Joseph, the alarm is sounded with specific code words that alert the staff to what type of child is missing — an infant or older child.

Even if you can't afford a technological upgrade right away, expanding your Code Pink drills to include older patients is one way to immediately improve your pediatric security, Chmieleski advises.

"Hospitals are pretty good about doing them in labor and delivery units, but make sure they are hospitalwide," she says. "It's amazing how many people can get off the unit with these infants when we do these drills and are actually on their way out the doors of the hospital. An older child may arouse even less suspicion unless your staff is aware of the risk." ■

Most abductions don't happen in mother's room

The labor and delivery department may be where the risk of infant abductions is greatest, but it is far from the only area of the hospital needing a risk manager's attention. Children are often taken from other areas of the hospital that may not receive as much attention.

The National Center for Missing and Exploited Children (NCMEC), which monitors infant abductions of all types, reports that when infants are taken from health care facilities, they are taken from the mother's room only 40% of the time.[1] The hospital nursery was the site of 10% of abductions.

"Another location for infant abduction is a facility's pediatric room. This room was the location of 13 cases or 10.9% of the cases studied," according to the report. "In most cases, the infant was hospitalized for an illness such as a feeding problem, digestive disorder, fever, meningitis, or bacterial infection."

Baby taken from peds unit

The NCMEC provides this example of an actual abduction from a pediatric unit: The morning hospital shift had just begun and the day nurse, in checking her assignment of infants, noted that a 23-day-old boy was not in his crib. He had been hospitalized for a digestive disorder and was due to be discharged that day. The night nurse had reported that the mother had been in during that shift caring for him.

At first, staff members thought that the mother may have taken the infant home, but a check showed that was incorrect. The infant then was reported missing, and local law enforcement was

Root causes of infant abductions identified

All the hospitals where infant abductions have occurred identified unmonitored elevator or stairwell access to the postpartum and nursery areas as a root cause, according to information from the Joint Commission on Accreditation of Healthcare Organizations.

The root causes fell into these six general areas:

- Security equipment factors such as security equipment not being available, operational, or used as intended.
- Physical environmental factors such as no line of sight to entry points as well as unmonitored elevator or stairwell access.
- Inadequate patient education.
- Staff-related factors such as insufficient orientation/training, competency/credentialing issues and insufficient staffing levels.
- Information-related factors such as birth information published in local newspapers, delay in notifying security when an abduction was suspected, improper communication of relevant information among caregivers, and improper communication between hospital units.
- Organization cultural factors such as reluctance to confront unidentified visitors/providers. ■

notified and began an investigation. The news media covered the story extensively.

The infant was recovered the next day at the home of one of the abductors. The two female abductors were visiting relatives at the hospital on another floor when they were told of an "abandoned baby" in pediatrics. They decided to pose as employees and entered the pediatrics unit. A nurse challenged the abductors when they asked her which infant was abandoned, but it is theorized that the women took the infant when the nurse left the unit for dinner.

Nurse impostor takes baby in clinic

In 7.6% of cases, the infant was abducted from some other area of the premises of the health care facility. These locations included clinics, corridors, waiting rooms, the parking lot, and curbside.

Here is an example from the NCMEC: Parents brought their 8-week-old daughter to the pediatric clinic for her checkup, registered at the desk, and went to the waiting room. A woman they thought was a nurse approached them. The woman, who was wearing a nurse's uniform, took the infant and mother into the treatment area where the infant was given an injection. The infant and mother were sent back to the waiting area, and then the woman returned shortly to ask if she could hold the infant.

Before the mother could say anything the imposter picked up the infant and said that she was going to show her to the other nurses. The mother objected, but the woman kept walking and said that she didn't need any more children because she already had two of her own. Two or three minutes went by, and the mother went to find the woman and her daughter, but they were gone.

The baby was recovered six months later when a relative of the abductor reported her suspicions.

Reference

1. Burgess AW, Lanning KV. *An Analysis of Infant Abductions.* Alexandria, VA: National Center for Missing and Exploited Children; July 2003. ■

Patient safety often is about more than errors

A recent incident in which a surgeon allegedly arrived drunk for a procedure illustrates an important lesson about how broadly risk managers should educate staff about the concept of patient safety, says one expert. Does your institution's culture encourage staff to speak up and "stop the line" when they sense someone is not in the proper frame of mind to care for patients, or do you focus entirely on tangible errors such as incorrect dosages?

Any effort to improve patient safety must include a broad range of scenarios and empower staff to act when it thinks unsafe conditions exists, says **Geri Amori**, PhD, ARM, FASHRM, president of Communicating HealthCare, a risk management consulting firm in Shelby, VT, and past president of the American Society for Healthcare Risk Management (ASHRM). It is a mistake to think that patient safety is all about

medication errors and other easily defined "errors" that might be caught before they cause harm, she says.

Tragedy also can be averted by realizing that individuals sometimes are just not in the proper state to care for patients, Amori says. Sometimes that condition will be caused by something as grievous as being under the influence of alcohol or drugs, she says, but it also may related to the individual's emotional state.

"In a culture of safety, everyone must be empowered to stop a situation that could endanger the patient. Everyone must be able to stop the line, as they say in manufacturing," she says. "We usually talk about errors, but we don't often talk about it in terms of someone being able to perform the services they're supposed to provide."

Staff report suspicious surgeon

One example is the recent case from the Boston area, where orthopedic surgeon Robert M. Caulkins, MD, is accused of showing up for surgery while under the influence of alcohol. Staff at Caritas St. Elizabeth's Hospital in Brighton reportedly became concerned when the surgeon appeared to be under the influence while preparing for a procedure, according to information from the state Board of Registration in Boston. The procedure was canceled for unrelated reasons, and no harm came to the patient.

Hospital spokesman **Carl Foster** confirms that Caulkins no longer has privileges at Caritas St. Elizabeth's. The hospital's procedures for reporting such staff concerns worked appropriately, Foster says, but hospital officials declined to elaborate. Amori says the incident is a good example of how staff members may be faced with situations in which they must feel empowered to speak up.

