Specialized Information Publishers Association Winner

Healthcare Risk Management™

AHC Media LLC

IN THIS ISSUE

Financial Disclosure: Author Greg Freeman, Associate Publisher Coles McKagen, Senior Managing Editor Joy Dickinson, Nurse Planner Maureen Archambault, and *Legal Review & Commentary's* authors Blake Delaney and Jon T. Gatto report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

FEBRUARY 2008
VOL. 30, NO. 2 • (pages 13-24)

Heparin error highlights risk and need for health care risk managers to take action

Mistake with Dennis Quaid's children brings attention

Heparin continues to pose a significant risk of dosage errors, and the recent tragedy involving actor Dennis Quaid's two young children has brought concern that hospitals have not taken the necessary steps to avoid this mistake even health care providers were warned about the risk a year ago. Risk managers must act now to avoid the same type of error, say medication safety experts.

Quaid recently announced that he is suing Baxter Healthcare Corp. in Deerfield, IL, the pharmaceutical company that manufactured the heparin involved in the incident. The actor's newborn twins accidentally were given 1,000 times the prescribed dose of the blood-thinning drug. Doctors at Cedars Sinai Medical Center in Los Angeles mistakenly administered the overdose of heparin after the children were admitted for a staph infection. The twins have recovered, according to statements released by the Quaid family, but they say the lawsuit is aimed at preventing the same mistake from happening to others. They are suing Baxter for more than $50,000 but had stated that they were not suing the hospital because they

EXECUTIVE SUMMARY

The recent drug error with actor Dennis Quaid's children has highlighted the continuing risk of dosage errors from heparin. Health care providers were alerted to the danger months ago, but many have not taken the necessary preventative steps.

- The hospital admits that its staff erred with the medication dosage.
- The Quaids are suing the drug manufacturer, but not the hospital.
- The manufacturer has changed the drug's packaging, but products with the old label still are in use.

thought the root cause of the error is in the product's labeling.

A subsequent report from the California Department of Public Health conflicted with the hospital's initial report that the children each received one vial containing 10,000 units per milliliter of heparin instead of the common dosage of 10 units per milliliter. The report found that the children actually each received two of the vials. In a statement, Dennis Quaid and his wife denounced the Cedars-Sinai Medical Center over a "lack of candor" about the nature of the medical error.

The investigation also found the hospital did not adequately educate staff about the safe use of heparin and that nurses and pharmacy technicians did not check labels on the vials and did not keep adequate records of when it was used.

The Quaids' attorney, **Susan Loggans**, JD, in Chicago, issued a statement saying the lawsuit alleges that the mistake was made because the two bottles containing different doses of heparin share remarkably similar blue labels and a common shape. The Quaids decided to sue, at least in part, she says, because the risk of heparin overdose was known to the manufacturer. Three premature babies died at an Indianapolis hospital in 2006 when nurses inadvertently switched heplock with the much stronger heparin. After that incident, in a safety alert dated Feb. 6, 2007, the Food and Drug Administration and Baxter warned of the dangers of switching 10- and 10,000-unit vials of the drug. However, the company did not change the product's packaging at the time. **(See p. 16 for the full alert.)**

After the incident with the Quaid children received extensive media attention, Baxter announced that it is introducing new packaging designed to help caregivers avoid the same error. **(See p. 15 for details on that change.)** A company spokesman says Baxter is now producing heparin products with the new labeling but that health care providers still may have heparin with the old labeling in stock.

Incident highlights major risk

Michael L. Langberg, MD, chief medical officer at Cedars-Sinai Medical Center, says the Nov. 18, 2007, incident with the Quaid infants was a "preventable error, involving a failure to follow our standard policies and procedures, and there is no excuse for that to occur at Cedars-Sinai." Unfortunately, the Cedars-Sinai incident is a reminder of how such preventable errors can occur even at high-quality institutions and after explicit warnings, says **Marlene R. Miller**, MD, Msc, vice president of quality at the National Association of Children's Hospitals and Related Institutions in Alexandria, VA.

Heparin poses particular challenges for risk management, Miller says. Unlike many other drugs, heparin often is readily available on patient care units, and there is a higher dependency on caregivers to select the right product and dosage, she says. "That is different from many other drugs where you have to order it for the patient and there are more safeguards in place to make sure you're using the right thing,"

Healthcare Risk Management® (ISSN 1081-6534), including **HRM Legal Review & Commentary**™, is published monthly by AHC Media, LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Healthcare Risk Management**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $495. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. For approximately 15 CE nursing contact hours, $545. Discounts are available for group subscriptions. For pricing information, call Tria Kreutzer at (404) 262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues**, when available, are $87 each. (GST registration number R128870672.)

AHC Media LLC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is valid 24 months from the date of publication.

Healthcare Risk Management® is intended for risk managers, health system administrators, and health care legal counsel.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Greg Freeman**, (770) 998-8455.
Senior Vice President/Group Publisher: **Brenda Mooney** (404) 262-5403 (brenda.mooney@ahcmedia.com).
Associate Publisher **Coles McKagen** (404) 262-5420 (coles.mckagen@ahcmedia.com).
Senior Managing Editor: **Joy Daughtery Dickinson** (229) 551-5159 (joy.dickinson@ahcmedia.com).
Senior Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Greg Freeman**, (770) 998-8455.

she says. "With heparin, it tends to sit around the unit more because there is such a high need for it. So it does pose this extra risk when you have multiple concentrations sitting around."

Miller says she supports the Quaids' decision to sue the manufacturer and not the hospital. While there is no denying that frontline caregivers made the actual error in administering the drug, she says they were set up for failure by the product design. "They two labels look nearly identical, with a lot of information in tiny print, and one of those tiny bits of information is the concentration," she says. "The key difference is how many zeroes you see, and you have to look closely."

Risk will continue

The similar packaging and small print put the burden on the caregiver to scrutinize each vial every time heparin is used. Miller says that is a recipe for disaster, and the heparin overdoses were practically inevitable.

"With packaging like that, you're left to rely on vigilance, and we know that fails," she says. "It's hard to be vigilant when the name of the drug is different, but when the name is the same and essentially everything is the same except the number of zeroes, that's tough."

Miller says Baxter's new packaging for heparin is encouraging, but the risk will exist as long as the old product packaging is in use. Miller advises risk managers to be proactive in reducing the risk of heparin overdoses. One option, she says, is to prohibit or sharply curtail how much heparin is stored on patient care units, making it available by request from the pharmacy as with many other drugs. That is an imperfect solution, Miller notes, because concentrated heparin is needed frequently on patient care units to flush central lines.

"So how do you make sure it's not a barrier to good care, that you can get it when you need it?" she asks. "But that is the approach that has worked with other medications like hypotonic saline, when you had very concentrated, dangerous medications. They have to be stored separately from all the low-concentration medications."

Verify how heparin is stored and used

The best, most immediate, step for a risk manager is to go for a walk around patient care units and see how heparin is stored and used, Miller says. Are there more vials than necessary in patient care areas? Is there any separation of the two concentrations? Do staff know to double-check the concentration every single time they use heparin?

Baxter is changing packaging for heparin

The primary manufacturer of heparin is changing the product packaging that has been blamed for dangerous dosing errors. Baxter Healthcare Corp. introduced the new drug safety initiative at the 2007 midyear clinical meeting of the American Society of Health-System Pharmacists.

The initiative is intended to help reduce medication errors "by creating enhanced packaging that provides additional safeguards to assist clinicians in the correct identification of critical medications," the company states. The company plans to improve packaging and labeling for many of its products, but as one of the top five high-alert medications as designated by the Institute of Safe Medication Practices, heparin is the first medication offered with the new enhanced label. The label features an increase of 20% font size, a unique color combination, and a large red cautionary tear-off label. Baxter is now producing heparin products with the improved labeling, but a spokesman points out that health care providers still may have products with the old labeling in stock.