"It could be a nurse who is emotionally upset about something at home, or a doctor who is distracted by another case, or anyone who is under the influence of alcohol or drugs. We're talking about anything, really, that takes your mind off of caring for the patient," she says. "We have to teach people that these problems can be just as dangerous as something more tangible like picking up the wrong syringe, and we have to encourage people to do something about it."

The problem, of course, is that the nurse who is upset about a problem at home or the doctor who is thinking about another difficult patient is more likely to pick up the wrong syringe, for example. Addressing the clinician who isn't in the right of state of mind can be a way of preventing errors even earlier, Amori notes.

"That person is a walking time bomb," she says. "The chance of that person making an error is very high."

But staff aren't likely to speak up when it is concerned, unless the institution has a strong culture of safety that assures them they won't be punished for voicing their concerns. There is a natural desire not to challenge co-workers, and especially authority figures like physicians, when they seem to be unfit for duty. Patient safety education must explain that it is important to take action in these difficult moments.

Teach staff how to speak up

How? Amori suggests encouraging staff to follow these steps:

1. Consult a colleague to confirm your concerns. Discreetly ask someone else who is present if he or she has the same concern. Confirmation can help avoid misunderstandings and overreaction, while encouraging further action if necessary.

2. Talk to the person in question in a supportive way. The staff can go to the person and express concern, offering help without making accusations. One nurse might say to another, "Mary, you just don't seem yourself today and I'm concerned that something could happen that you'll regret. Maybe you could use a day off?"

The key at this point, Amori says, is to keep the conversation supportive and nonconfrontational. Don't blurt out anything like, "You're a danger to the patient and too messed up to do your job today." That will only make the subject defensive.

3. If necessary, the concerned staff must be able to contact a senior administrator immediately. Exactly who this contact will be can depend on your organization's particular structure, but it should be a top leader in the hospital, such as a vice president. Going through the chain of command by contacting the immediate supervisor and working on up is not sufficient, Amori says. That can result in the concerns being bogged down in bureaucracy.

"When someone's concerns are serious enough that they need to stop the line, they need to speak with someone with the authority to make it happen right then," she says. "But this only works if there is a culture in place that assures those concerns are taken seriously and that there is no fear of punishment for speaking up. They also need to

know that the impaired person is not going to be fired summarily but rather will be dealt with humanely." ■

A nightmare situation yields valuable lessons

Imagine a scenario in which a patient dies from a medication error and then things just go downhill from there. As things get worse, the only good thing is that you're bound to learn something useful from the experience.

That was the situation faced by **Monica Berry**, BSN, JD, LLM, DFASHRM, CPHRM, regional director of risk management with SSM Health Care of Wisconsin in Madison, and past president of the American Society for Healthcare Risk Management (ASHRM) in Chicago. She spoke on the topic at the recent ASHRM meeting in Nashville, TN. She tells a story from her experience that illustrates how the most painful experience can yield valuable lessons.

The incident involved a diabetic patient after surgery with an order for 10 mg morphine sulfate every four to six hours. The patient was under the care of a hospitalist, who ordered a dressing change and indicated the pain medication should be given 20 minutes before. But the nurse misread the order as calling for 20 mg of the drug, and the patient ended up with an overdose and died.

The family was notified of the death and, at 5 a.m., the hospitalist called the risk manager to report that the death was caused by an accidental overdose. The risk manager cautioned the hospitalist not to jump to the conclusion that the overdose caused the death and role-played with him to prepare him for how to inform the family of the circumstances.

The hospitalist met with the family without any other hospital representative and the charge nurse overheard him saying that "the nurse gave an overdose of pain medication and killed your mother." One of the family members became enraged and physically attacked the charge nurse, who was not the nurse in question, prompting a security response that ended with the family being escorted off the campus.

Risk manager's nightmare

Soon after, five physicians reported to the risk manager that the hospitalist was telling everyone the nurse "killed the patient" and the family created a disturbance in medical records demanding the patient's chart. By 6 a.m. the next day, the risk manager was on site to gather facts and review the medical record. Upper administration was notified by 7 a.m., and an administrative huddle occurred at 8:30 a.m.

"The window of opportunity to interface with the family is lost, and the campus rumor mill is very active," Berry says. "The risk manager was called at 5 a.m., and by 7 a.m., the window of opportunity is closed. It closed very quickly and very soundly."

Berry never knew what to expect when she tried to contact the family, as each family member seemed to have a different temperament and there was no consensus on how they wished to proceed.

The situation only got worse from there — the night nurse involved in the medication error was involved in another the very next night and had to be put on administrative leave. The nurse who was attacked by a family member had multiple sclerosis and suffered an exacerbation of the condition. She filed a workers' compensation claim and was on leave for 10 weeks, during which she was admitted to rehab.

"I simply could not have imagined a worse risk management nightmare," Berry says. "My imagination is not that good."

Failings made error possible

In addition to the inevitable lawsuit against the facility, Berry herself was sued for fraudulent concealment when her superiors ordered her not to reveal certain clinical findings to the family.

With a situation that bad, it's nearly impossible not to learn something useful. Here's what Berry took away from the experience:

- Processes that are changed midstream create an opportunity for things to run amok. The modification of the physician's orders late in the day shifted the dynamics of the workflow and the team functionality.
- The mind sees what is expected. Human factors research refers to this phenomenon as "slips." In this case, the nurse expected to see "mg" in the second medication order just as she had in the first order. Instead, the second order actually said "mins" for minutes.
- The night nurse was a recent graduate who was not assigned to the patient but was helping out when asked to give the medication. She

thought 20 mg was a lot but justified it in her mind because of the patient's size and was hesitant to question the order. She referred to a carbon copy of the medication order to confirm the dosage.

"We subsequently found out that they were in the habit of using the carbon copy as their working copy of the medication order," Berry says. "Imagine the carbon copies you've seen that are not at all clear — smudged and blurred because they had many things stacked on them and scratched out. So you could easily see how milligrams and minutes could easily look alike."

Buddy system for disclosures

• The night nurse was on her first shift after orientation. She came from a long-term care setting and had no previous acute care experience. The length of time a nurse has practiced is not as important as the need for acute care experience in the past three to five years, Berry says.

• She had had multiple preceptors in orientation and several recommended that she stay in orientation longer because she was not ready to solo. The unit manager disregarded that advice because she was short-staffed. The hospital decided to limit the number of preceptors and improve communication among them. Policy also now requires that the preceptors and unit manager all agree the new nurse is ready to come off of orientation.

• The nurse took three attempts to pass the orientation medication test. The hospital subsequently changed its policy so that only two attempts were allowed and then the nurse had to go back for orientation focused on medications or process.

• The organization did not have a medication order template. Pharmacy had not had an opportunity to clarify the orders.

• The automated drug dispensing system allowed 20 mg morphine sulfate to be removed, but a more modern version of the system would not. An upgrade of the system had been denied in the previous two budget cycles.

• Senior leadership at the hospital wanted notification as early as possible. Risk managers naturally try to gather information before alerting senior leaders, but it is better to go ahead and notify them even if that means having to say, "I don't know yet" when they start asking questions.

• The hospitalist blamed the nurse for killing the patient when the family members backed him into a corner and he couldn't think of anything else to say. For that reason, Berry says it is a good to always have another representative with the primary discloser so that when that happens, the second person can speak up and redirect the conversation.

"You need the other person to break in and give the primary discloser a chance to gather himself, regroup, and get the message back on target," she says. "That was an important lesson for us." ■

Jury awards remain level over past three years

Jury awards for medical malpractice have remained level for the past three years, according to an analysis released recently by Jury Verdict Research, a company in Horsham, PA, that maintains a national database of verdicts and settlements.

The latest analysis shows that while median malpractice jury awards more than doubled from 1996 to 2000, the awards have remained level since then, according to the report "Current Award Trends in Personal Injury." The median malpractice jury award in 2002, the latest year included in the report, was $1.01 million, a small increase from $1 million in 2001 and 2001.

In 1996, the median award was $473,000. About 52% of malpractice jury verdicts have been for $1 million or more since 1999. The report also shows that physicians still win most medical malpractice cases — 58% in 2002, down slightly from 60% the year before.

The steady medical malpractice figures are in contrast to overall personal injury liabilities, which fell significantly in the same period. The median jury award for personal injury cases fell 30% in 2002 to $30,000, from $43,000 in 2001. ■

Study: Fetal monitors do not predict brain injury

Fetal heart monitoring does not identify babies who are diagnosed with white matter brain injury after birth, according to a new study by researchers at Johns Hopkins University in Baltimore.

The study results were reported recently during the Society for Gynecologic Investigation's meeting in Houston. One of the authors, **Janyne Althaus**, MD, a perinatology fellow at Hopkins, says the study helps explain why the incidence of cerebral palsy (CP) in term infants has not changed since the 1960s.

"Fetal heart monitoring is the primary way doctors have tried to identify babies who may later be diagnosed with brain injury," she says. "If the fetal monitoring that we currently have doesn't help us identify those babies who are later diagnosed with these brain lesions, then we need to explore other options."

White matter brain injury

During labor, if a fetus has difficulty getting an adequate supply of oxygen from the mother's blood supply, white matter brain injury can occur. White matter is located in the border zones between the ends of major blood vessels, an area that is very sensitive to cerebral blood flow. Doctors think that less than 10% of CP cases are caused by this so-called hypoxic-ischemic encephalopathy.

For some years, doctors have thought they would be able to tell when a baby was about to undergo this type of brain injury by electronically monitoring fetal heart rate.

"Doctors assumed that they could decrease cerebral palsy incidence by intervening when they identified babies in trouble," Althaus says.

Because the incidence of CP has not gone down in 40 years, Hopkins researchers decided to take a close look at this monitoring system to see if it was doing its job.

They searched through a database of infants born between June 1999 and September 2001, and identified 40 babies who were born with white matter brain injury. They then matched those infants with 40 babies who were delivered at the exact same gestational age and in the same manner. All babies were born at Hopkins between the ages of 23 and 34 weeks.

The researchers then scrutinized fetal heart monitoring data to see if they could detect any differences that would have warned of impending brain injury. The researchers did not find any signs from the last hour of the first stage of labor in vaginal deliveries or the hour prior to delivery in cesarean deliveries.

"We may need to go back to the drawing board," Althaus says. ■

Reader Questions

Suicide prevention is important in all settings

Question: How much do we need to worry about the liability risk of patients committing suicide, as long we're not treating them for a psychiatric problem? Can't we argue that we had no duty to detect their suicidal tendencies when treating them for something completely unrelated?

Answer: The liability risk is actually very high for health care providers providing services other than psychiatric care, says **Robert Hanscom**, JD, director of loss prevention and patient safety with the Risk Management Foundation, the service arm of CRICO insurance in Cambridge, MA.

"With facilities that deal with these at-risk patients all the time, they are very alert to the risk and are careful to take the proper precautions," he says. "Others may have a psychiatrist on staff and have a psychiatric unit but they still don't see a lot of these patients, so they can let their guard down."

Suicides not decreasing

For those health care providers, the failure usually falls into two categories: They don't have a sufficient protocol in place that is known by all the appropriate staff, or they don't have the ability to formulate a plan of action when the patient is showing signs worthy of concern.

"We've seen patients commit suicide who have been in the facility being treated for something completely different, but they also were despondent and the suicide came as a total shock to the staff," Hanscom says. "What seems to be missing in those cases is that the staff didn't know what to look for in assessing the patient. We point that out as a major red flag to organizations that don't normally deal with these patients. You can let your guard down if this is not a common situation for you."

He says the number of suicides in health care settings is relatively small but has held steady for a long time, with no indication of decreasing. "It's worrisome because it never seems to decrease," he says. "They always seem to be there."

But what is the liability risk? Can you argue

that you had no duty to detect the suicidal tendency? Not necessarily, Hanscom says. If someone is under the care of a physician for something completely unrelated to depression or a psychiatric condition, the physician may still be obligated to detect and react to signs of depression.