According to the Institute of Medicine, 1.5 million Americans are injured each year from medication errors in hospitals, nursing homes, and outpatient clinics/surgery centers. An estimated 7,000 Americans die each year as a result of medication errors. Incorrect drug administration accounts for the largest proportion of harmful medication errors. High-alert medications bear a heightened risk of causing significant harm to patients when administered incorrectly or in error. Sixty percent of life-threatening or lethal errors involve intravenous (IV) drugs such as heparin.

In a statement released by the company, **David Bonderud**, U.S. Region president of Baxter's Medication Delivery business, says Baxter conducted multiple interviews with more than 100 pharmacists, physicians, and nurses to identify areas for improvement. The feedback received from health care professionals guided the design of the new vial packaging.

In research conducted after the three-phase development program, clinicians indicated that the new packaging design enhancements addressed the current clinical needs for safer injectable drug administration and could help reduce medication errors. ■

SOURCES

For more information on preventing heparin errors, contact:

- **Michael Langberg**, MD, chief medical officer, Cedars-Sinai Medical Center, Los Angeles. Telephone: (310) 423-3277. E-mail: michael.langberg@cshs.org.
- **Susan Loggans**, JD, Susan E. Loggans & Associates, Chicago. Telephone: (312) 201-8600. E-mail: loggans@logganslaw.com.
- **Marlene R. Miller**, MD, Msc, Vice President of Quality, National Association of Children's Hospitals and Related Institutions, Alexandria, VA. Telephone: (703) 684-1355. E-mail: mmiller@nachri.org.
- **C. Scott Nichols**, JD, Strasburger & Price, Houston. Telephone: (713) 951-5621. E-mail: scott.nichols@strasburger.com.

"I remember when I was a resident seeing units that had plats of 50 bottles just sitting there, wide open for anyone to grab, and then the next little plat over is the more concentrated stuff," she recalls. "I imagine there are still hospitals doing that. That would be the first step, the no-brainer, to just go see how it's used in your facility."

Miller points out that while the most notorious incidents have involved pediatrics, the risk of heparin overdose is an issue with adults also. So don't restrict your efforts to the pediatrics units. "Having both vials there in open storage, so the nurse can just grab it when you need it, is probably the most dangerous way to use heparin," Miller says. "Even if you don't sharply restrict access like with other dangerous drugs, there should be something in place like requiring a supervisor confirm the correct concentration. We can't count on one overworked nurse counting the right number of zeroes on the bottle every time."

Serious malpractice liability

A hospital making such an error with heparin would face significant potential for liability, says **C. Scott Nichols**, JD, an attorney with the law firm of Strasburger & Price in Houston. Though he won't comment on the specifics of the Cedars Sinai incident because he doesn't know details, Nichols says the likelihood of being sued after such an error often depends on how the hospital responds when the error is discovered.

"If they revealed the error, and then made attempts to change the process that results in this error, that is always a good start," Nichols says. "If the hospital was up front, apologetic, and eager to make amends, that could be why the family chose not to bring a lawsuit against the hospital. That is often what we see in these cases."

Cedars-Sinai appears to have avoided a lawsuit, but Nichols points out that any hospital's exposure is great when it already was aware of the potential for this error, yet it still occurs. Because there was a major alert about exactly this type of error a year ago, the patient could wield that fact effectively in court.

"Hospitals often can look back and say that the event was easy to prevent if only they had taken some simple steps, like not storing these two concentrations together, or marking the vials differently," he says. "It sounds to me like they took notice of the potential for error but didn't really change their policy. If the family had chosen to sue them, that might have been a hard to case to defend." ■

Baxter and FDA warned of heparin risk in 2007

This is an excerpt from the "Important Medication Safety Alert" that was issued on Feb. 6, 2007, by Baxter Healthcare Corp. and the Food and Drug Administration involving Heparin Sodium Injection 10,000 units/mL and HEP-LOCK U/P 10 units/mL:

The currently marketed 1 mL vials of Heparin Sodium Injection 10,000 units/mL and the HEP-LOCK U/P 10 units/mL use shades of blue as the prominent background color on their labels. Healthcare professionals should be reminded to:

• Never rely on color as a sole indicator to differentiate product identity.

• Always carefully read the product label to verify that the correct product name and strength have been selected.

• Always carefully review both the drug name and dose on the label before dispensing and administering these products.

• Double-check your inventory as soon as possible, to ensure that there is no mix-up of the products.

• Notify all staff of the potential for errors in dispensing and administering these products. It is advised that you provide color photographs to staff to assist in

their understanding of the product similarities.

The alert goes on to say that providers should "ensure that all staff responsible for the dispensing and administration of Heparin Sodium Injection and HEP-LOCK U/P products are aware of these medication errors and that the staff are familiar with your policies and procedures."

Baxter says risk managers with further questions can contact the company at (800) 262-3784. The full text of the alert, including photographs of the products, is available at the FDA web site at www.fda.gov. Enter "heparin medication safety alert" in the search box at the upper left of the home page, and then click on "IMPORTANT MEDICATION SAFETY ALERT." ■

Hospitals pledge no charges for adverse events

The Massachusetts Hospital Association recently announced that all Massachusetts hospitals are adopting a uniform policy to not charge patients or insurers for certain serious adverse events as defined by the National Quality Forum (NQF), including wrong-site surgeries and serious medication errors. In doing so, Massachusetts becomes only the second state in the nation to take this voluntary action.

Lynn Nicholas, FACHE, president and CEO of the Massachusetts Hospital Association says the new policy builds on several groundbreaking transparency and quality initiatives. "This policy sends a strong message to patients that their hospital is committed to doing everything possible to eliminate these types of events," she says.

The policy, to be put into effect in early 2008, will codify long standing safety practices and fortify hospitals' commitment to preventing adverse medical events, Nicholas says. The policy will apply to any of the defined events and any subsequent care needed to manage the event. The hospital community will work collaboratively with an advisory group comprised of hospital members from clinical and financial departments, the physician community, the health insurance companies, and patient-consumer representatives to implement the plan, Nicholas says.

The policy initially will cover nine rare but serious adverse events and is based on nationally accepted definitions. This is the initial list:

- surgery on wrong body part;
- air embolism-associated injury;
- surgery on wrong patient;
- medication error injury;
- wrong surgical procedure;
- artificial insemination/wrong donor;
- retention of foreign object;
- infant discharged to wrong family;
- incompatible blood-associated injury.

Nicholas says that as hospitals gain experience with the policy, the list will be expanded to include other events.

Bills should be intercepted

Under current practice, Nicholas says Massachusetts hospitals disclose the incident and apologize to the patient, as well as reporting the incident to separate programs at the Department of Public Health and the Board of Registration in Medicine. However, bills still are frequently sent to insurers and patients.

"Obviously, the ultimate goal is to reduce these errors," Nicholas says. "But as human error is inevitable, we'll attempt to learn from our mistakes, acknowledge the profound effect they have on patients and, ultimately, expand the list of serious adverse events that should not occur and for which hospitals should not charge."

John Banja, PhD, assistant director for health sciences and clinical ethics at Emory University in Atlanta, says the Massachusetts policy is the right thing to do, but he notes that hospitals may have questions as the list or errors grows. "Currently, the nine error categories that the Massachusetts Hospital Association has identified are all slam-dunk errors. Things will start

EXECUTIVE SUMMARY

Hospitals in Massachusetts have joined hospitals in Minnesota in announcing that they will not charge patients for certain serious adverse events. The policy covers nine types of errors that should be preventable.

- All hospitals in Massachusetts have agreed to the voluntary policy.
- The effort is intended to promote a more responsible, ethical response to serious errors.
- Minnesota hospitals report a good experience with a similar policy.

New policy clearly right, ethicist says

Policies that prohibit charging patients and insurers for medical errors are clearly the right way to go, a "no-brainer" in an ethical and moral sense, says **John Banja**, PhD**,** assistant director for health sciences and clinical ethics at Emory University in Atlanta.

After all, he says, if a house painter mistakenly paints a room the wrong color, he needs to correct that error and absorb the costs rather than pass them on to the homeowner or someone else. Why should much more serious medical errors be any different?

"That's just common, moral sense," Banja says. "The fact of the matter, which many health professionals won't like to acknowledge, is that a third party paying for the costs of their errors is indicative of a history of their being rather economically spoiled."

But Banja says the economics go deeper than simply letting an insurer pick up the cost of your mistake. He offers the example of a patient who is self-employed and makes $200 a day. When a modest hospital error results in the patient having to stay an additional day in the hospital, he loses a day of work.

"A hospital really interested in patient-centered justice would cut a check to that patient for $200 or deduct $200 in costs that the patient would have to pay from his bill," Banja says. "Of course, no plaintiff's lawyer would take that case because the damages are so minimal. But it's not just for the patient to have lost $200 by virtue of another's error. Anyone putting themselves in the patient's position, which health providers often resist doing, would categorically agree."

Banja also questions how many patients and family members even know when a medical error has occurred. Ensuring that the patient or listener understands that an error occurred should be a higher priority, he says. "We know that some physicians can be extremely careful in choosing their words. They don't say 'error' or 'mistake,' but rather we will say, 'We had a problem' or 'This shouldn't have happened' or 'There was this complication,'" he says. "From what risk managers have told me over the last few years, a lot of patients don't understand, and it's not their fault." ■

getting epistemologically interesting when the list is expanded and we start being confronted with provocative questions like, 'Was there really an error here?'" Banja says. "This forces the question of how you define errors. Then there will be the issue of 'Did the error cause harm? How much harm?'"

The policy will force hospitals and health professionals to drill down to a finer understanding of the error and its effects, Banja says. The effort is worthwhile, he says, because the financial impact on patients can be significant after medical errors**. (See article, left, for more on Banja's explanation of the impact on patients.)**

Minnesota reports good results

Massachusetts follows Minnesota, the first state to formalize such a policy. On Sep. 18, 2007, Minnesota Gov. Tim Pawlenty announced a statewide billing policy for care made necessary by preventable medical errors, such as wrong-site surgeries and serious medication errors. Under the agreement, hospitals in Minnesota will not bill insurance companies and others for any of 27 types of reported adverse health events. The adverse health events are defined by the NQF. *(Editor's note: For more on the NQF's adverse event definitions, see the group's web site at www.qualityforum.org. Enter "serious reportable events in healthcare 2006" in the search box, and click on "Serious Reportable Events in Healthcare 2006 Update — Reports.")* The Governor's Health Care Cabinet endorsed the plan created by the Minnesota Hospital Association and the Minnesota Council of Health Plans.

The policy built on past experience in which Minnesota hospitals individually recognized the need for a proactive billing policy. HealthPartners, a Minnesota-based insurer, was at the forefront of the issue in enacting a 2005 policy of not paying for care provided to their enrollees when it included certain serious preventable medical errors. Over the last few years, Blue Cross-Blue Shield worked closely with the hospital association to create the framework for this statewide policy.

Bruce J. Rueben, president of the Minnesota Hospital Association, says the policy is working well in his state and has not caused any problems so far. "Everything is going along smoothly because it was not a radical idea when we formalized the policy. We had been building toward this with individual hospitals," he says. "Now we are working with the health plans to pull out the care that is made necessary by an adverse event, because it can

SOURCES

For more information on the Massachusetts and Minnesota billing policies, contact:

- **John Banja**, PhD, Assistant Director for Health Sciences and Clinical Ethics, Emory University, Atlanta. Telephone: (404) 712-4804. E-mail: jbanja@emory.edu.
- **Lynn Nicholas**, FACHE, President and CEO of the Massachusetts Hospital Association, Boston. Telephone: (617) 367-9667. E-mail: lnicholas@mhalink.org.
- **Bruce J. Rueben**, President, Minnesota Hospital Association, St. Paul. Telephone: (651) 641-1121. E-mail: brueben@mnhospitals.org.

still get into the billing cycle. Occasionally you don't know you had an adverse event until the bills have already gone out."

The policy has not had a financial impact on Minnesota hospitals because the events are rare, Rueben says. Most hospitals nationwide already waive the charges when responding to an adverse event, but usually on an informal basis and only when the right people intervene, Reuben says. A formal policy helps ensure that the charges are waived more consistently. "The idea that there is service that won't be billed is of no consequence financially, in the grand scheme of things. When these things happen, the last thing that matters is what you bill for," he says. "So there's no reason not to do what's right. More than anything, it's just a matter of sorting through the complex billing process to take those charges out of the system." ■

Will staff really speak up if needed?

The health care community has been urging staff and patients to "speak up" when necessary to protect patient safety, but how do you know if your staff truly will make a stand in a difficult situation? After all, it's easy to say you will do the right thing, but in the heat of the moment, a staff member can be intimidated by superiors and fearful of rocking the boat.

So how can a risk manager know if nurses and other staff really will speak up? Finding the answer will require some work, says **Grena Porto**, RN, MS, ARM, CPHRM, senior vice president with Marsh, a health care management company in Philadelphia, PA, and past president of the American Society for Healthcare Risk Management (ASHRM). The work is necessary because it is foolhardy to just assume that staff will speak up because you tell them to, Porto says. Employees will quickly get the idea that the correct response is, "Yes, I will speak up to protect patient safety." But that doesn't mean they really feel empowered to do so, Porto says.

"A lot of people want to just say, 'We'll train the nurses, tell them what to do, and they will do it.' In fact, they don't," Porto says. "The culture really needs to support what you're telling them to do. Organizations that want to put all their focus on training the staff are missing the boat, because you have to create a systemwide culture."

Nurses and other staff are astute observers of the employer's culture and will respond accordingly, she says. They are quick to recognize that leaders are preaching about the virtues of speaking up for safety but at the same time dismissing staff concerns or even punishing those who speak. "It only takes one or two instances to undermine your whole effort. The staff say they're not going to speak up because they saw what happened to someone else who opened their mouth," Porto says. "Of course, they'll still tell you that they will do the right thing and speak up, because that's what you want to hear. I see that a lot."

Data can help reveal truth

If you want a "stop-the-line" culture, in which even the lowest-ranking employee can intervene when patient safety is threatened, that attitude

EXECUTIVE SUMMARY

Nurses and other staff must be empowered to speak up when necessary to protect patient safety, but it can be difficult to know if they really will speak up in a difficult situation. Risk managers should take steps to assess whether staff members are empowered to intervene when necessary.

- Do not accept staff's assurances that they will speak up.
- Staff may say they feel empowered to intervene because they know that it is what management wants to hear.
- Studies indicate that staff are not as empowered as you might think.

must be modeled across the board, up to the highest levels of management, Porto says. That culture can be reinforced, for instance, by having top management personally and publicly praise employees who do speak up. An item in the employee newsletter, with the hospital president praising a housekeeper who spoke up to protect a patient, for example, can go a long way toward showing that the organization really supports this effort, Porto explains.