If no one responds to the symptoms of depression and the patient commits suicide on the premises or soon after, "the exposure is pretty great," he says.

"The tendency is to argue that the physician was not a psychiatrist, and that's not what the patient was being treated for," Hanscom says. "Unfortunately though, the doctor does have a duty to the patient to make a proper assessment of any condition, and they should have referred that patient on to a psychiatrist."

On the other hand, if there is no noticeable sign, no reason the doctor should have known a suicide was possible, those cases can be defended pretty easily when the patient was being treated for something totally unrelated, Hanscom says.

The risk is even higher from a facilities perspective. If a patient commits suicide because a door was left open and they were able to access the roof and jump off, "the institution is probably liable," Hanscom says. In essence, plaintiffs have to prove that a physician knew or should have known the patient was at risk of suicide, but the burden of proof is much lower for the facility. The hospital could liable for merely allowing circumstances that made the suicide possible.

"The bar is set much lower for proving facility liability," he says. "Those cases can be massive payouts if you allowed someone to get into an area where suicide was enabled."

More training in how to spot suicide would go a long way toward addressing the problem, Hanscom says. All doctors should be specifically trained, and suicide assessment and prevention should be built into continuing education for nurses.

"They're the ones by the bedside so it is critical that they be aware of the risk and now to asses for suicidal tendencies in all patients, not just those in for psychiatric problems," he says. "Make sure there is a protocol in place for providing assessment. This must be part of annual staff training."

Premiums still going up, but slower

Question: What can we expect to see in the near future with malpractice premiums? Are they still going up steadily, or can we expect some relief from what we've experienced in the past few years?

Answer: The cost of insurance isn't getting better, but it's not getting worse at quite the astonishing pace you've seen in the past few years, says **R. Stephen Trosty,** JD, MHA, CPHRM, director of risk management for American Physicians in East Lansing, MI.

Trosty says the industry is slowing the amount of insurance increases and probably will continue to do so for the next year or more. That may sound like a feeble attempt at good news, but many risk managers who have seen their insurance premiums soar through the roof might welcome any hint that the pace is at least slowing.

"We've been seeing so many double-digit increases, even into triple digits for so long," he says. "Hopefully, we won't see so many 30%, 40%, and 50% increases. You're more likely to see increases in the teens, between 10% and 20%."

The hard market will continue at least through 2004 and probably into 2005, Trosty predicts. In addition to smaller increases, he predicts that health care providers will be less likely to suffer more than one increase in year. Midyear adjustments have been common in past years since premiums started to spiral up, as if getting a 50% premium increase wasn't enough to enough to ruin your bottom line for the year.

Market still making up losses

The slowing of the increases is a result of the insurance market regrouping after years in which health care providers benefited from grossly undervalued products, Trosty says. In the 1990s, health care providers were getting a sweet deal before insurers realized their error and started frantically raising premiums to rates that more accurately reflected their costs. By then, claims severity had shot through the roof and insurers couldn't send get the rate increases in the mail fast enough.

Several years of increases are starting to show some effect, he adds, but there still isn't enough competition in the market to cause lower rates.

"The last two or three years of increases have probably helped bring the rates closer to where they should be," Trosty says. "But we're still not seeing more companies coming in to the market. We're seeing more captives and risk retention groups in medical malpractice, but those focus on only a limited number of physicians."

In addition to larger premiums, he notes that risk managers can expect to see a continuation of fairly strict underwriting criteria. Bad risks will not be underwritten in the first place or their carriers will drop them. Facilities and physicians in the riskiest geographic areas, and those in high-risk specialties or care types, will continue to pay through the nose for coverage when they are lucky enough to find any.

Nursing homes, for instance, are still seen as extremely high risk for insurers, Trosty says. Even a physician who simply has a lot of patients in nursing homes may have trouble finding coverage at an affordable rate, he says.

Same old problems

Other specialties, such as obstetrics, radiology, and emergency medicine, still produce frequent lawsuits with large payouts, so they will prompt the highest premium increases and the strictest underwriting criteria, Trosty says.

"Many of those specialists are hospital-based, so the hospital risk manager can get involved and can have some impact," he says. "Identify what specialties are high risk and what type of lawsuits are being generated, the most prevalent allegations. Work on those with physicians and nursing staff, focusing on what can be done to reduce them with clinical guidelines, protocols, and making sure they are adhered to."

In each specialty, you will find that there are four or five allegations or case types that are driving the liability risk, Trosty says. The problems haven't changed recently, but the number of million-dollar verdicts has increased.

"Clearly, the risk management message hasn't been getting across. Risk managers need to ask how they can more successfully get their message heard," he says. "When I do seminars, physicians say they've heard this so many times, but I respond that these are still the areas where we get the most claims. So the message isn't being taken to heart. We need to ask why protocols aren't being followed, why our clinicians aren't following best practices."

But what about all the recent efforts at tort reform and establishing malpractice liability caps? Trosty says they may have some effect on insurance costs at some point, but not yet.

"It is going to take at least four or five years before anyone knows whether those are going to be upheld constitutionally," he says. "Until there is some feeling that the tort reform caps are going to hold, we're not going to see it truly having a major impact on claims and premiums. Insurance companies have an obligation to make sure they are adequately reserved, so they have to follow a worst case scenario and assume the caps will not be upheld." ■

COMING IN FUTURE MONTHS

- Waivers against malpractice claims
- Defamation lawsuits threaten peer review
- EMTALA signs: How much is enough?
- Top 10 slip-and-fall claims you can avoid

CE objectives

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

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. Identify solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
4. Employ programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE 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 activity each semester, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

17. According to data from the Joint Commission on Accreditation of Healthcare Organizations, recent efforts to reduce child abductions in health care facilities are having what effect?
A. Abductions have decreased nationwide.
B. Abductions have increased nationwide.
C. Abductions have remained steady across the country.
D. Abductions have decreased only in large metropolitan areas.