How do you know if you have that culture in place? Porto says you may have to collect data. Never just rely on what people tell you or the "feel" you get in the workplace, she says. Porto recommends using the "Hospital Survey on Patient Safety Culture: 2007 Comparative Database Report" from the Agency for Healthcare Research and Quality (AHRQ) in Rockville, MD. This report discusses data from 108,621 hospital staff respondents across 382 participating hospitals, and it provides insight into how staff members see patient safety efforts. The report includes detailed guidelines for how risk managers can compile similar data in their own organizations and compare it to the data in the AHRQ report, which can give you some idea of how successful your effort is. **(See story on p. 21 for more on that data and other research.)**

"So many of the respondents say it's not safe to speak up, and I don't think those organizations are unusual," Porto says. "And those are in organizations that cared enough to ask the question. In those that weren't willing to actually ask, I'd have to guess that the responses would be even worse. From this report, it's astonishing how little progress we've made." **(For more on how the history of nursing can be used to improve current performance, see the story, right.)**

Local culture can be important

The effort to encourage nurses to speak up is worthwhile because each instance of an error, near miss, or policy violation is an opportunity to improve patient safety, says **Lori A. Paine**, RN, MS, patient safety manager at Johns Hopkins Medicine in Baltimore.

"If we merely see nurses as the executors of provider orders, we miss the opportunity for the nurses to be that final check," she says. "That's how we see nurses, as a vital part of the system, sometimes the last gatekeeper for safety. If they are not empowered to speak up and if we don't listen to them, the organization misses a huge opportunity to improve safety."

Paine points out that, while organizational culture is important, the "local" culture of a staff member's unit or work area can be the driving factor in whether someone speaks up. Even if the overall culture of an organization is on the right track, there may be considerable variability from one unit to another, she says. "We see this sometimes in our event reporting, which we watch carefully and mine for any signs of problems that we need to address," Paine says. "Sometimes we will see reports that a nurse or supervisor is resistant to reporting from others, or we may also see a sharp discrepancy in the number of event reports coming from one unit. That can suggest

Nurses have a long history of speaking up

Risk managers should remember that there is nothing new about urging nurses and other staff to speak up, says nursing historian **Martha M. Libster**, PhD, RN, CNS, associate professor of nursing at East Carolina University in Greenville, NC.

"You're not blazing a new trail here, and that's a good thing," she says. "There is a long history of nurses standing up to physicians and others, speaking up when necessary to protect their patients. So if you keep that in mind, the prospect of encouraging nurses to speak up isn't such a formidable challenge."

Libster advises risk managers to keep that in mind when approaching nurses about the necessity of speaking up and to remind them that this responsibility has long been a part of the nurse's role in health care. This strategy will be more effective, and more historically accurate, than addressing the nurses as if you are now going to ask them to do something new and different, she says. "I would suggest that you remind them that this has always been an important part of their job, that it is their professional and ethical responsibility to speak up," she says. "What you can offer now is some help in terms of advising them about how to speak up. Emphasize the practical, how they can do this, rather than implying that this concept is something new and different." *[Editor's note: Contact Libster at (252) 744-6448 or libsterm@ecu.edu.]* ■

SOURCES

For more information on encouraging nurses and other staff to speak up, contact:

- **Christy Dempsey**, BSN, MBA, CNOR, Senior Vice President of Clinical Operations, PatientFlow Technology, Boston. Telephone: (617) 358-5060. E-mail: cdempsey@patientflowtech.com.
- **Lori A. Paine**, RN, MS, Patient Safety Manager, Johns Hopkins Medicine, Baltimore. Telephone: (410) 955-2919. E-mail: lapaine@jhmi.edu.
- **Grena Porto**, RN, MS, ARM, CPHRM, Senior Vice President, Marsh, Philadelphia. Phone: (215) 246-1144. E-mail: grena.porto@marsh.com.

that the staff in that particular unit are feeling discouraged from reporting these events to us."

Paine also notes that there are continuing concerns among some staff about the risk manager's role and what will happen if a concern is reported to the risk manager. Some staff may fear the intervention of a risk manager more than punishment from their supervisors, she says. "Risk managers can help by tearing down some of those walls and showing what you can do to help in those situations," she says.

Staff must be assured that you will support them when they act on behalf of a patient, says **Christy Dempsey**, BSN, MBA, CNOR, previously vice president and director of perioperative services at St. John's Regional Health Center in Springfield, MO, and now senior vice president of clinical operations for PatientFlow Technology, a health care consulting firm in Boston.

"From a management perspective, that's what I did to encourage people to speak up and act," she says. "I told them that as long as they followed the proper procedures and acted in the best interests of the patient, I would stand by them completely and support their actions. I wanted them to feel that they weren't going to be out there by themselves if they stuck their necks out." ■

Data show staff don't always speak

The *Hospital Survey on Patient Safety Culture: 2007 Comparative Database Report* from the Agency for Healthcare Research and Quality (AHRQ) in Rockville, MD, cites "nonpunitive response to error" as one of the areas with potential for improvement for most hospitals.

"This score — the extent to which staff feel that their mistakes and event reports are not held against them and that mistakes are not kept in their personnel file — was the patient safety culture composite with the lowest average percent positive response (43%), indicating this is an area with potential for improvement for most hospitals," the report said. "The survey item with the lowest average percent positive response (35%) was: 'Staff worry that mistakes they make are kept in their personnel file,' (an average of only 35% strongly disagreed or disagreed with this item)." *(Editor's note: To obtain the complete report, go to the group's web site at www.ahrq.gov and search for the report's title: "Hospital Survey on Patient Safety Culture: 2007 Comparative Database Report.")*

Another study suggests that only one in 10 nurses and other health care professionals speak up when safety is at risk. According to the study "Silence Kills: Seven Crucial Conversations for Healthcare," 80% of health care professionals regularly witness their co-workers break rules, make mistakes, or demonstrate incompetence. Yet, less than one in 10 says anything about it. Nurses are especially timid when the issue is with a physician or superior, the data suggest. The survey was conducted by VitalSmarts, a staff training company in Provo, UT, and The American Association of Critical-care Nurses in Aliso Viejo, CA. *(Editor's note: See the complete research results at www.silencekills.com.)*

Cell phone used to photograph genitals

The latest example of how the omnipresent cell phone camera can threaten patient privacy and invite lawsuits comes from Phoenix, where a surgeon is accused of using his cell phone to photograph a patient's tattooed genitals and then distributing the picture to friends.

Fox News reports that Adam Hansen, MD, chief resident of general surgery at Mayo Clinic Hospital in Phoenix admitted taking the photo with his cell phone on Dec. 11, 2007. The tattoo on strip club owner Sean Dubowik's penis reads "Hot Rod."[1]

The 27-year-old Dubowik was anesthetized for a gallbladder operation when the photo was

taken. The patient told Fox News that he learned of the photo when an administrator from the Mayo Clinic called and said Hansen wanted to tell him about a problem. Hansen told him that he took the picture while inserting a catheter into his penis, Dubowik says. *The Arizona Republic* newspaper also reported that a member of the surgical staff made an anonymous call about the photo, Fox News reports.

The Mayo Clinic issued a statement saying Hansen has been placed on administrative leave and could face a range of punishment from probation to dismissal. **Joseph Sirven**, MD, education director for Mayo Clinic Arizona, the hospital's parent organization based in Scottsdale, said, "Patient privacy is a serious matter, and photographing someone in this manner without a good reason is something we will investigate down to the last detail."

Dubowik said he planned to contact an attorney. "The longer I sit here, the angrier I get," he told Fox News. **(For a complete report on the risks from cell phone cameras in health care settings, see *Healthcare Risk Management*, September 2007, pp. 97-101.)**

Reference

1. Surgeon in hot water after photographing patient's tattooed genitals. Fox News, Dec. 19, 2007. Accessed at: www.foxnews.com/story/0,2933,317468,00.html. ■

IT systems linked to better outcomes

Patients are more likely to have better health outcomes if they are treated at hospitals using information technology (IT) systems, according to a new study from Florida State University in Tallahassee.

The study compared overall IT adoption with patient discharge data at 98 hospitals across Florida, which provided the most comprehensive analysis to date of the relationship between information technology use and health outcomes.[1] The study found that the more information systems adopted at a given hospital, the better that hospital performed on a variety of important patient outcome measures, says **Nir Menachemi**, PhD, MPH, lead author of the study and director of the Center on Patient Safety at the Florida State University College of Medicine in Tallahassee.