18. According to the National Center for Missing and Exploited Children, what percentage of child abductions from health care facilities take place in a pediatric room?
A. 2%
B. 5.3%
C. 10.9%
D. 26.2%

19. In the adverse event described by Monica Berry, BSN, JD, LLM, DFASHRM, CPHRM, regional director of risk management with SSM Health Care of Wisconsin, what was determined to be one cause?
A. The physician was not properly credentialed.
B. The night nurse was on her first shift after orientation, came from a long-term care setting and had no previous acute care experience.
C. Medication was improperly labeled.
D. The patient's allergies were not properly documented.

20. According to R. Stephen Trosty, JD, MHA, CPHRM, director of risk management for American Physicians, what can risk managers expect to see with insurance premiums in the coming year?
A. They will rise more severely than in the past few years.
B. They will rise, but not as severely as in the past few years.
C. They will fall sharply.
D. They will fall slightly.

Answers: 17-A; 18-C; 19-B; 20-B.

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

Premature discharge of baby leads to $1.77 million Texas verdict

By **Jan J. Gorrie**, Esq., and **Blake J. Delaney**, Summer Associate
Buchanan Ingersoll Professional Corp.
Tampa, FL

News: A newborn boy exhibited extremely low blood-sugar levels and was diagnosed with intrauterine growth retardation (IUGR). Neither a CT scan nor an MRI were ordered, and the baby was discharged within 24 hours of his birth. Three days later, the parents realized something was wrong with their child and returned to the emergency department (ED) at the hospital. The family waited for two hours before an ED physician saw their baby. A CT scan and MRI showed that the baby had intracranial bleeding and brain damage.

After filing suit alleging negligence against the treating physicians and hospital, the plaintiffs settled with the ED doctor for a confidential amount. A jury then returned a $1.77 million verdict against the hospital and the baby's pediatrician.

Background: On June 26, 1997, a baby boy was born showing signs of low blood sugar levels. The child was immediately diagnosed with IUGR, a condition that hinders a child's ability to store energy reserves such as fat and sugar, making it very difficult for the body to self-regulate blood sugar levels. Despite this, the pediatrician discharged the mother and her newborn from the hospital within 24 hours of the birth. Three days later, on June 29, the parents realized something was wrong with their baby and returned to the hospital. The ED physician let the baby sit for two hours before ordering a CT scan and MRI. These tests showed that the boy had catastrophically low glucose levels, brain damage, and intracranial bleeding. Further, the two-hour delay in treatment during the return visit had worsened the brain damage.

The parents, on behalf of their son, sued the pediatrician, the ED physician, and the hospital for negligence, alleging they should not have been discharged so quickly after birth and that additional tests should have been performed prior to discharge. The hospital's tests suggested the boy had low glucose levels; this was confirmed by the fact that the child exhibited symptoms consistent with this condition. The plaintiffs also argued that the boy was known to be at risk for low glucose as a result of being diagnosed at birth with IUGR. Damages were sought for future medical care, loss of earning capacity, mental anguish, and pain and suffering. The parents also sought damages for mental anguish and past medical expenses.

The ED physician who delayed treatment of the baby boy for two hours immediately settled out of court for a confidential amount. In 2002, the plaintiffs' case against the hospital and the pediatrician went to trial. The parties sharply disagreed as to whether the defendants acted reasonably, whether the defendants' actions caused the baby's brain damage and intracranial bleeding, and the amount and degree of the boy's damages.

To prove that the hospital acted unreasonably,

the plaintiffs contended that the hospital's official policy regarding the treatment and monitoring of newborns with low glucose levels was unreasonable. The hospital should have, at a minimum, ordered a CT scan or an MRI to further assess the baby's condition, even if the pediatrician failed to do so. As evidence of this assertion, the plaintiffs brought to light the fact that the hospital had, by its own initiative and one month prior to the incident in this case, decided to improve its policy. Despite the hospital's prudence in creating the more stringent policy, it had neglected to actually implement it until June 30, 1997, the day after the baby was brought back to the ED. After putting forth evidence of the hospital's negligence, the plaintiffs then claimed that the nursing staff acted unreasonably by not following the policies that the hospital did have in effect.

The defendants, however, rebuked the contention that it acted unreasonably and that the hospital's existing policies were unreasonable. A significant amount of medical literature suggests that the presence of intracranial bleeding is normal from birth trauma. Consequently, the hospital still would have not found the baby's condition alarming, even had it performed a CT scan and/or MRI on the day of the birth.

The defendants also disagreed with the claim that the defendants' negligence caused the baby's brain damage and intracranial bleeding. The defense experts argued that it was unclear exactly how the baby's injuries came about, but that something must have happened to the child in between the time the baby was discharged and the time when he was brought back to the ED. The boy's injuries could have been the result of some undetermined trauma such as a spontaneous stroke not related to the low glucose levels or an episode of shaken baby syndrome, even though there was no evidence of any retinal hemorrhages, which is typical with shaken baby syndrome.

The parties also disputed the severity of the boy's injuries. The plaintiff pointed out that the child, even now at 5 years of age, could not talk and still was in diapers; they suggested he would have to live in a supervised setting at some point. The defendants, however, disagreed. Defense experts argued that the child might be able to dress himself and go to the bathroom unaided within five or six more years.

In November 2002, the trial concluded. The jury found the hospital and the pediatrician negligent and awarded $1.77 million in total damages. The jury award included $1 million for future medical care, $600,000 for loss of earning capacity, $100,000 for the past and future mental anguish suffered by the parents, and $70,000 in past medical expenses. The jury placed no individual liability on the nurses.

What this means to you: Newborn cases, like obstetrical cases, are difficult to defend because there almost invariably is a sympathetic defendant on the other side. The defense of such a case is even more pragmatic when there is seemingly clear evidence of negligence.

"The discharge of newborn with extremely low blood sugar levels and a known diagnosis of intrauterine growth retardation within 24 hours of birth represents questionable practice of medicine by both hospital and pediatrician. Many jurisdictions have enacted laws requiring health care insurance companies to pay for stays of at least 48 hours following delivery, and that is in the absence of any known complications or abnormal diagnoses with the mother or child. Regardless of who was paying for the delivery of this particular child, the discharge of the newborn with both of these medical conditions within 24 hours of birth is likely to be found outside existing standard of care," observes **R. Stephen Trosty**, JD, MHA, CPHRM, director of CME and senior risk management consultant for American Physicians in East Lansing, MI.