Menachemi says the results were particularly interesting because the hospitals were of various types, not the academic medical centers in which IT systems have most commonly been studied. Because academic medical centers are not typical of most U.S. hospitals, it was not clear if the results of those studies could be generalized to hospitals across the country, he says. "Our study is the first to link the use of IT to improved outcomes across a large number of community hospitals," Menachemi says. "The evidence we found is a compelling reason for hospitals to make sure they are utilizing the most up-to-date information systems.''

Deaths as a result of postoperative blood infections have doubled in the United States over the past 20 years. However, such deaths decreased for patients in hospitals using IT systems in the treatment process, as did deaths from postoperative respiratory failure and other infections. Such conditions can be prevented when clinicians have:

- up-to-date patient information;
- standardized medical order sets;
- evidence-based guidelines on best treatment procedures.

Menachemi says he found that hospitals properly using IT networks are best able to ensure that clinicians receive critical information at the point of care to assist physicians in adhering to proven clinical guidelines. *[Editor's note: Contact Menachemi at (850) 644-2362 or nir.menachemi@med.fsu.edu.]*

Reference

1. Menachemi N, Saunders C, Chukmaitov A, et al. Hospital adoption of information technologies and improved patient safety: A study of 98 hospitals in Florida. *J Healthc Manag* 2007; 52:398-409. ■

Just one more RN can save lives

If hospitals added one more full-time registered nurse (RN) on staff to care for patients, the number of hospital-related deaths in the United States could decrease significantly, according to a new review that also acknowledges adding one more RN isn't as easy as it sounds.

The report is the result of a systematic review aimed to examine whether there was a link between a hospital's registered nurse-to-patient ratio and the health outcome of the patients under their care, says lead author **Robert Kane**, MD, a patient safety researcher at the University of Minnesota School of Public Health in Minneapolis.[1] The results are clear, he says, but that doesn't mean health care administrators will rush right out to hire more RNs.

"The issue is not making them aware of the possibility; it's convincing them that it is in their best interests to act on it," Kane says. "From a business perspective, the savings in reduced lengths of stay would not offset the costs of the added staffing. The case would have to be made in terms of image and liability."

The researchers evaluated 27 studies of patient outcomes in relation to the registered nurse-to-patient ratio. Per shift, RN staffing averaged about three patients per RN in intensive care units, four patients per RN on surgical units, and four patients per RN for medical patients. The studies included in the review used data on patient outcome rates from sources such as the Uniform Health Discharge Data Sets and Centers for Medicare and Medicaid Services databases.

16% fewer surgical deaths

Kane and fellow reviewers found that a greater number of RNs on staff was associated with a reduction in the number of hospital-related deaths and other negative outcomes. Their results showed that by increasing the number of full-time RNs on staff per day by one, there were 9% fewer hospital-related deaths in intensive care units, 16% fewer in surgical patients and 6% fewer deaths in medical patients.

For every 1,000 hospitalized patients, the reviewers estimated that an increase by one full-time RN per patient day could save five patient lives in intensive care units, five lives on medical floors and six surgical patient lives.

Kane acknowledges that while increased nurse-patient ratios can lead to better patient outcomes, it is difficult to maintain a reasonable number of RNs on staff in light of the current shortage of available RNs. *[Editor's note: Contact Krane at (612) 624-1185 or kanex001@umn.edu.]*

Reference

1. Kane RL, Shamliyan TA, Mueller C, et al. The association of registered nurse staffing levels and patient outcomes: systematic review and meta-analysis. *Med Care* 2007; 45:1,195-1,204. ■

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

- Time management for risk managers
- Proving risk management's value to the CEO
- Falls analysis: Update on the latest tools
- Tips for minimizing your legal expenses

CNE Questions

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

5. What does Marlene R. Miller, MD, Msc, suggest as "the best, most immediate, step for a risk manager" to take to reduce heparin errors?
A. Go for a walk around patient care units and see how heparin is stored and used.
B. Issue a memo urging nurses to watch for the error.
C. Enact a strict policy of disciplining clinicians responsible for heparin errors.
D. Discontinue use of heparin in all but the most necessary instances.

6. According to C. Scott Nichols, JD, would the hospital involved in the heparin error with Dennis Quaid's family have faced much of a challenge if the family decided to sue?
A. If the family had chosen to sue, that might have been a hard to case to defend.
B. If the family had chosen to sue, the hospital could have easily and successfully defended itself.
C. If the family had chosen to sue, the hospital definitely would have lost.
D. If the family had chosen to sue, a court would have thrown out the case before it reached a jury.

7. What does Grena Porto, RN, MS, ARM, CPHRM, say about the importance of training staff to speak up?
A. It is not necessary to train staff to speak up because they already understand the idea.
B. Training staff is necessary, but organizations that want to put all their focus on training the staff are missing the boat.
C. Training staff to speak up can be counterproductive.
D. Training staff to speak up doesn't help, but it doesn't hurt either.

8. According to Nir Menachemi, PhD, MPH, why do information technology (IT) systems help improve patient safety?
A. Hospitals properly using IT networks are best able to ensure that clinicians receive critical information at the point of care to assist physicians in adhering to proven clinical guidelines.
B. IT networks provide a better record of the care provided.
C. Clinicians are more motivated to provide quality care when working with IT networks.
D. An IT network can provide Internet access for data outside the health organization.

Answers:
5. A; 6. A; 7. B; 8. A.

HIPAA Regulatory Alert

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

Are HIPAA privacy changes coming?

Many contend privacy rule has had negative impact on human subject research

With studies indicating researchers and the general public have concerns about HIPAA privacy provisions (although not necessarily the same concerns), the Institute of Medicine has convened a committee to look into the issue. That group is expected to make recommendations for possible changes in the law and for greater guidance from the U.S. Department of Health and Human Services to institutional review boards (IRB) or other groups by this summer.

The committee has been meeting for six months, according to University of Pittsburgh School of Public Health epidemiologist **Roberta Ness**, who made a presentation on her survey of epidemiologists at the committee's October meeting. "We hope that after a thorough consideration of all the issues, the committee will make some recommendations about the legislation, guidance, or both," Ness tells *HIPAA Regulatory Alert*.

In her presentation to the committee, Ness said the vast majority of clinical scientists surveyed said the HIPAA Privacy Rule has had a substantial, negative influence on conducting human subject research, often adding uncertainty, cost, and delay.

Some 13 epidemiology societies distributed a national web-based survey, which was answered anonymously by 1,527 professionals. Results were published in the Nov. 14, 2007, *Journal of the American Medical Association*.

Ness says the HIPAA Privacy Rule was intended to strike a balance between protecting the privacy of individually identifiable health information and preserving the legitimate use and disclosure of that information for important social goals. But many researchers have expressed concerns that since its April 2003 implementation, the Privacy Rule has adversely affected the progress of biomedical research.

Survey respondents were asked questions about both positive and negative potential influences of the HIPAA Privacy Rule, including the rule's influence on participant privacy, confidentiality, and public trust, as well as on research procedures.

In giving general perceptions, a majority of respondents reported that the degree to which the rule made research easier was low (84%) and the degree to which it made research more difficult was high (67.8%). Nearly 40% indicated that the Privacy Rule increased research costs in the high range and half said that the additional time added by the rule to complete research projects was high. Almost half said the Privacy Rule had affected research related to public health surveillance at the high level. The perceived benefit of the rule strengthening public trust was reported as high by only 10.5% of respondents and only 25.9% believed the rule had enhanced participant confidentiality/privacy in the high range.

Negative impact on protecting subjects

When asked about the proportion of IRB applications in which the HIPAA Privacy Rule had a positive effect on protecting human subjects and the proportion in which the rule had a negative effect on human subject protection, more respondents indicated that the rule had a negative rather than a positive human subject influence.

Nearly half the respondents reported accessing deidentified data without authorization, and 40.2% indicated they experienced a high level of difficulty. About 40% had attempted to obtain a waiver, and 30.6% reported a high level of difficulty in doing so. Of epidemiologists involved in multi-institutional studies, 76.8% reported the protocols elicited Privacy Rule concerns, and among these protocols, rule concerns resulted in site-specific variability in 39.6%. A minority of

respondents (17.3%) knew of covered entities unwilling to do clinical research, and 15% reported an IRB-approved protocol had not been honored by an IRB because of Privacy Rule concerns. Some 11.5% of the responding epidemiologists had conceived of a study but not submitted it to an IRB because they thought they could not obtain approval under the HIPAA Privacy Rule.

Just more than half of respondents identified a particular protocol most affected by the Privacy Rule and were asked to assess specific logistic hurdles and benefits. Ness says the frequency of "most affected" protocols was relatively constant each year from 2003 through 2006. Modifications were necessary in 84.8% of protocols because of Privacy Rule considerations and 37.6% of respondents reported the modifications strengthened confidentiality. At the same time, 67.5% indicated the modifications caused a high increase in recruitment difficulties.

Ness says several themes were evident in the comments. First, researchers expressed frustration and concern that implementing the Privacy Rule had added patient burden without substantially enhancing privacy protection. Second, respondents documented substantial variability among institutions' interpretations of Privacy Rule requirements. Third, respondents voiced concerns that HIPAA slows research progress. Finally, some respondents indicated confusion within governmental agencies about the demarcation between public health surveillance, which is often exempt from the Privacy Rule, and research.

Systemic problems

While questions have been raised about whether adverse effects of the Privacy Rule on human health research represent growing pains associated with implementation rather than a continuing effect, Ness says the survey documented that the frequency of most affected applications has been stable since the rule's implementation. Respondents reported it was often difficult to obtain waivers and deidentified data sets intended to allow access to health information in human subjects research without patient authorization. But, she says, case reports show some better understanding of Privacy Rule restrictions over time. Thus, Privacy Rule implementation triggered several California hospitals to restrict research access to the longstanding rapid case reporting system provided by the California State Cancer Registry. More than a year later, the University of California reversed its stance.

Ness says that inconsistencies among academic institutions in interpreting the Privacy Rule are an important challenge. Survey respondents provided responses widely distributed from "no" to "yes, conditionally" to "yes with no conditions" when asked whether particular case studies would be approved by their IRB. Also, she says, many specific instances of perceived institutional variability were documented in the open response section of the survey, suggesting either that IRBs differ in their responses given to a given protocol or that investigators vary in their perceptions of IRB responses.

She says two concerns not raised in previous research were found in this study. First, only 25% of respondents indicated that the rule enhanced privacy/confidentiality in the high range of the five-point scale used. More globally, respondents perceived that the rule's influence on overall research participant protection is more negative than positive.

Commenting on the role of institutional review boards, Ness says she believes that the fact that this complex law is so often interpreted locally is a problem. "We reported substantial variation in what is and is not acceptable to local IRBs," she says. "That suggests there isn't a uniform interpretation."

However, she adds, some portions of the law are onerous to researchers on their own without being interpreted by an IRB, and thus there is a need for changes to the law as well as for more guidance for IRBs.

Most researchers see negative impacts

When researchers were asked for their "HIPAA stories," some 90% gave negative responses, while only 5% had a neutral story and 5% had a positive story. Among the anecdotal comments, one researcher said that "an already cumbersome patient consent form now has an additional page and a half explaining HIPAA restrictions. This detracts from the informed consent process pertaining to the more critical issue: the actual medical risks and benefits of participating."

Another researcher said that no one argues with the merits of patient protection, but the guidelines "lend considerable variance in interpretation by IRB and other governing boards that may preclude a patient from participating in beneficial research."

And a third clinician said that while research has not been prevented, what the privacy requirement

has done is to "slow the research enterprise through its training and compliance elements. I and my staff spend more and more time doing compliance-related things and less and less time doing actual research."

Although the Privacy Rule is intended to protect patients, another presentation at the Institute of Medicine committee's meeting suggested it has not succeeded with that audience either. Columbia University professor of public law and government emeritus **Alan Westin**, who now is director of the Privacy Consulting Group's health privacy program, reported on his survey of the public regarding health privacy and health research. He said that large majorities of the public continue to hold and apply very strong privacy perspectives in the health area. But the majority also does not believe current law and organizational policies provide enough privacy protection.

Some 40% of consumers said they would want to be notified that researchers want to access their health information and would want to give their consent. And that percentage is significantly higher in some key demographic groups.

*[You can contact **Roberta Ness** at repro@pitt.edu or (412) 624-3056. Contact **Alan Westin** at afwestin@gmail.com or (201) 836-9152.]* ■

HIMSS backs Wired for Health Care Quality Act

The Healthcare Information and Management Systems Society (HIMSS) has endorsed S. 1693 — the Wired for Health Care Quality Act of 2007 — and has strongly urged action on it. **David Roberts**, HIMSS vice president for government relations, tells *HIPAA Regulatory Alert* Congress was not likely to deal with the bill in 2007 but he hoped it could be approved in 2008.

In a letter to Sens. **Edward Kennedy** (D-MA), **Hillary Clinton** (D-NY), **Mike Enzi** (R-WY), and **Orrin Hatch** (R-UT), HIMSS said it endorsed the legislation subject to these additions and clarifications:

- the "partnership" language in Section 3003 is intended to be AHIC 2.0 that is focused on the sequence of activities from issue identification (use case) to adoption and is not duplicative of CCHIT or HITSP;
- the "partnership" language in Section 3003 addressing development of a body to implement HIT standards should specifically include the recognition of the existing standards developed by the Health Information Technology Standards Panel (HITSP) and certification requirements established by the Certification Commission for Health IT (CCHIT);
- the privacy and security provisions in Section 3013 will be deleted from the legislation and handled in separate legislation, and therefore those concerns need not be raised at this time;
- the authors of the bill will be more inclusive of key private sector membership constituencies including specific references to health care IT vendors and other stakeholders directly affected by the legislation and the authors are flexible on the membership requirements to make them "less governmental;"
- the legislation would codify AHIC 1.0 as the governmental body that deals with the policy issues that are government's responsibility including but not limited to security and privacy policies, and interoperability use-cases necessary to support federal programs that require the sharing or exchange of health information.

The Congressional Budget Office has estimated S. 1693 would cost $47 million in 2008 and $317 million over the period 2008-2012, assuming appropriation of the necessary amounts.

S. 1693 would amend the Public Health Service Act to codify the establishment and responsibilities of the Office of the National Coordinator of Health Information Technology and the American Health Information Community (AHIC) to support adoption of health information technology. The two groups were established by executive order in 2004. The bill also would authorize funding for grants to facilitate widespread adoption of certain health information technology.

The National Coordinator of Health Information Technology is the senior advisor to the HHS secretary and the president on all health information technology programs and initiatives, and is responsible for:

- developing and maintaining a strategic plan to guide the nationwide implementation of electronic health records in both the public and private health care sectors;
- coordinating spending by federal agencies for health information technology programs and initiatives;
- coordinating outreach activities to private industry and serving as the catalyst for change in the healthcare industry.

S. 1693 would specify the responsibilities of

ONCHIT, AHIC, and a new organization to be known as the Partnership for Health Care Improvement. AHIC's current responsibilities would be divided between AHIC and the partnership, with AHIC focusing on development of policy and the partnership focusing on the technical aspects of developing and promoting adoption of health information technology.