As some state legislatures have recognized, drive-by deliveries are increasingly being discouraged and in some instances prohibited.

"Twenty-four hours is simply not enough time for the mother to recover, let alone to perform adequate and/or comprehensive enough diagnosis and observation of infants. This is particularly true for infants who are exhibiting extremely low blood sugar levels and have been diagnosed with IUGR. Hospital policies and procedures should specifically address the issue of discharge of an infant such as the one presented in this case," notes Trosty.

Not enough can be said for developing adequate policies and procedures. In this case, the hospital seems to have recognized that need, but in the interim failed to abide by existing and soon-to-be implemented policies. Too, the timing of the implementation the facility's new policy on point is rather ironic, if not circumspect.

"Policies and procedures should deal directly with the time within which discharge would be appropriate and those policies and procedures

should be specific to the infant's condition (e.g., for normal birth with no complications, for an infant who has extremely low blood sugar, for an infant diagnosed with intrauterine retardation, for an infant with multiple presenting medical problems or conditions). Policies and procedures should address which tests should be performed when certain conditions are present, and how the results of those tests should be received. At a minimum, critical test results should be evaluated and dealt with prior to discharge," adds Trosty.

Policies and procedures that are developed and not utilized become double-edged swords, for it is not enough to have the policies and procedures in place, if there are no assurances that they will be adhered to.

"Hospitals should have policies and procedures requiring testing in certain circumstances and certainly in instances where newborn infants exhibit serious medical conditions. Tests would be performed to determine, what, if any, additional complications exist, and/or determine if any immediate care or treatment is required prior to discharge. These tests are critical to determining the course of treatment and care of the newborn. Hospitals should be sure all staff are knowledgeable about existing policies and procedures and/or know where to easily access them," says Trosty.

With regard to the care provided by the pediatrician, "he should have conducted tests on the infant and obtained results prior to discharge. Both the pediatrician and hospital staff should have adequately and appropriately communicated with the parents regarding the infant's condition; what they should expect; whether any follow-up should occur, what it would be, and when it should occur. In addition, the caregivers should have advised the parents on what they should look for in terms of signs and symptoms, which would indicate the need for follow-up care or treatment. Given the two complications, the pediatrician should have run a CT scan and/or MRI on day of birth to identify any problems or medical condition either resulting from, and/or causing, the intrauterine growth retardation. Further, the pediatrician should have recognized the possibility of intracranial bleeding and/or brain damage with a diagnosis of intrauterine growth retardation in the newborn and conducted appropriate tests prior to discharge from hospital to determine if the complications existed. Finally, the pediatrician should have run tests prior to discharge to determine if he could identify the reason for extremely low blood sugar in the newborn, if any related complications existed, and/or if any immediate treatment was required," notes Trosty.

Once the testing and follow-up errors were made and the child was discharged, the hospital and pediatrician had greater difficulty in arguing that their negligence did not cause the baby's brain damage and intracranial bleeding since they performed no tests prior to discharge of the infant in an effort to determine either the extent and/or cause of the medical problems or injury at birth. It stands that the infant was diagnosed with two serious medical conditions that should have alerted the hospital and the physician of the need to try to ascertain the extent and/or cause of injury prior to discharge — not three days later.

"Even if the IUGR diagnosis occurred later, no testing was done prior to discharge and no effort made during the 24 hour stay to see if there were any contributing factors to the infant's low blood-sugar levels. Nothing was seemingly done to explain the reason for this problem or alert the

parents to the possibilities. Running tests closer to the time of birth and the time in which the abnormality was detected would likely have resulted in less brain damage to the child because appropriate interventions could have been initiated," adds Trosty.

Once the child returned to the hospital, the ED "should have had an appropriate and adequate triage system to identify the order in which patients presenting to the ED should be seen. The emergency department triage system should have identified the infant as needing immediate attention and not allowed for an additional delay in a time-sensitive situation. The delay in the ED's seeing the infant and performing the CT scan and MRI likely worsened the brain damage, thereby making it more difficult for the hospital and physician to successfully argue that the injury, or the extent of the injury, was not due to the negligence of the hospital and/or physician," observes Trosty.

When going forward with the defense of a case, particularly in instances where the plaintiff is sympathetic, the defense must pay attention to every detail, including the selection of experts.

"Defense presentation of expert testimony to the jury disputing the severity of the boy's injuries by arguing that the child might be able to dress himself and go to the bathroom unaided within five or six more years ([the] child already is 5 years old) did little to negate severity of injuries and likely angered the jury against the hospital and physicians. While it is not always possible to predict what your expert is going to say or do on the stand, once the unexpected happens you should be prepared to immediately address the situation," says Trosty.

Trosty added that "it is very important to review the testimony your expert witness will present prior to the actual trial and to determine the most effective way to present all expert testimony. It is too late to do this after the trial has begun. Defense counsel not only should know what their expert witnesses will say before they put them on the stand but also should know the most effective way to present evidence in order to gain the support of the jury."

In this instance, other avenues may have been used to present evidence regarding the severity of injuries and future needs of the child.

Reference

- Harrison County (TX) Circuit Court, Case No. 99-0700. ■

Visit *HRM*, *ED Legal Letter* site

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HRM's 2003 salary survey also is available in its entirety.

Find links to other web sites that are essential references for risk managers. There also is a guide to upcoming conferences and events of interest to risk managers. Click on the User Login icon for instructions on accessing this site. ■

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

Latest HIMSS survey shows slow compliance

Only half of respondents completed TCS testing

The latest survey of 631 providers, payers, companies, and clearinghouses by the Healthcare Information and Management Systems Society (HIMSS) indicates that as of mid-January, only half had completed testing for the Transaction and Code Standards (TCS), which standardized what information must be contained in electronic claims and how it should be transmitted.

Consultants who provide services to physicians say that even though enforcement remains complaint-driven, physicians will have an increasingly compelling incentive to comply with the law as claims that do not follow the regulations are rejected.

John Thomas, CEO of Dallas-based MedSynergies Inc., has estimated that only 15%-20% of physician claims are in compliance with the standard. He says that as accounts receivable numbers show more unpaid claims, physicians will get the message.

Karen Trudel, director of the Department of Health and Human Services (HHS) Office of HIPAA Standards, says the agency has not set a time frame for ending contingency plans.

"TCS represents an activity the magnitude of which the health care industry had never attempted before," she says. "You've got so many different moving parts that a lot of people underestimated the complexity of the process." She estimates that two-thirds of Medicare claims being received by HHS are compliant.

More culture than technology

HIMSS officials say the stumbling block for providers is more culture than technology. Many delays, they say, simply relate to the fact that physicians have many demands on their times that they assign a higher priority than technology.

"With any systems upgrade, the technology is probably the easiest part, and culture change the most difficult part," says **Joyce Sensmeier**, director of professional services at HIMSS.

The HIMSS survey showed that while 45% of providers and 56% of payers were ready to accept or transmit the standardized transactions, only 40% of the companies that make software for the industry were prepared. That was down from an earlier survey in which 47% of the companies reported they were ready to handle the transactions.

The consulting firm Frost & Sullivan has estimated that providers such as hospitals, managed care organizations, and physicians have spent $1.2 billion on HIPAA.

Apparently, most of that spending was by organizations characterized as early adopters, especially large organizations with the resources available to use for experimenting with new initiatives.

But most physicians practice in small groups; approximately two-thirds of all physicians are in group practices of eight or fewer members, and they may have only recently installed a computer and assigned information technology duties to the office manager. Thus, they're dragging their feet on coming into compliance with transaction and code standards, even as the deadline for compliance with security requirements is only 12 months away.

Security standards

The security standards require health care groups to assess their systems' susceptibility to unauthorized access and put a policy in place to deal with that concern. Trudel says the security standards may not pose as much of a problem as TCS because of flexibility built into the requirements. "We're saying you have to think about your risk and how you can best mitigate that risk," she said. "But a lot of people are going to be asking us to tell them exactly what they have to do." ■

Workgroup urges patience on HIPAA compliance

Entities making 'good-faith effort,' WEDI says

The Workgroup for Electronic Data Interchange (WEDI), which advises the Department of Health and Human Services (HHS) on issues related to administrative simplification under HIPAA, says the agency should show continued patience as covered entities continue to make progress in implementation of the HIPAA transactions and code sets (TCS) requirements.

WEDI chairman **Ed Jones** gave HHS Secretary Tommy Thompson results of a December 2003 session at which WEDI took testimony on TCS standards implementation status, data content requirements, and implementation sequencing.

In general, Jones said in a March 8 letter, hearing testimony indicated that:

1. Covered entities are making good-faith efforts to move toward standard claim compliance under HHS' July 2003 contingency guidelines.
2. HHS guidance to implement contingency plans has helped ease the transition.
3. Most covered entities are focusing on implementing compliant claims rather than on other TCS standards.
4. Cost benefit from TCS has not been fully realized.
5. A small number of large payers and providers account for a large but unknown volume of compliant transactions.
6. A large but unknown number of covered entities have not yet achieved TCS standards compliance with their trading partners because of difficulties in completing testing with them.
7. Payment disruptions to providers, providers dropping claims to paper instead of sending noncompliant electronic transactions, and health plans rejecting noncompliant claims have occurred during the transition.
8. Covered entities are experiencing some data content challenges that require further guidance from the federal government.
9. Covered entities need rapid deployment of standard provider and health plan identifiers to achieve interoperability.

Based on that testimony, WEDI made recommendations in four areas — continue the HHS policy of allowing contingency plans, enhance the implementation process, revise and enhance the standards development process, and validate costs and benefits of TCS implementation.

WEDI says it recommends HHS continue its contingency plans with an emphasis on moving health plans and clearinghouses into full compliance while providers complete testing and implementation. Until a number of issues identified in the December testimony are resolved, the organization says, covered entities only may be able to implement the standard format without supplying all of the required data content.

To enhance the implementation process, a major consensus that emerged in the testimony is that the TCS implementation is trying to do too much at one time. "For example," the WEDI letter says, "the current TCS rule mandated several transactions at one time, even though each transaction represented a significant amount of effort. Claims status, eligibility, and authorization/referral can be separated from the claim and payment transactions and implemented on unique timelines."

WEDI recommended that future rules consider and establish realistic timelines for completing all required actions for successful implementation. If it appears that an implementation can't be accomplished in a reasonable period, it says, the implementation should be divided into component parts that can be completed separately.

WEDI also supports the concept of a staged implementation and recommends that software vendors be considered in staging, since most providers, payers, and clearinghouses use translators and other purchased software and are unable to be ready without availability of compliant software.

Revision and enhancement of the standards development process could be helped by reaching out for provider input in the standards development process, WEDI says. Also, business decision makers should be encouraged to participate in standards development.

According to the WEDI letter, the cost of implementing the HIPAA TCS has exceeded industry expectations. It recommends that realistic cost and benefit studies be conducted to validate proposed savings and encourage industry movement toward cost-effective solutions.

It also recommends that HHS schedule follow-up studies to determine the effectiveness of the implementation, and that the health care industry continue to identify ongoing opportunities to drive costs from the systems and simplify administration of the health care system. ■

Researchers: HIPAA may hurt outcomes studies

Rules affect ability to follow patients post-discharge

University of Michigan (UM) researchers said at the annual scientific session of the American College of Cardiology held March 7-10 in New Orleans that HIPAA has significantly affected their ability to study heart attack patients after they are discharged from the hospital.

Long-term outcome studies are crucial for evaluating medical care, such as the number of patients who die or have complications after surgery or hospitalization. But HIPAA requires written authorization from a patient before he or she can be contacted to gather personal health information for a research study. Before HIPAA, UM researchers used a verbal privacy authorization they obtained when they called patients at home months after they left the hospital.