Roberts says he hopes that in 2008 differences over privacy provisions can be resolved so the bill can be voted on. "We need to have more input so we can be sure doctors have the data they need," he says. ■

Study: National provider numbers are outdated

Some 20% of business addresses of physicians who were issued a National Provider Identifier (NPI) by the Centers for Medicare & Medicaid Services (CMS) are invalid because the physician moved to a new location, retired, or died, according to a 2007 audit by SK&A, a health care solutions and research company.

Findings showed 68% of NPI numbers were enumerated more than eight months before, and the average age of an NPI number is 13.16 months. CMS began issuing the identifiers in May 2005.

SK&A said it found the data to be inaccurate, even though CMS delayed release of the full NPI database numerous times to give health care providers an opportunity to update their mailing addresses and other contact data.

"This study on NPI data quality highlights the challenges that health care payers and marketers will face when trying to accurately match or link their provider legacy information to the new federally mandated NPI number," said SK&A President **Dave Escalante**. ■

HIPAA allows disclosure to state oversight group

An Ohio federal court has ruled that HIPAA's confidentiality requirements don't excuse the state's Medicaid agency from disclosing patient information sought in a class-action suit to enforce Medicaid's Early Periodic Screening, Diagnosis, and Treatment (EPSDT) requirements.

The proposed class-action suit was brought by the Ohio Legal Rights Service (OLRS) as the federally designated protection and advocacy agency charged with protecting the rights of persons with mental illness, mental retardation, developmental disabilities, and other disabilities. The named plaintiffs were children under age 21 whose disabilities made specific early childhood intervention services medically necessary.

Plaintiffs sought certification of a statewide class of all Medicaid-eligible children up to age 21 who were denied access to necessary services that should have been provided through Ohio's EPSDT program. The Medicaid agency objected, and the court ordered the parties to go through the discovery process relative to class certification.

The legal services group subpoenaed county agencies involved in administering Medicaid and EPSDT programs for information on Medicaid recipients who might qualify as members of the proposed class. The counties and Medicaid program administrators argued that Medicaid law, HIPAA, and Ohio law prevented them from disclosing such private health information.

Observers say the Social Security Act limits disclosure of protected information about Medicaid beneficiaries to purposes directly connected with administering the state Medicaid plan. The court found that a section of the law provided that establishing eligibility, determining the amount of medical assistance, and providing services to recipients are directly connected with plan administration and thus could be disclosed to OLRS in a suit concerning enforcement of Medicaid requirements. The court said OLRS was a particularly appropriate recipient of the information given its government-created role in protecting patient rights.

Likewise, the court noted that HIPAA permits disclosure to a health oversight agency for oversight activities authorized by law. It said OLRS qualifies as a health oversight agency engaged in authorized oversight activities. The court directed the parties to negotiate the terms of an appropriate protective order to prevent unauthorized disclosure.

The Medicaid agency also argued state law contains more stringent protections of private health information than federal law and barred disclosure. But the court said the state law of privilege could not be applied in litigation in federal court to enforce rights under federal law. ■

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

Failure to discover that autistic child swallowed foreign object leads to death and $1 million verdict in Illinois

By **Jon T. Gatto**, Esq.
Blake J. Delaney, Esq.
Buchanan Ingersoll & Rooney
Tampa, FL

News: An autistic girl with a history of swallowing foreign objects was taken to the emergency department by her mother following repeated episodes of vomiting and constipation. The girl was admitted to the hospital by her pediatrician, and X-rays were ordered. After more than eight hours, a radiologist finally read the films and discovered that the girl had swallowed a small rubber ball. His report, however, was not transmitted to the pediatrician. The girl's condition worsened, and she subsequently coded and died. After the girls' estate sued the hospital and the pediatrician, a jury returned a verdict of $1 million. It assessed the pediatrician with 25% fault and the hospital with 75% fault.

Background: An 8-year-old autistic girl was rushed to the emergency department by her mother after the child had experienced repeated episodes of vomiting since the previous day and had had no bowel movement for two days. The mother informed emergency department personnel that her daughter had swallowed foreign objects in the past but that she had no knowledge of her having done so recently. The child was unable to relay any history herself.

The ED physician noted that the girl was dehydrated, had abdominal pain, and had an elevated white blood cell count. The doctor consulted with the child's pediatrician, who decided to admit the girl for observation. The ED physician ordered abdominal X-rays to rule out a possible foreign body ingestion and bowel obstruction even though he knew there was no radiologist at the hospital to review them. The X-rays were taken, but the ED physician did not review the films himself.

Seven hours later, the girl's pediatrician examined the child and observed her to be in stable condition. He also noted that results were not yet available from the radiology films. An hour and a half later — and 8½ hours after the X-rays were taken — a radiologist finally arrived at the hospital and read the films. He noted an obstruction in the girl's small bowel, apparently as a result of the girl having swallowed a 1-inch rubber ball. However, either the radiologist's report never made it to the floor, or the nurse failed to call the pediatrician with the results.

The child's condition subsequently worsened. She coded a few hours later and was taken to surgery for an exploratory laparotomy. The ball was not found during the procedure, and the girl died the next morning. During the subsequent autopsy, the ball was discovered in the child's colon, where it had apparently moved from the small bowel.

The girl's estate sued the hospital, the pediatrician, and the pediatrician's practice for negligence. She argued that if the obstruction had

been promptly treated, the child would have survived.

The hospital defended the suit by arguing that the ED physician did not need to read the X-rays because the girl had been admitted by her pediatrician. The hospital also contended that its nurses acted properly and that it was the pediatrician who should have reviewed the films. The pediatrician defended the claim by arguing that he does not read X-rays, but instead he relies on a radiology report, which always was relayed to him by nurses. He pointed out that no one had told him of the X-ray results or of any change in the girl's condition. Both defendants then argued that the child would have died in any event.

After a trial, a jury found the pediatrician to be 25% at fault and the hospital to be 75% at fault. Damages were assessed at $1 million.

What this means to you: "This case was doomed for a large jury award just because it involved a child, with the added dimension that the negligence was the immediate cause of the child's death," says **Lynn Rosenblatt**, CRRN, LHRM, risk manager at HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL. "Juries will more likely than not to find for the plaintiff if they strongly believe the defendants breached a standard of care." In this particular case, she finds, it would have been wise for the defendants and their insurance companies to attempt to reach a mediated settlement with the parents rather than expose the defendants to the terrible publicity and grief that such cases can cause.

Indeed, this case evokes every parent's worst nightmare: A child dying after swallowing a common household object. The highest incidence of swallowed foreign bodies is in children between the ages of 6 months and 4 years. Young children put foreign objects in their mouths out of a natural sense of curiosity. Older children may swallow objects for attention, or due to psychological conditions or alcohol or drug abuse. In this case, the child was a victim of severe autism.

Eighty to 90% of swallowed objects pass through a child's digestive system without event, usually within two to five days. Often, such objects pass with no symptoms whatsoever. However, there are times when a child can swallow an item that is too large or too long to pass through the child's system, or an object that is sharp or poisonous. Those types of objects present tremendous risks to a child's health. For babies and small children, an object is too long to pass through a child's system if it is 1¼ inches or longer, and it is too large to pass if it is more than ¾ inch in diameter. For older children and adults, an object is too long to pass if it is 2 inches or longer, and too large to pass if it is 1 inch or larger in diameter.

In a scenario where a child has swallowed an object that cannot pass through his or her system, the most critical factor is detection. If detected within a reasonable time, almost any object can be surgically removed without severe harm to the child. If undetected, however, the presence of a foreign object can lead to death or severe injury if it cannot pass through the child's system. The injury to the child may result from aspiration or, as here, from the object becoming lodged in the child's digestive system. It is particularly dangerous when ingestion of a foreign body results in blockage of the small intestine. Due to the narrow diameter of the small intestine, many foreign bodies in this location cause a complete obstruction. At that point, immediate surgery is required.