They reported that when they switched from the verbal OK to a HIPAA-compliant written authorization that had to be mailed to patients and mailed back, there was a significant reduction in the percentage of patients consenting to be called, down from 96.1% to 38.5%. As a result, they said, the consented population was not representative of the entire population of patients the researchers wanted to study, and that could bias the study results.

"On top of the impact on the quality of the data, the costs involved in asking for the written authorization were substantially larger than those for the verbal system," said researcher **Eva Kline-Rogers**. "To get consent from one patient, we calculated we'd spend $14.50 per patient in the first year of the study for computer, training, staff, administrative, and mailing costs, and $7.50 each year afterward." She says that asking patients for consent while they still are in the hospital to avoid the mailing costs would be labor-intensive and cost-prohibitive.

"The balance between protecting patient privacy, while at the same time we strive to learn about the best methods by which to treat patients after certain types of conditions and/or treatments is delicate," said study senior author **Kim Eagle**, MD, clinical director of the UM cardiovascular center. "If long-term patient outcomes are to be used to 'inform' current care, we must develop better ways of working with patients and regulatory agencies to define the proper balance."

Kline-Rogers said she and her colleagues set out to obtain written consent from heart patients six months after they left the university hospital after being treated for acute coronary syndrome — either a heart attack or unstable angina episode. They got the list of patients retrospectively by reviewing discharge diagnoses for each patient, which is allowed under HIPAA as part of a research study.

Between Sept. 1, 2001, and March 31, 2003, the researchers sent letters and consent forms to the patients, and followed up with phone calls to those who responded to ask questions about their health.

Because the HIPAA compliance mandate was not fully operational at the time of the study, they also were able to call patients who did mail back an authorization form to try to obtain verbal consent.

In addition to the drop in authorizations, researchers found that those who returned the HIPAA-compliant written consent were more likely to be older, married, or to have high blood cholesterol than those who didn't. They also were less likely to be widowed.

There also was a significant difference in the ability to receive consent from a spouse or authorized relative to obtain information on patients who had died. Some 10% of the patients in the group where contact was made verbally or records were searched had died, vs. 3.3% of the group contacted for written consent.

"HIPAA compliance will challenge researchers, institutions, and ultimately patients as we try to learn about the outcomes of health care while trying to maintain patient privacy," Eagle said. ■

Possible incentive for physician compliance

Reduced premiums could boost compliance

A security consulting firm that is providing security risk assessment and compliance review services for small health care related businesses says one way to increase incentives for physicians to come into compliance with HIPAA requirements would be for malpractice insurers to offer reduced premiums to those who have done a risk assessment and are moving forward on implementation.

Robert Aanerud, chief risk officer at St. Paul, MN-based HotSkills Inc., tells *HIPAA Regulatory*

Alert there is precedent for such a move in the financial services field and other market segments, and he expects it to be offered by medical malpractice insurers within a year or so.

"I'm in discussions with several insurance companies," he says. "There are several insurers already offering that type of discount on professional liability insurance in the financial services and other fields."

That type of incentive, Aanerud says, is going to be important to get physicians and physician groups to think in terms of assessing their compliance level and moving forward.

He notes that many firms implementing compliance initiatives are too focused on technology, and many of those assessments don't go far enough. Aanerud says his company is using a holistic, quality-based ISO standards approach that addresses all aspects of business risk, including physical, technical, personnel, and procedural.

"We involve the organization's management team in this process to ensure they understand the business risks, and then they determine the degree of risk they're willing to accept," he says. "Management's involvement is a necessary and often overlooked measure to building a defensible security management program."

Some ignoring obligations

According to Aanerud, ISO17799/BS7799 is a management-driven process that can be implemented by businesses of all sizes. "Certification for information security can provide businesses with many competitive and operational advantages, including increased trust and credibility with customers, stakeholders, and business partners; more effective operations in other countries that use these standards; and reduced liability risk, which may result in lower business insurance premiums."

Aanerud says his sense is that many physicians and physician networks still are ignoring their obligation to comply with HIPAA. "Sometimes they're in denial about whether it applies to them or really will be enforced," he says. "They also often don't understand the requirements, don't yet see the risk to themselves in not complying with the requirements, and are more concerned about patient care than complying with HIPAA standards."

Aanerud says the April 2005 deadline is creating a false sense of security because "businesses that release personal information can be liable right now for the complete scope of this regulation if they have not shown intent to protect that information." He says the first step in proactively addressing the standards is to conduct an overview risk assessment that, for many physician organizations, can take one to two days.

The fact that enforcement by the Department of Health and Human Services (HHS) currently is complaint-driven also is encouraging the false sense of security, Aanerud says. "HHS hasn't yet identified the agencies that are going to perform compliance reviews," he says. "The need to comply with the requirements isn't going to become real to many people until they do that. People have to see that the 'HIPAA cops' are coming. But I think it's going to be quite a while until the agency acts."

In the meantime, Aanerud and other consultants are urging covered entities to take their obligations seriously, perform a risk assessment so they will have a good sense of the gaps they are facing and the costs to address them, and then move into implementation.

For example, the Information Technology Solution Providers Alliance, a national organization established to help the nation's small to medium businesses understand how local technology providers can help them, is devoting a lot of energy to HIPAA and offers the following tips for complying with the regulations:

- **Provide** employee reviews and give all employees an opportunity to review and change, if necessary, their protected health information.
- **Distribute** privacy notices that spell out HIPAA requirements for all employees.
- **Update** health care documents to reflect current HIPAA regulations regarding permissible uses and disclosures of protected health information.
- **Put** safeguards in place, such as assigning someone the responsibility of handling privacy issues and establishing methods for handling complaints.
- **Work** with service providers to establish agreements with outside companies that help administer the organization's health plan to ensure compliance with privacy rules.
- **Train** employees in HIPAA privacy rules.
- **Lock up** records and files that contain employee health care information, and use computer passwords and firewalls to protect on-line information.
- **Increase** computer security features.
- **Ask** an information technology solution provider for assistance. ■