Symptoms of a swallowed foreign object include choking; vomiting; bleeding in the throat; drooling; painful swallowing; pain in the chest, throat, or abdomen; gagging; refusal to feed; and bloody stool. Foreign objects may be detected by X-ray, sometimes enhanced with the swallowing of barium, or by endoscopy.

In this case, the physicians correctly suspected the swallowing of a foreign object, but negligently failed to confirm and treat the condition due to a very unfortunate failure of communication. There is plenty of blame to go around to all of the providers involved in the care of this child. However, Rosenblatt says, "The case revolves around who is 'on first,' as the saying goes, or who had primary responsibility." The decision by the pediatrician to admit the girl was consistent with her presentation. The ED physician followed up his suspicion of a possible obstruction by ordering an X-ray. "So far, so good," says Rosenblatt. Unfortunately, however, from that point forward, neither physician took responsibility, nor did either act to ensure that an accurate diagnosis was made.

Generally, as a provider of emergency services, it falls on the ED physician to ensure that any diagnostic evaluations, including radiology reports, are read and evaluated as soon as possible. This is the standard of care in emergency medicine. The ED physician was aware that there was no radiologist available. Without a doubt, he should have looked at the films himself or

ensured that they were promptly read off-site, with the results telephoned to him or the attending pediatrician immediately. This process is referred to as a "wet read," meaning that it is done as soon as the films are developed.

Another blunder was when the pediatrician did not seek out information that would have confirmed the original diagnosis of a possible obstruction. Bowel obstruction is a serious, life-threatening emergency condition. If the girl's intestinal tract was obstructed, she would have required immediate surgery. "This is clearly not a 'wait-and-see' diagnosis," says Rosenblatt. A positive X-ray would have revealed the need for immediate surgery to relieve the obstruction, as at that point the identified object would not be at all likely to pass through without possibility of further, severe complications.

Rosenblatt urges, however, that there also is blame on the part of the radiologist, who would have read the film and should have realized the urgency of the situation. While he may have thought that the film had been read at the time it was developed, and that his report was a mere documentation formality, he should have taken the safest next step and notified the nurse by telephone of his findings. The very act of a specialty physician notifying a nurse of a serious situation should trigger that nurse to immediately notify at least the attending physician of those findings. Otherwise, the urgent situation becomes even more so, as no one is aware of the "ticking time bomb."

Had the radiologist not discovered the foreign object in the girl's small bowel, one could say that he was acting within the standard of care by merely dictating his report and letting it follow the usual course of transcription. At that point, the film would not have provided any additional information and the girl's condition would have been noted as stable. In such a scenario, the radiologist could not be held accountable for not doing something because there was no pressing evidence that he needed to. To the contrary, in this case the findings were positive, and there was an urgent need to communicate them to those that needed to know. Even if the radiologist thought that the report was a formality and that the results had been communicated, it is better to err on the side of redundant communications than to risk a communication lapse of the type that occurred in this case.

At this point, hospital policy would dictate who he was to notify. The policy may call for the radiologist to telephone the nursing unit, provide an immediate reading of the film, and fax a handwritten copy of the report to the nursing station to support his phone message. This is a common practice in hospitals, particularly where films are read off-site.

Another option would be the professional courtesy of notifying an attending physician directly that something is amiss with his patient. This does not bypass the notification to the nursing unit described above, but rather ensures that information gets to the pediatrician as quickly as possible so that he can act on it. Again, if the communication is redundant, that is fine. It is better to err on the side of patient safety.

In this case, any number of events could have occurred, any of which could have caused the report to be delayed. The report either was sent off for transcription, faxed to a wrong number, never retrieved from the fax, or filed prematurely before it was brought to the pediatrician's attention after it was received. Regardless of why the report was delayed, all parties to the care of this patient share in the blame for not seeking positive assurances of the outcome of the X-ray in a timely manner.

Additionally, the nurse may not have been aware that X-rays had been taken and that she should have been looking for the results. Patients transferred from one service to another, in this case the emergency department to a nursing unit, should be "handed off" in a manner that provides accurate and concise information as to the patient's condition and what had been previously done to stabilize the patient, including any diagnostics and available results.

"This brings up the standard of care regarding communication between providers," Rosenblatt says. In any medical situation, one caregiver has an obligation to "hand off all available information" while the other has an obligation to ask sufficient questions to ensure that they have gotten all of the available information. In this case, the nurse admitting the patient should have inquired as to what had transpired in the emergency department and whether any tests were pending. In fact, this entire situation could have been avoided if any of the professionals involved would have been more inquisitive and taken responsibility for the confirmation of the suspected diagnosis.

It was not until the child coded, went to emergency surgery, and then died that anyone was aware that a foreign object actually existed in her intestines. Had the emergency department physician ordered a wet read, thereby establishing the

urgency of the situation and setting into motion a corrective action plan, the child might have survived.

Had the pediatrician followed up on the original premise that his patient may be suffering from a bowel obstruction and made the effort to inquire as to the radiology results, the child might have survived. And had the staff in the emergency department "handed off" the patient in the customary manner, where information is shared and appropriately acted upon, the child might have survived. Also, the nurse apparently never addressed the possibility of a lost X-ray report when the patient's condition deteriorated. She should have been proactive in seeking additional information.

In this case, the child suffered from severe autism. The fact that the child was in this condition and was unable to convey the fact that she had swallowed the rubber ball, certainly made it more difficult for the professionals to determine exactly what happened. However, the professionals were made aware of the child's history of swallowing objects and were on the right track in terms of ordering an X-ray and looking for an object. In fact, the X-ray ultimately revealed the object.

Nevertheless, due to a tragic lapse in communication, a patient whose condition had been accurately diagnosed did not receive the life-saving treatment that she needed. None of these professionals acted within the expected standard of care for such a situation. The jury appropriately found all of them liable. "Without a doubt, communication — or rather a serious lack of it — was the root cause of a most unfortunate situation," concludes Rosenblatt. In spite of the fact that it was clear to all parties that ingestion of a foreign body was a likely cause of this young girl's symptoms, and in spite of the presence of a radiology report accurately diagnosing her condition, simple miscommunication caused the tragic death of this child.

Reference

- Adams County (IL) Circuit Court, Case No. 01L-68. ■

When interviewing, 'harmless' questions could get you sued

By **Stacey Kusterbeck**
Contributing Editor
ED Legal Letter
Atlanta

When you are interviewing, any comments about race, national origin, religion, age, family, military or marital status, and disability are off-limits, says **John W. Robinson** IV, a shareholder in the employee litigation department in the Tampa, FL, office of Fowler White.

Avoid any attempts at humor involving these topics, which are "protected categories" under the law, he advises. Gratuitous questions or statements about these topics can backfire with an unsuccessful applicant, Robinson warns. "Nobody blames herself when she does not get a job. She is looking for other reasons," he says.

Inappropriate comments can lead to Equal Employment Opportunity Commission (EEOC) charges and litigation by rejected candidates, warns **Katrina Campbell**, general counsel at Brightline Compliance, a Washington, DC, firm specializing in workplace issues. Avoid "creative" questions or remarks that could lead you down an inappropriate path, she advises. For example, don't joke or comment about your own age or the age of the staff by saying "There are a lot of gray hairs around here," or "It's like a college campus here." Candidates may take these statements as signs that they will not fit in, or if they are not hired later, may conclude it had something to do with their age, says Campbell.

In addition, questions that seem to relate to protected categories can be risky. For example, questions about whether a person has children and how old they are may indicate to a candidate that you question the candidate's ability to work certain hours. Instead, ask direct questions about the candidate's ability to work the specified schedule, to travel (if necessary), to working overtime, and other job requirements. For example, say: "Working in the emergency department requires that you work different shifts, including overnight shifts. Can you meet this job requirement?" ■